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Original Paper

Comparing an eHealth Program (My Hip Journey) With Standard Care for Total Hip Arthroplasty: Randomized Controlled Trial

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Abstract

Background: The role of eHealth programs to support patients through surgical pathways, including total hip arthroplasty (THA), is rapidly growing and offers the potential to improve patient engagement, self-care, and outcomes.

Objective: The aim of this study is to compare the effects of an eHealth program (intervention) versus standard care for pre- and postoperative education on patient outcomes for primary THA.

Methods: A prospective parallel randomized controlled trial with two arms (standard care and standard care plus access to the eHealth education program) was conducted. Participants included those who underwent THA. Outcome measures were collected preadmission, at 6 weeks, and at 3 and 6 months after surgery. The primary outcome was the Hip Dysfunction and Osteoarthritis Outcome Score. Secondary outcomes were a 5-level 5-dimension quality of life measure and the self-efficacy for managing chronic disease scale. Demographic and clinical characteristics were also collected. A satisfaction survey was completed by all participants 6 weeks after surgery, and those in the intervention arm completed an additional survey specific to the eHealth program.

Results: A total of 99 patients were recruited: 50 in the eHealth program (intervention) and 49 in standard care (control). Clinical improvements were demonstrated in both groups across all time points. Per-protocol analysis demonstrated no differences between the groups for all outcome measures across all time points. Participants in the eHealth program reported that the program was accessible, that they felt comfortable using it, and that the information was helpful.

Conclusions: This study demonstrated that the eHealth program, in addition to standard care, had no additional benefit to THA recovery compared with standard care alone. The study found that the eHealth program was highly valued by participants, and it supported the preoperative preparation, recovery, and postoperative rehabilitation of participants.

Trial Registration: Australian New Zealand Clinical Trial Registry ACTRN12617001433392; http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=373657

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KEYWORDS

hip arthroplasty; education; eHealth program; rehabilitation; economic evaluation

Introduction

eHealth programs can provide individualized patient care at the preoperative, perioperative, and postoperative stages and have the potential to improve patient engagement, self-care, and outcomes across the surgical pathway [1,2]. The implementation of eHealth has many benefits, including enabling a single source of information that can be regularly and easily updated within a rapidly changing environment and enabling equitable access to all patients regardless of geographical location. Various capabilities can be incorporated into eHealth programs, including platforms to communicate directly with health professionals and electronic reminders to prompt patients to complete an exercise or take medication, and it can also be used by other health professionals and caregivers to provide an enhanced continuity of care [2].

One surgical pathway where preadmission, perioperative, and postoperative education is essential is total hip arthroplasty (THA) to prepare people physically and psychologically before surgery and to promote recovery after surgery. THA is a surgical procedure that improves both joint function and quality of life (QoL) in patients with hip osteoarthritis [3]. Osteoarthritis is a major disabling joint disorder worldwide, with the hip being the second most affected joint, and can result in pain, decreased function, and reduced QoL [4]. Within Australia and internationally, the number of people undergoing THA has increased annually over the last 10 years [5,6]. In Australia, over half of all hip arthroplasties (59.7%) are conducted in private hospitals [3].

The most prevalent form of education delivery for THA currently includes a combination of one-to-one verbal discussions, patient group sessions, educational booklets, and educational videos [7]. Many studies and reviews have demonstrated the benefits of these education programs, including reduced length of hospital stay, lower readmission rates, fewer adverse events, increased functional abilities, improved QoL, less anxiety, more effective pain management, and improved cost-effectiveness [8-12].

The incorporation of eHealth programs in the delivery of education has shown some potential to further enhance the educational experience and outcomes for postsurgical rehabilitation for orthopedic patients, including those undergoing THA [13]. Most studies have focused on the use of telerehabilitation in either the pre- or postsurgical periods [1,13-15]. A systematic review conducted on the evidence of the benefit of telerehabilitation after orthopedic surgery has shown strong to moderate grades of evidence for hip replacement interventions; the review recommends that high-methodological quality studies are needed [13]. Therefore, this study adds to the body of knowledge by conducting a high-quality randomized controlled trial (RCT) that aims to investigate the use of telerehabilitation across the perioperative period and not only the rehabilitation phase and compares the addition of an eHealth program (intervention) versus standard care (control) for pre- and postoperative education on patient outcomes for primary THA.

Methods

Study Design

A prospective RCT was conducted in a private metropolitan hospital in Western Australia. The trial consisted of two arms: one receiving the eHealth program and standard care (intervention) and the other receiving only standard care (control).

Participants

Participants included patients undergoing primary elective THA in a private hospital. Patients were included if they were (1) 18 years or older, (2) able to provide informed consent, and (3) had at least three weeks' lead-up time before THA surgery. Exclusion criteria included (1) admission to undergo a THA revision, a bilateral THA, THA following a fractured neck of the femur, or a previous THA; (2) inability to write or speak in English; (3) no access to a web-based device; and (4) a risk assessment and prediction tool score less than 6.

Recruitment

Participants were screened and invited to hear more about the study by the preadmission nurse during the routine preadmission phone call. Eligible participants were then provided with additional study information and invited to participate by a member of the research team. The recruitment for the study was conducted from January 2018 to January 2019.

Randomization

Participants were randomized one-to-one using permuted block randomization to ensure that an equal number of participants were allocated to each arm of the trial. Allocation concealment in the order of recruitment was conducted *off site* after consent had been obtained by a researcher, separate to participant recruitment. Blinding of the participant or health care team was not possible due to the type of intervention.

Standard Care

The standard practice was an enhanced recovery program (ERP) based on an orthopedic recovery program developed in the United Kingdom [16]. The ERP included an enhanced recovery booklet received before admission; a 1-hour, hospital-based, face-to-face preoperative education session presented by a registered nurse, occupational therapist, pharmacist, and physiotherapist; and follow-up phone call post discharge. The program included information and education to support patients to prepare for hospital, during hospital, discharge, and post discharge.

Intervention

Participants in the intervention arm received standard care plus access to the *My Hip Journey* eHealth education program. Depending on the participant's surgical approach (posterior, anterior, or SUPERPATH), which was determined by the surgeon's discretion, they were allocated into 1 of 3 types of programs. Access to the program was provided at least 2 weeks before surgery, and the program was run until 6 weeks post surgery.

My Hip Journey provided participants with web-based access to a range of educational resources, including fact sheets, videos, exercise videos, and email reminders about the pre- and postoperative care of a THA. Participants were encouraged to log in daily to view their *My Program* window displaying a list of videos and information as well as exercises that had been allocated for them to view or complete that day. Participants could also communicate with the health care team at the hospital using the communication log within the program; they could also invite other health care professionals or support persons to be part of the program.

Data Collection

Participants completed data collection electronically in four phases: (1) preadmission, (2) 6 weeks, (3) 3 months, and (4) 6 months after surgery. Across all the four phases, participants completed the primary outcome measure Hip Dysfunction and Osteoarthritis Outcome Score (HOOS) and the secondary outcome measures of EuroQoL 5-Dimension 5-Level (EQ-5D-5L) and self-efficacy for managing chronic disease (SEMCD). The EQ-5D-5L consists of 2 parts, the EQ-5D visual analogue scale (VAS) and the index score, which are scored 0-100 and 0-1. At 6 weeks postsurgery (phase 2), participants also completed a satisfaction survey, and those in the intervention arm completed an additional survey specific to the eHealth program, and web-based analytics were also sourced. Further information on the data collection tools is outlined in a protocol paper [17].

Sample Size

Sample size calculations were conducted based on the primary outcome (HOOS). The calculations were conducted for 3 out of the 5 HOOS subscales, and the QoL subscale required the largest sample size with a minimal clinically important improvement of 17 [18] and a SD of 23.5 [19]. On the basis of a power of 90% and a 5% significance level, 42 participants per group were required. A sample size of 50 per group was required to allow for a dropout rate of approximately 15%. Therefore, the estimated and required sample size for this study was 100 participants.

Statistical Analysis

Data were reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials). The mean (SD) and percentages were used to describe the characteristics of the study group and survey responses. The categorical responses for the 5 dimensions of the EQ-5D-5L (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) for each participant were transformed into an index score using the UK EQ-5D-5L value set [20].

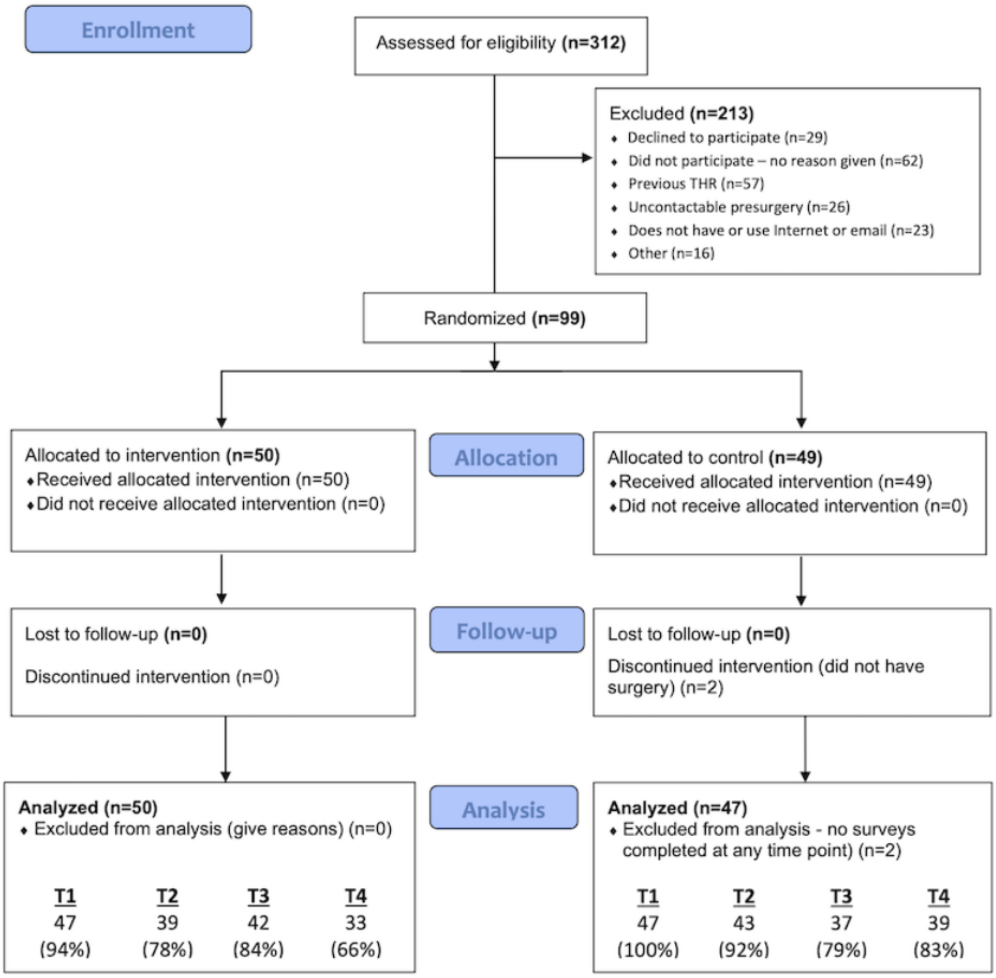
Independent sample *t* test and chi-square or Fisher exact tests were conducted to determine any differences in baseline characteristics. Independent *t* tests were used to examine the differences in baseline outcome scores. Treatment effects were calculated on the pre- to postintervention outcomes at 6 weeks using an independent sample *t* test to examine the differences between groups. Further analysis was performed on the posttreatment effects at 3 and 6 months postsurgery. The clinical treatment effect of each intervention group was further analyzed using multilevel mixed-effects linear regression pre- to postintervention changes across the range of outcome measures to account for repeated measures with the covariates of age and gender.

Results

In total, 99 participants were recruited for the study, with 50 allocated to the intervention group and 49 to the control group. Two participants withdrew because their surgery was postponed when their private health fund did not cover THA, leaving 47 participants in the control group.

Data collection commenced in January 2018 and was completed in July 2019. Loss to follow-up occurred during each phase of the study. At the end of phase 4 (6-month follow-up), 66% (33/50) of participants remained in the intervention group and 82.9% (39/49) in the control group. A flow diagram of the patients participating in this study is outlined in the CONSORT diagram (Figure 1).

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram of patients participating in the study.



Baseline Demographics and Clinical Characteristics

No significant difference was found between the control and intervention groups in terms of baseline demographic data and clinical characteristics (type of surgery and length of hospital stay; Table 1). A statistically significant difference at baseline for pain and activities of daily living was found between the groups for the HOOS scores (Table 2).

Table 1. Baseline demographics of participants in the intervention and control groups.

Characteristics	Intervention (n=50)	Control (n=49)	*P* value
Gender, n (%)			.76[a]
Male	26 (52)	24 (49)	
Female	24 (48)	25 (51)	
Age (years), mean (SD)	61.7 (12.1)	64.6 (9.7)	.20[b]
Age (years), n (%)			.69[a]
60	20 (40)	16 (33)	
61-70	17 (34)	17 (34)	
≥71	13 (26)	16 (33)	
RAPT[c] score, mean (SD)	10.5 (1.2)	10.6 (1.3)	.79[b]
RAPT score, n (%)			>.99[d]
Additional interventions needed before discharge directly home (score 6-9)	7 (14)	6 (12)	
Discharge directly home (score 10-12)	43 (86)	42 (86)	
Missing	0	1 (2)	
Type of hip surgery, n (%)			.42[d]
Left THR[e]	21 (42)	22 (45)	
Right THR	29 (58)	25 (51)	
No surgery	0	2 (4)	
Surgery approach, n (%)			.18[d]
Posterior	26 (52)	19 (39)	
Anterior	23 (46)	24 (49)	
SUPERPATH	1 (2)	4 (8)	
No surgery	0	2 (4)	
Length of stay (days), mean (SD)	3.9 (1.5)	3.7 (1.2)	.46[b]
Attended education class, n (%)	25 (50)	26 (53)	.76[a]
Known readmission, n (%)	4 (8)	2 (4)	.68[d]

[a]Chi-square test.
[b]Independent *t* test.
[c]RAPT: risk assessment and prediction tool.
[d]Fisher exact test.
[e]THR: total hip replacement.

Table 2. Primary outcome assessment Hip Dysfunction and Osteoarthritis Outcome Score.

Time periods	Intervention		Control		Difference	
	Mean (SD)	n (%)	Mean (SD)	n (%)	*d* (95% CI)	*P* value
Baseline/preadmission[a]						
Symptoms	49.48 (18.28)	47 (100)	43.38 (20.34)	47 (100)	6.10 (−1.82 to 14.02)	.13
Pain	51.49 (12.41)	47 (100)	45.33 (14.07)	46 (98)	6.16 (0.70 to 11.62)	*.03*[b]
Activities of daily living	56.44 (15.50)	47 (100)	47.78 (14.86)	47 (100)	8.67 (2.44 to 14.88)	*.007*
Sport/recreation	35.99 (23.45)	47 (100)	30.34 (19.93)	46 (98)	5.65 (−3.32 to 14.62)	.21
Quality of life	30.72 (17.57)	47 (100)	27.26 (16.09)	47 (100)	3.46 (−3.44 to 10.36)	.32
Change baseline—6 weeks[a]						
Symptoms	27.42 (21.01)	37 (95)	31.62 (25.17)	41 (95)	−4.20 (−14.71 to 6.32)	.43
Pain	30.07 (19.41)	37 (95)	33.00 (18.67)	40 (95)	−2.93 (−11.58 to 5.72)	.50
Activities of daily living	23.43 (16.23)	37 (95)	27.44 (20.38)	41 (95)	−4.02 (−12.39 to 4.35)	.34
Sport/recreation	18.24 (26.49)	37 (95)	21.19 (30.9)	40 (95)	−2.95 (−16.07 to 10.16)	.66
Quality of life	28.72 (21.72)	37 (95)	27.74 (26.45)	41 (95)	0.97 (−10.01 to 11.96)	.86
Change baseline—3 months[a]						
Symptoms	32.68 (23.01)	39 (93)	37.53 (28.41)	37 (100)	−4.85 (−16.64 to 6.94)	.42
Pain	36.6 (17.5)	39 (93)	39.65 (21.62)	36 (97)	−3.05 (−12.07 to 5.97)	.50
Activities of daily living	28.56 (18.67)	39 (93)	35.13 (23.35)	37 (100)	−6.57 (−16.21 to 3.07)	.18
Sport/recreation	32.53 (30.29)	39 (93)	39.70 (32.01)	36 (97)	−7.17 (−21.50 to 7.17)	.32
Quality of life	39.42 (24.72)	39 (93)	42.91 (26.4)	37 (100)	−3.48 (−15.16 to 8.19)	.55
Change baseline—6 months[a]						
Symptoms	34.36 (22.97)	32 (97)	41.25 (24.61)	39	−6.89 (−18.25 to 4.48)	.23
Pain	38.52 (19.01)	32 (97)	40.72 (18.88)	38	−2.21 (−11.27 to 6.86)	.63
Activities of daily living	30.71 (19.50)	32 (97)	37.55 (19.76)	39 (100)	−6.84 (−16.19 to 2.50)	.15
Sport/recreation	40.04 (31.74)	32 (97)	44.19 (28.30)	38	−4.15 (−18.47 to 10.17)	.57
Quality of life	45.12 (27.39)	32 (97)	47.44 (22.75)	39 (100)	−2.34 (−14.19 to 9.55)	.70

[a]Independent *t* test.

[b]*P* value in italics are statistically significant.

HOOS

From the analysis of the HOOS scores, it was found that both groups improved immediately after surgery, and this improvement was demonstrated across all 5 HOOS domains. Participants continued to improve at 3 months and 6 months after surgery. Baseline scores for pain and activities of daily living were significantly different between the intervention and control groups. No significant differences in changes between the intervention and control groups were detected at baseline and at 6 weeks, at 3 months, and at 6 months after surgery for the HOOS scores (Table 2).

EuroQol EQ-5D-5L

An improvement in health-related quality of life (HRQoL) was observed at 6 weeks, 3 months, and 6 months after surgery in both the control and intervention groups, as measured by the EQ-5D-5L VAS and the EQ-5D-5L index scores (Table 3). However, there were no statistically significant differences between the groups at any of the time points.

Table 3. Secondary outcome assessment 5-level 5-dimension quality of life measure.

Time periods	Intervention		Control		Difference	
	Mean (SD)	n (%)	Mean (SD)	n (%)	*d* (95% CI)	*P* value
Baseline/preadmission[a]						
Index	0.64 (0.19)	47 (100)	0.59 (0.21)	47 (100)	0.05 (−0.03 to 0.14)	.20
VAS[b]	64.79 (20.02)	47 (100)	68.55 (18.23)	47 (100)	−3.77 (−11.62 to 4.09)	.34
Change baseline—6 weeks[a]						
Index	0.17 (0.20)	37 (95)	0.19 (0.26)	42 (98)	−0.02 (−0.12 to 0.09)	.77
VAS	10.43 (15.05)	37 (95)	10.52 (15.73)	42 (98)	−0.09 (−7.01 to 6.83)	.98
Change baseline—3 months[a]						
Index	0.21 (0.21)	40 (95)	0.23 (0.21)	37 (100)	−0.02 (−0.11 to 0.08)	.72
VAS	12.82 (20.08)	39 (93)	9.76 (15.05)	37 (100)	3.06 (−5.08 to 11.21)	.46
Change baseline—6 months[a]						
Index	0.22 (0.18)	32 (97)	0.27 (0.22)	39 (100)	−0.05 (−0.15 to 0.05)	.29
VAS	15.77 (16.90[c])	31 (94)	13.23 (13.21)	39 (100)	2.54 (−4.63 to 9.72)	.48

[a]Independent *t* test.

[b]VAS: visual analogue scale.

[c]Large outlier (−62)—intervention participant (ID#51) not included.

SEMCD

Both groups reported an increased sense of postsurgical self-efficacy. Both groups had an above-average level of self-efficacy preoperatively. Participants continued to improve at 3 months and 6 months after surgery. However, no significant differences in changes between the intervention and control groups were detected at baseline and at 6 weeks, at 3 months, and at 6 months after surgery (Table 4).

Table 4. Secondary outcome assessment self-efficacy for managing chronic disease score; per-protocol analysis.

Time Periods	Intervention		Control		Difference between groups	
	Mean (SD)	n (%)	Mean (SD)	n (%)	*d* (95% CI)	*P* value
Baseline/preadmission[a]	6.52 (1.88)	47 (100)	6.60 (1.80)	47 (100)	−0.07 (−0.82 to 0.69)	.86
Change baseline—6 weeks[a]	1.29 (2.09)	37 (35)	1.51 (1.70)	42 (98)	−0.22 (−1.06 to 0.63)	.62
Change baseline—3 months[a]	1.85 (2.06)	41 (98)	1.49 (1.67)	37 (100)	0.36 (−0.49 to 1.21)	.40
Change baseline—6 months[a]	2.06 (2.24)	32 (97)	1.76 (1.61)	39 (100)	0.31 (−0.61 to 1.22)	.51

[a]Independent *t* test.

Repeated Measures Analysis

A repeated measure analysis based on per-protocol analysis was performed using multilevel mixed-effects linear regression accounting for age and gender. We found no effect over time with the interaction of intervention by time, considering any differences in baseline measures. Thus, the results were the same regardless of the intervention group.

Economic Evaluation

As there were no statistically significant differences in the primary and secondary outcomes for the eHealth program and standard care, no further economic analysis was conducted.

Satisfaction Survey Results

The satisfaction survey was administered electronically 6 weeks after surgery to all participants, with 43 participants in the control group and 39 participants in the intervention group completing the survey and 92% and 78% response rate, respectively. Across all 6 questions, no statistically significant difference in the satisfaction levels between the intervention and control groups was noted (Table 5). The majority of participants either strongly agreed or somewhat agreed that the information was easy to follow (intervention group: 39/39, 100%; control group: 40/43, 93%), found the presurgery information helpful (intervention group: 39/39, 100%; control group: 40/43, 93%), found the postsurgery information helpful (intervention group: 37/39, 94.8%; control group: 39/43, 90.7%), and the content gave me a good understanding of my surgery pathway (intervention group: 38/39, 97.4%; control group: 37/43, 86%), The majority of participants either strongly agreed or somewhat agreed that the content gave me a good understanding of how to maximize recovery (intervention group: 37/39, 94.8%; control group: 38/43, 88.4%), and I feel that the package that was supplied assisted me in my recovery (intervention group: 36/39, 92.3%; control group: 37/43, 86%).

Table 5. Satisfaction survey results by group.

Survey questions	Control group (n=43), n (%)	Intervention group (n=39), n (%)	*P* value[a]
I found the information easy to follow			.34
Strongly disagree	0 (0)	0 (0)	
Somewhat disagree	2 (4.6)	0 (0)	
Neither agree nor disagree	1 (2.3)	0 (0)	
Somewhat agree	11 (25.6)	8 (20.5)	
Strongly agree	29 (67.4)	31 (79.5)	
I found the presurgery information helpful			.15
Strongly disagree	3 (7.0)	0 (0)	
Somewhat disagree	0 (0)	0 (0)	
Neither agree nor disagree	0 (0)	0 (0)	
Somewhat agree	12 (27.9)	8 (20.5)	
Strongly agree	28 (65.1)	31 (79.5)	
I found the postsurgery information helpful			.51
Strongly disagree	2 (4.65)	0 (0)	
Somewhat disagree	0 (0)	1 (2.6)	
Neither agree nor disagree	2 (4.65)	1 (2.6)	
Somewhat agree	12 (27.9)	10 (25.6)	
Strongly agree	27 (62.8)	27 (69.2)	
The content gave me a good understanding of my surgery pathway			.42
Strongly disagree	1 (2.3)	0 (0)	
Somewhat disagree	2 (4.6)	0 (0)	
Neither agree nor disagree	3 (7)	1 (2.6)	
Somewhat agree	5 (11.6)	6 (15.4)	
Strongly agree	32 (74.4)	32 (82)	
The content gave me a good understanding on how to maximize recovery			.70
Strongly disagree	2 (4.6)	0 (0)	
Somewhat disagree	1 (2.3)	1 (2.6)	
Neither agree nor disagree	2 (4.6)	1 (2.6)	
Somewhat agree	11 (25.6)	10 (25.6)	
Strongly agree	27 (62.8)	27 (69.2)	
I feel that the package that was supplied assisted me in my recovery			.80
Strongly disagree	2 (4.7)	1 (2.6)	
Somewhat disagree	0 (0)	0 (0)	
Neither agree nor disagree	4 (9.3)	2 (5.1)	
Somewhat agree	12 (27.9)	10 (25.6)	
Strongly agree	25 (58.1)	26 (66.7)	

[a]Chi-square test.

Over 80% (51/82) of the participants in both the intervention and control groups responded to the open-ended questions. Most of the intervention group (n=16) stated that there was no further information that they needed, and they felt *well informed*. In contrast, others (n=11) reported a lack of information pertaining to the expected physical abilities after the surgery and weaning off crutches and suggested including additional videos from physiotherapists and occupational therapists along with more information on anesthetic options, medications, and risks associated with surgery. One participant suggested that the program should have additional information for people living without a support person. In addition, many participants in the control group (n=15) provided suggestions for additional information, including the need for additional occupational therapy and physiotherapy advice, information on presurgery exercise, postsurgery exercises, and the recovery pathway. Other feedback was specific to the individual participant experiences and included suggestions for further information about medication, postoperative complications, and variations in length of stay.

eHealth Program Survey

Participants in the intervention group completed an additional survey specific to the use of the eHealth program 6 weeks after surgery. In total, 39 participants completed the survey, of which 97% (n=38) accessed the program at least once. Participants accessing the program varied: 30% (11/37) used it daily, 27% (10/37) used it 2-3 times a week, 13% (5/37) used it at least once a fortnight, and 30% (11/37) only accessed the program a couple of times overall (less than once a fortnight). The majority felt that the "application was easy to use" (35/37, 95%,), they felt "comfortable using the application" (35/37, 95%), it was "easy to find the information needed" (35/37, 95%), "the organization of the information on the application screen was clear" (35/37, 95%), the "information was effective in helping them complete the daily tasks" (33/37, 89%), and the "content in the emails were helpful" (33/37, 89%). All participants said they somewhat agreed or agreed that they would recommend the app to others; however, some participants stated that they would still prefer paper-based information. Most participants were satisfied with the app (33/37, 89%). Only a small percentage of respondents contacted the health professional using the email within the app (7/37, 18%), of which 3 neither agreed nor disagreed that the health professional's response supported them in their recovery, 1 somewhat agreed, and 3 agreed that the responses supported them in their recovery.

In response to what participants liked most about the program, the majority provided feedback (n=31), including ease of access to the information (n=10) and the information provided was informative, concise, and clearly presented (n=10). Others commented on the benefits of the program through videos, exercise videos, clear layout of the program, environmentally friendly program, reinforcing good day-to-day practice, and benefit of using in your own time. A total of 17 participants shared dislikes of the program related to repetition of information, frequency of emails, and timing of information. Moreover, 19 participants provided additional comments, with the majority (n=15) sharing positive feedback, including "it was an excellent tool to assist my recovery," "the information provided kept me informed," "wonderful resource" and "it made me very well informed for my surgery." Other participants (n=4) provided further feedback, including the importance of including a social worker, having more practical advice from an occupational therapist, having too many boxes to record their daily activities, and their lack of confidence in technology affected their use of the program.

Safety and Adverse Events

For all participants involved in the study, there were a total of 6 readmissions to hospitals, 4 from the eHealth program, and 2 from standard care. Reasons for readmission included revision of the hip, excision trochanter bursa, gluteal tendon repair, washout of THA, dislocation of THA with revision, and development of deep vein thrombosis in the leg. Two participants from the intervention group transitioned to the rehabilitation ward following surgery for further in-hospital support.

Discussion

Principal Findings

ERPs for patients undergoing THA have become increasingly common and have been shown to reduce hospital length of stay and complications [21]. Preoperative patient education is a key part of ERP protocols, and health care facilities are exploring eHealth as a flexible option to support patient education and enhance patient involvement. This study used an eHealth program for pre- and postoperative education for THA and found it to be as effective as standard care. Participants in both groups demonstrated improvement in the primary outcome measure (HOOS) at 6 weeks, 3 months, and 6 months after surgery. No statistically significant differences were observed between the intervention and control groups. Other studies have also compared the effectiveness and benefits of eHealth apps in joint arthroplasty and reported similar findings [22-24]. Across the secondary outcomes of length of stay, HRQoL, and SEMCD, no statistically significant difference between the intervention and control groups was observed. Self-reported HRQoL increased in both groups after surgery, which was consistent with other studies reporting improved QoL with increased functionality [25].

Preoperative patient education was identified as being important in contributing to patient recovery by providing patients with more realistic expectations and an understanding of the postoperative period while empowering them to be actively engaged in their recovery [5,26]. Patient satisfaction with both the standard care education and the eHealth program was high, and there was no significant difference between the groups. More specifically, the presurgery education information and postsurgery information were found to provide a good understanding of the surgical journey and of how to maximize recovery. Previous studies also found positive benefits of preoperative patient education in THA [6,27]. Participants in the intervention group reported high satisfaction scores for the eHealth program, in the helpfulness of the pre- and postsurgery information, and for the content supporting their understanding of the surgery and maximizing their recovery. In addition, most participants stated that there was no further information that they needed, and they felt *well informed*. This was an important finding as a key part of ERPs for hip arthroplasty was pre- and postoperative patient education, particularly exercises, to achieve functional recovery and reduced hospital stay [28]. Constructive feedback from both groups identified areas for development in patient education, with specific feedback from the control group on the need for more information on pre- and postsurgery exercises. This was not reported by the intervention group, and the exercise videos in the eHealth program most likely addressed this need, but they did suggest including additional information about preoperative preparation within the presurgery videos.

Health professionals have identified that a patient's knowledge of postoperative exercises and undertaking these exercises correctly contributes to the success of hip arthroplasty, and eHealth apps can facilitate better patient engagement with the discharge exercise regime [29]. The overall satisfaction with using the eHealth program was positive and the regular use (at least once per week) by most of the participants may have contributed to the perceived benefits. Over 75% reported positive benefits focused on ease of use, including good visual display, access via any device, quality of information through the daily email reminders, web-based resources and videos encouraging regular use, and flexibility. These reported benefits align with the usefulness, utility, and usability (including learnability, memorability, and satisfaction) criteria identified for usable eHealth programs [30].

Participants' individual differences and preferences formed the basis of suggestions for improvement, including considering the frequency of emails, the volume of information, and the need for a dedicated focus on recovery for people who have limited or no care support. Overall, the positive feedback identified that the program was a valuable resource in supporting patient recovery, and participants would recommend the use of the program to others. These findings support the notion that developing effective eHealth programs requires feedback from end users and recognizes the value in supporting patient engagement in their own recovery [31,32].

Interestingly, only a few participants reported using the functionality to contact other health professionals or hospitals via email. This may indicate that the platform provided sufficient information to support recovery, and urgent concerns may have been directed to the surgeon. This area could be explored further, and the program expanded to include discharge plans on the platform as a record for patients and to communicate directly with the primary health care team.

On the basis of the findings of this study, it is recommended that the eHealth program be provided as an option to support patients in their perioperative journey for hip arthroplasty. The results of this study can help inform the development and future research of telerehabilitation programs for other surgical procedures.

Limitations

The study was developed and conducted according to the CONSORT statement. This study had two key limitations. The study was conducted in an acute private hospital; hence, the findings may not be generalizable to other hospitals because the results are limited to the study population and may not be representative of participants at other hospitals. The study may have lent itself to participants who were more comfortable with technology, which may have created a potential selection bias.

Conclusions

Preoperative patient education is important for positive patient outcomes following hip arthroplasty, and eHealth patient education is becoming an increasingly flexible option to deliver these resources to patients and guide the preparation and recovery from surgery along with their direct contact with health care professionals. This study demonstrated that participants in the intervention group did not differ in outcome measures compared with the control group, who received standard patient education. The study demonstrated that an eHealth program created an opportunity to provide preoperative guidance on preparation and recovery and supported postoperative rehabilitation. The acceptance of the program was high, with participants reporting that it was easy to use and enabled them to access information when they wanted to. These promising results demonstrate that health care organizations can implement and adapt digital health systems with good uptake by patients. Larger studies would help further inform how eHealth programs can be adapted for other orthopedic and surgical procedures.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 3063 KB - rehab_v8i1e22944_app1.pdf]

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Abbreviations

ERP: enhanced recovery program
EuroQol EQ-5D-5L: 5-level 5-dimension quality of life measure
HOOS: Hip Dysfunction and Osteoarthritis Outcome Score
HRQoL: health-related quality of life
QoL: quality of life
RCT: randomized controlled trial
SEMCD: self-efficacy for managing chronic disease
THA: total hip arthroplasty
VAS: visual analogue scale

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Review

Impacts of Low-cost Robotic Pets for Older Adults and People With Dementia: Scoping Review

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Abstract

Background: Older adults and people with dementia are particularly vulnerable to social isolation. Social robots, including robotic pets, are promising technological interventions that can benefit the psychosocial health of older adults and people with dementia. However, issues such as high costs can lead to a lack of equal access and concerns about infection control. Although there are previous reviews on the use of robotic pets for older adults and people with dementia, none have included or had a focus on low-cost and familiarly and realistically designed pet robots.

Objective: The aim of this review is to synthesize evidence on the delivery and impact of low-cost, familiarly and realistically designed interactive robotic pets for older adults and people with dementia.

Methods: The Arksey and O'Malley framework was used to guide this review. First, the research question was identified. Second, searches were conducted on five electronic databases and Google Scholar. Studies were selected using a two-phase screening process, where two reviewers independently screened and extracted data using a standardized data extraction form. Finally, the results were discussed, categorized, and presented narratively.

Results: A total of 9 studies were included in the review. Positive impacts related to several psychosocial domains, including mood and affect, communication and social interaction, companionship, and other well-being outcomes. Issues and concerns associated with its use included misperceptions of the robotic pets as a live animal, ethical issues of attachment, negative reactions by users, and other pragmatic concerns such as hygiene and cost.

Conclusions: Overall, the findings resonate with previous studies that investigated the effectiveness of other social robots, demonstrating the promise of these low-cost robotic pets in addressing the psychosocial needs of older adults and people with dementia. The affordability of these robotic pets appeared to influence the practicalities of real-world use, such as intervention delivery and infection control, which are especially relevant in light of COVID-19. Moving forward, studies should also consider comparing the effects of these low-cost robots with other robotic pets.

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KEYWORDS

social robot; assistive technology; robotic animals; pet robots; older adults; dementia; low-cost robot; psychosocial intervention; intervention; robot; review; intervention

Introduction

The incidence of dementia increases with age [1], as such, it is one of the biggest challenges associated with a rapidly ageing population worldwide [2]. Older adults and people with dementia are especially susceptible to social isolation and loneliness [3-5], which can further dispose them to other morbidities such as decreased resistance to infection [6], depression, and further decline in cognitive functions [7]. This issue is especially pertinent with the ongoing COVID-19 pandemic [8], where older adults are largely confined within the home or residential care settings. Therefore, there is a need for innovative solutions to address the psychosocial needs of this population.

With technological advancements, promising innovations such as social robots have been developed to render emotional support and companionship [9,10]. A social robot may be defined as "an autonomous or semi-autonomous robot that interacts and communicates with humans by following the behavioural norms expected by the people with whom the robot is intended to interact" [11]. Robotic pets are a type of social robot with the appearance and behaviors of pets or companion animals [12]. A recent systematic review was conducted to understand the experiences and effects of older adults' interactions with robotic pets in residential care facilities [13]. A total of five types of pet robots were identified across 19 studies, including 2 robotic cats (NeCoRo and JustoCat), a dog-like robot (AIBO), a robotic teddy bear (CuDDler), and a seal-like robot (Paro). The review showed that these robotic pets had positive benefits on psychosocial domains such as reduced agitation, reduced loneliness, and improved quality of life. These findings are congruent with another recent systematic review that similarly found the positive psychosocial benefits of using social robots in improving engagement and interaction, and reducing loneliness for older adults and people with dementia [14].

Despite positive benefits, there are important issues that may impede the uptake of robotic pets beyond the research setting. Some authors have argued that researchers appear to have a selection bias toward using Paro [15], which is one of the most widely deployed social robots in research to date [16]. Paro was designed to resemble an unfamiliar animal to improve its acceptability to users, based on the premise that users would have less preconceptions or expectations of it as compared to a familiar animal [17]. Nevertheless, it is worth considering that design preferences are unique and may differ across individuals. For instance, a recent study [15] showed that roboticists chose Paro as their preferred design while none of the older adults chose it. Instead, most chose the Joy for All (JfA) robotic cat and dog as their preferred designs and reported stronger preferences for familiarly designed robotic pets over unfamiliar ones such as Paro. Nonrealistic robotic pets such as Pleo, a robotic dinosaur, were also not preferred by older adults. Such preferences have been demonstrated in other studies [18-20], where older adults and people with dementia reported a preference for more familiar and realistic robotic pets such as a cat or dog. Hence, there is value in exploring the impacts of pet robots that are both familiarly and realistically designed.

Another impediment to the uptake of robotic pets relates to cost, which has been widely cited as a pragmatic concern by multiple key stakeholders including older end users [21], family members [18], organizations, and researchers [22-24]. For instance, each unit of the Justocat costs about US $1350, an AIBO dog costs US $3000, and a Paro costs approximately US $6000. Cost and affordability can therefore influence equal access to such innovations by older adults and people with dementia [25]. Furthermore, the high cost of social robots may make it difficult for older adults to own individual social robots. Instead, they are often shared among users [13]. This then raises concerns about hygiene and infection control [22,26]. In light of COVID-19, the issue of infection control is especially pertinent, as shared use may increase the risk of transmission of infections between users [27,28]. In fact, the shared use of robotic pets within care settings has recently been advised against [29]. Therefore, there is value in exploring lower cost alternatives.

Bradwell et al [15] identified several commercially available robotic pets. Among them, those that are low-cost and are realistically and familiarly designed include the Perfect Petzzz pets as well as the JfA robotic pets [15] (Figure 1). The Perfect Petzzz cats and dogs costs between US $15-$35; however, they are noninteractive in nature, and they may be considered as toys rather than social robots [30]. On the other hand, the JfA robotic cat and dog have interactive features and contain touch- and light–activated sensors to enable autonomous responses through vocalizations and movements for the purpose of social interaction. Although they are objectively less technologically advanced and cannot be programmed, older adults perceived them to be highly interactive as compared to another more technologically advanced robot [31]. As each unit of the JfA robotic pet costs between US $110-$130 (as of November 2020) [32], they are substantially more affordable. Furthermore, a cost-effectiveness study, which evaluated the use of a robotic pet with advanced touch capacities for people with dementia in long-term care settings, showed that a plush toy alternative offered marginally greater value for money [33]. Therefore, even though the JfA robotic pets have less technological features, they may be promising as a low-cost solution to address the psychosocial needs of older adults and people with dementia.

Although there has been previous reviews on the use of robotic pets for older adults [13], none have included or had a focus on low-cost, familiar, and realistically designed robotic pets. To the best of our knowledge, the JfA robotic pets are the only commercially available robotic pets that meet all three criteria as previously established. As such, the aim of this scoping review is to synthesize evidence on the delivery and impact of familiarly and realistically designed low-cost interactive robotic pets (ie, the JfA robotic cat and dog) for older adults and people with dementia. A scoping review methodology was chosen, as it is well suited to explore the breadth and depth of literature in this field [34].

Figure 1. Low-cost, familiarly designed robotic pets and toys. Left to right: Joy for All cat, Joy for All dog, Perfect Petzzz cat, Perfect Petzzz dog.

Methods

This scoping review follows the methodological framework proposed by Arksey and O'Malley [35], which includes five stages. The stages of conducting the review and analysis were as follows.

Stage 1: Identification of the Research Question

The research question for this scoping review is "What is known about the impacts of low-cost, familiarly and realistically designed interactive robotic pets (i.e., the JfA robotic dog and cat) for older adults and people with dementia?"

Stage 2: Identification of Relevant Studies

Published articles and grey literature were identified and searched in the following electronic databases: CINAHL, Web of Science, Scopus, MEDLINE via Ovid, and PsycINFO via Ovid. All relevant literature that were written in English, regardless of methodological quality, were included. Since the JfA robotic pets were only developed in 2016, only studies published after 2016 were included. The search strategies were developed in consultation with a research librarian based on the *Population, Concept, and Context* (*PCC*) framework that is recommended by the Joanna Briggs Institute for scoping reviews (Textbox 1). The full search strategy can be found in Multimedia Appendix 1. To cover the breadth of available literature and to ensure that the search was comprehensive, searches were also conducted on Google Scholar and through forward and backward citation tracing. The search was initially conducted in May 2020. To maximize the currency of this review [36], an update of the search was conducted in September 2020.

Textbox 1. The Population, Concept, and Context framework.

Population

Older adults (60 years and older) and people with dementia

Concept

Interventions using low-cost and realistically and familiarly designed robotic pets (ie, the Joy for All robotic cat and dog)

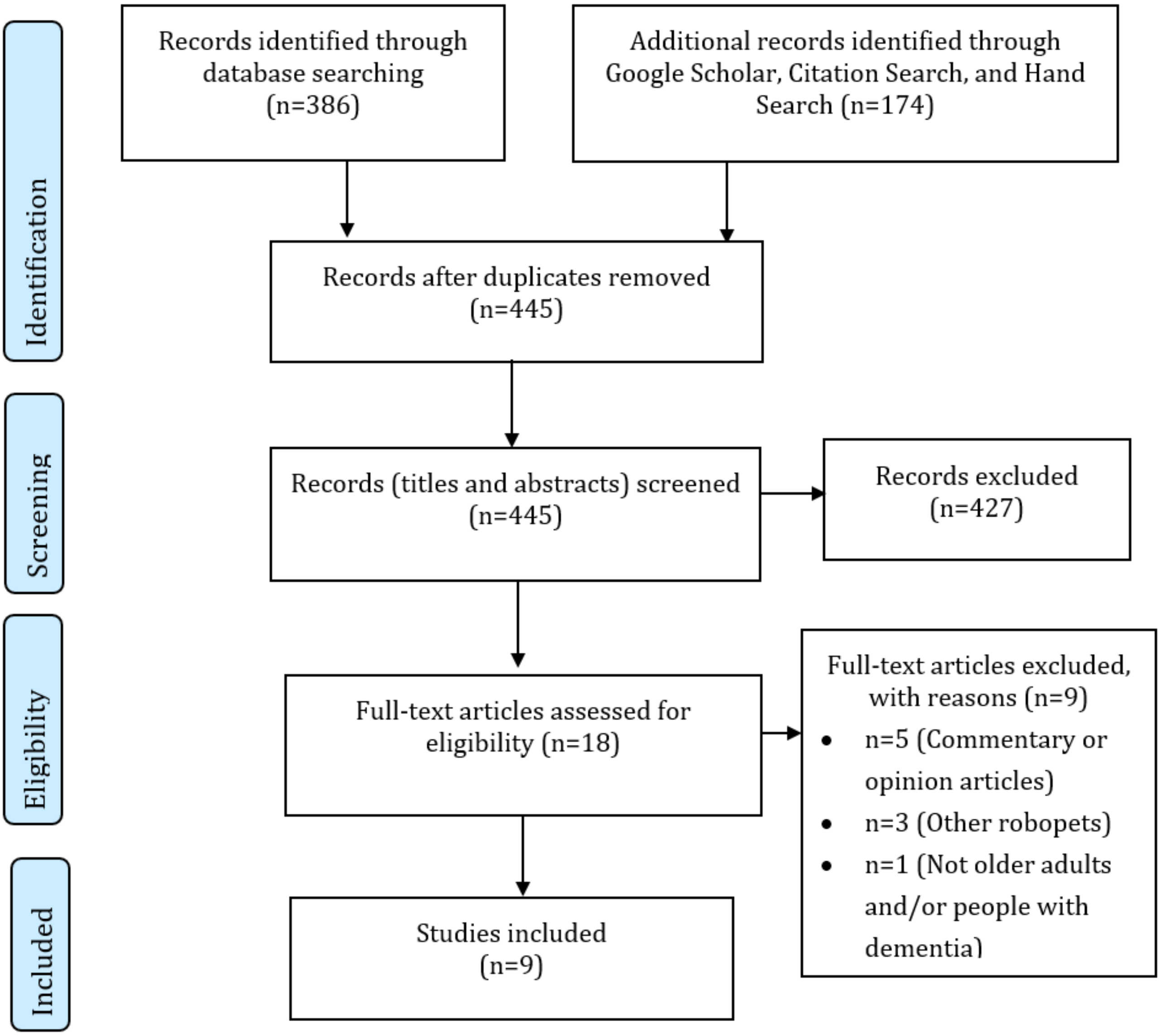
Context

No limits applied to the study context (eg, participants' homes, care settings)

Stage 3: Selection of Studies

The selection of studies followed a two-stage screening process. Two independent reviewers (authors WQK and FXHA) were involved in the screening process. Any nonconsensus or discrepancies were discussed and resolved among both reviewers and with author DC, as necessary. First, the titles and abstracts of identified articles were independently screened. We anticipated that information regarding the specific type of robotic pet (ie, the JfA robotic cat and dog) may not be mentioned in the title or abstract of publications and may only be available in the body of the text. Therefore, all studies were included if they met the following inclusion criteria based on the PCC framework: had any type of primary study; used a robotic cat or dog as an intervention; included older adults 60 years or older, or people with dementia; and were published in the English language. The exclusion criteria included if they were noninterventional studies such as expert opinion and commentaries, used any other robotic pets such as Pleo or AIBO, did not include older adults (ie, younger than 60 years), and were published in languages other than English. If these criteria were unclear in the title and abstract screening, they were included for full-text screening. Second, the full texts of included articles were reviewed. Studies that employed the JfA robotic pets were included, and studies using any other robotic pets such as the Justocat and NeCoRo cat were excluded. Any disparities were discussed and resolved. A bibliographic reference management tool, EndNote, was used to ensure that all articles were systematically accounted for. The search strategy was recorded using a PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart (Figure 2).

Figure 2. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart.



Stages 4 and 5: Charting the Data and Summarizing and Reporting the Results

A standardized data extraction form was created using Excel (Microsoft Corporation). The data that were extracted included authors, country of the study, research design, research setting, participants' demographics, sample size, intervention delivery, positive impacts, and negative impacts. Authors of included studies were contacted as necessary to attain additional information. Both reviewers (WQK and FXHA) charted the data independently before making comparisons afterward. Both reviewers discussed to collate the extracted data into categories and refined them to develop the final themes. The PRISMA-ScR (Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews) checklist (Multimedia Appendix 2) was used to guide the reporting of the results [37].

Results

A total of 9 publications were included in the final review.

Quality Appraisal

Although quality appraisal is not necessitated for scoping reviews, it has been recommended to evaluate the methodological integrity of included articles [38]. Two reviewers (WQK and FXHA) independently appraised the quality of the included studies before meeting to discuss any discrepancies, which were resolved through discussion and a consensus was reached.

Qualitative studies and the qualitative strand of the mixed method study were appraised using the Critical Appraisal Skills Program qualitative checklist [39]. The research aims and rationale of all studies (n=7) were clearly stated. With the exception of 1 study [40], most studies confirmed that ethical approval was obtained from a relevant research ethics committee. Most had appropriate research designs (n=4) [40-43] and recruitment strategies (n=5) [40,41,43-45]. However, the data collection and analysis methods were not clearly described in 4 studies [42,46,47]. These factors subject the studies to assessor bias and reporting biases [48]. Emails were sent to the authors to request for more information; however, no responses were received. Most studies (n=6) did not provide sufficient information to illustrate if the relationship between the researchers and participants were adequately considered [40-43,45,47].

The National Institutes of Health (NIH) quality assessment tool for pre-post studies [49] was used to appraise the quantitative study and quantitative strand of the mixed method study. The tool contains 12 questions to guide reviewers' judgement of whether a study is of "good," "fair," or "poor" quality. The quality of these studies were rated as poor and fair, respectively. In the mixed method study by Marsilio et al [45], it was unclear whether all eligible participants were enrolled, which subjected it to selection bias. In addition, the intervention was not clearly described, suggesting the potential for information bias. The other study by Tkatch et al [50] had a significant attrition rate. Furthermore, both studies did not state whether assessors were blinded, which raised concerns about reporting biases [45,50].

Finally, the Authority, Accuracy, Coverage, Objectivity, Date, Significance (AACODS) checklist [51] for appraising grey literature was used to evaluate the quality of McBride et al's [46] article. This article did not have a clearly stated aim or research design. An email was sent to the authors requesting more information, and an author clarified that the study was *unstructured*, and there was no additional information beyond what was presented in the article. Hence, this article was rated to be of poor quality. The full quality appraisal tables can be found in Multimedia Appendix 3.

Overall, the quality of reporting in the included studies varied from poor to good, with most classified to be of poor to fair quality. Nevertheless, all studies were included in this scoping review, as the intention of this review is to identify the breadth of literature in this topic (Table 1).

Table 1. Characteristics of included studies.

Author	Aim	Robotic pet and cost	Method	Setting	Participants	Outcome measures
McBride et al 2017 [46]	Not clearly stated, appears to have explored impacts of low-cost interactive robotic pets for older residents	JfA[a] cat and dog (US $99-$119 per unit)	Not clearly stated	Nursing home	Older adults living in residential care (n=33)	• Clinical observation
Picking and Pike 2017 [47]	To explore the potential of an affordable robot, with a view to making a realistic difference in quality of life for people with dementia and their carers	JfA cat (<£100 [US $136.90] per unit)	Qualitative (multiple case study)	Own homes	Older people with dementia (n=3)	• In-depth interviews with participants and carers, where they are encouraged to tell their story using aids such as photographs
Marsilio et al 2018 [45]	To determine whether introducing a robotic companion cat into a long-term care facility may improve affect and increase participation for residents with dementia; determine potential benefits for caregiver roles and relationships with individuals with dementia	JfA cat (no info on cost)	Mixed method	Nursing home	Long-term care facility residents with dementia (required assistance for some or all activities of daily living; n=11)	• Agitation, using the Cohen-Mansfield Agitation Inventory • Physiological measures (heart rate and oxygen saturation) • Changes in the use of psychotropic and pain medications (review of the medication dispensing record) • Clinical observations and staff report of participants' behavior • Questionnaire post study to evaluate staff perceptions of the effects of the robot on participants
Pike et al 2018 [42]	To explore the effects of a robot cat as companion robots for people living with dementia in their own homes	JfA cat (no info on cost)	Qualitative (multiple case study)	Own homes	Older people with dementia or early symptoms of dementia (n=6)	• Interviews with people with dementia and their family, using photo elicitation when a photograph was available
Brecher 2019 [40]	To describe a case study on the effectiveness of using a robotic cat to successfully assist in the treatment of a patient with terminal restlessness	JfA cat (<US $100 per unit)	Qualitative (case report)	Veteran Affairs community living center	Older person with dementia (n=1)	• Clinical observation
Bradwell et al 2020 [41]	To report ecologically valid diary data from two supported living facilities for older people with dementia or learning difficulties	JfA cat and dog (~£100 [US $136.90] per unit)	Qualitative (descriptive qualitative)	Two supported living facilities	Older adults with dementia or learning disabilities (no info on number of participants)	• Diary entry by two members of staff at each supported living facility, using event-based sampling (ie, observations are logged after each observation) over a period of 6 months
Pike et al 2020 [43]	To investigate the use of robotic companion robots for people with dementia living at home with family or carer support	JfA cat (£100 [US $136.90])	Qualitative (multiple case study)	Own homes	Older adults with dementia or early symptoms of dementia (n=6)	• Multiple interviews with participants and their family: first interview 2 weeks after they receive the cat and second interview at 3 months
Hudson et al 2020 [44]	To explore the efficacy of robotic pets in alleviating loneliness for older adults	JfA cat and dog (US $109.99-$129.90 per unit)	Qualitative (descriptive qualitative)	Own homes	Community-dwelling older adults (n=20)	• Individual in-depth interviews

Author	Aim	Robotic pet and cost	Method	Setting	Participants	Outcome measures
Tkatch et al 2020 [50]	To determine the feasibility of an animatronic pet program and whether ownership of animatronic pets would decrease loneliness and improve well-being among lonely older adults	JfA cat and dog (US $109.99-$129.90 per unit)	Quantitative (cohort study)	Own homes	Community-dwelling older adults (n=216)	• Quality of life, using the VR-12[b] • Loneliness, using the UCLA[c] Loneliness scale • Resilience, using the BRS[d] • Purpose in life, using the NIH[e] Tuberculosis Meaning and Purpose Scale Age 18+ • Optimism, using the LOT-R[f]

[a]JfA: Joy for All.
[b]VR-12: Veteran's RAND.
[c]UCLA: University of California, Los Angeles.
[d]BRS: Brief Resilience Scale.
[e]NIH: National Institutes of Health.
[f]LOT-R: Life Orientation Test-Revised.

Participants and Study Settings

The sample sizes in 8 studies ranged from 1 to 216 and included a total of 296 participants. It was not possible to ascertain the sample size in 1 study [41]. Most studies (n=6) were conducted with older adults with dementia [40-43,45,47]. However, 1 study also included older people with learning disabilities [41]. Healthy older adults were the participants in 2 studies [44,50]. In the remaining study, participants were older residents in a nursing home. However, there was no information on their ages or diagnoses [46]. Studies were conducted in participants' homes (n=5) and in long-term care settings (n=4).

Intervention Delivery

The majority (n=5) used the JfA robotic cat [40,42,43,45,47], while the others (n=4) employed both the robotic cat and dog [41,44,46,50]. Only 1 study offered participants' their choice of robotic pet (ie, cat or dog) and reported no differences between the type of pet to the intervention outcomes [44]. The intervention duration ranged from 2 weeks to 6 months. The majority (n=9) delivered the robotic pet as a one-to-one intervention. Only 1 delivered the intervention both individually and communally [41]. Most (n=5) provided the robopet to participants on a full-time basis [42-44,50]. In 1 study, their use progressed from structured 1-2 hour sessions during the first 2-3 months to full-time use by the third month [41]. Finally, 2 studies reported intervention delivery on a weekly basis, between 1-3 times each week [41,46].

In most studies (n=7), minimal facilitation or instructions were provided by the researchers to guide intervention delivery with the robotic pets to allow their use to be scaffolded naturally [40-44,47,50]. Among studies that provided information about intervention delivery during the research, 3 reported facilitation by formal caregivers [41,45,46]. In 1 study, staff placed the robotic pet in the resident's arm, talked about it, and then left the resident alone with it [45]. It was also made available during other times when residents asked for it or when the nurses were motivated to use the robotic pet with residents. Another study reported that, although the robotic pets were available in communal areas for unfacilitated interactions, structured group sessions with the robotic pets were also delivered by staff [41]. Finally, difficulties integrating the use of the robotic pets into nursing routines were reported in 1 study [46]. As such, nurses relied on therapeutic recreation staff to use them with nursing home residents [46].

Positive Impacts of the Robotic Pets

The positive impacts included improved mood and affect, improved communication and interaction, companionship, and other well-being outcomes (Table 2).

Table 2. Positive impacts of the robotic pets.

Author (study setting)	Mood and affect	Communication and social interaction	Companionship	Well-being outcomes
McBride et al [46] (nursing home)	✓[a]	✓	—[b]	—
Picking and Pike [47] (participants' homes)	✓	✓	—	—
Marsilio et al [45] (nursing home)	✓	✓	—	—
Pike et al [42] (participants' homes)	—	✓	✓	—
Brecher [40] (nursing home)	✓	—	—	—
Bradwell et al [41] (assisted living)	✓	—	—	—
Pike et al [43] (participants' homes)	✓	✓	✓	—
Hudson et al [44] (participants' homes)	✓	✓	✓	—
Tkatch et al [50] (participants' homes)	—	—	—	✓

[a]Observed in this study.

[b]Not observed in this study.

Improved Mood and Affect

Reduced agitation among older people with dementia was reported in 5 studies. Only 1 study used the Cohen-Mansfield Agitation Inventory and physiological indexes, and evaluated medication records to measure effects on agitation quantitatively [45]. Results showed statistically significant improvements in participants' agitation scores and oxygen saturation. Nevertheless, there were no significant changes to participants' heart rates. There were also no changes to the use of psychotropic or pain medications. Other studies reported their results based on observational data, where use of the robotic pets was reported to reduce aggression and disruptive behaviors [40,41,46]. The robotic pets were also found to be useful in de-escalating situations when people with dementia were agitated or anxious by providing calming effects [43,45-47]. Brecher [40] reported that a participant's physical aggression almost completely resolved within 24 hours of interacting with the robotic pet. Similar effects were reported in other studies, where behavioral issues were described as having been reduced [45,46]. This calming effect was also reported by older people without cognitive impairments [44].

Communication and Social Interaction

The robotic pets were found to have positive impacts on participants' communication and social interactions (n=8). When participants used the robopets in the presence of others, conversations and social interactions were facilitated [41-46]. In a study that was conducted to evaluate community-dwelling older adults' experiences of using robotic pets, participants shared that their opportunities to connect with others was increased through sharing their pets in public spaces [44]. For people with dementia, the robopets provided a topic of conversation, which increased social interaction between participants and their care providers, family members, and other residents [41-43]. Furthermore, the robotic pets' interactivity such as movements and sounds were observed to facilitate participants' interaction with the pet or with others [41,43,45,46]. However, during unfacilitated robot interactions, some people with dementia were unaware that they needed to pet the cat to stimulate responses and reported concerns that their robopet had not interacted with them [45]. In such instances, staff had to prompt residents to touch the robot.

Companionship

People with dementia were reported to have developed companionship with their robotic pets [41,42,45,47] and in some instances had *formed a strong bond and attachment* with the robotic pets [41]. Only 1 study conducted a quantitative evaluation of loneliness with cognitively healthy older adults using the University of California, Los Angeles (UCLA) loneliness scale. Results showed a statistically significant decrease in older adults' perception of subjective loneliness after 1 month of using the robotic pets [50]. This change was sustained after a second month of use. In the subsequent qualitative study, older adults shared similar sentiments that their perception of loneliness had reduced due to the presence of and interactions with the robopets [44]. This sense of presence was perceived to be comforting and enjoyable [43,44].

Other Well-being Outcomes

Quantitative measures of other outcomes were reported in 1 study [50]. In this study, there were no improvements to physical well-being of cognitively healthy older adults as recorded on the physical component of the Veteran's RAND (VR-12). However, their mental well-being, resilience, and purpose in life, as measured on the mental component of VR-12, the Brief Resilience Scale, and the adapted version of the NIH Tuberculosis Meaning and Purpose scales, respectively, showed statistically significant improvements after 1-2 months of using the robotic pets. In a qualitative study that investigated the use of robotic cats for people with dementia living at home, interviews with family members revealed that the pet robot provided participants with a sense of purpose, which led to an overall improvement in well-being and function [43]. As a result, one of the participants in the study did not have to move to a residential care facility.

Issues and Concerns Relating to Use of the Robotic Pets

Issues and concerns related to the use of the robotic pets included misperception and attachment, no impact or negative impacts, and practical issues.

Misperception and Attachment

Staff members in nursing homes reported that some people with dementia misperceived the robotic pets as live animals (n=2), which had implications on participants' acceptance and interaction with the technology. In 1 study, some participants declined the pet robot as they did not want to be responsible for caring for the cat [45]. In another study, one participant requested for a cage and collar for the robotic pet and showed concerned about its care. Correspondingly, he became frustrated because of a perceived responsibility to care for the cat [46]. The issue of attachment to the robotic pets was also raised [41,45]. Some authors felt that attachment had the potential to cause emotional distress for users if a technical fault or breakdown were to occur [45]. In 1 study where participants shared the robotic pets in a group setting, some participants were reported to exhibit jealousy of others using the robot, as they were hesitant to share the robotic pets with others [41].

No Impact or Negative Impacts

Some participants with dementia declined or had no interactions with the robotic pets and reported negative preferences (ie, dislikes) toward animals [42,43,45,47]. Some participants perceived the robots as "creepy" and rejected their use [41,43]. The interactivity of the robots was also raised as an issue. Vocalizations of the robopet (eg, meowing) were reported to cause anxiety in a participant with dementia who felt concerned about its well-being [43]. In such instances, family members turned the robot off. Similarly, another participant with dementia who had active psychosis was reported to feel disturbed by the robopet's sounds [46]. Some movements of the robotic cat, such as rolling over, also caused distress in some people with dementia, as they perceived that the cat was falling down [43]. A few participants exhibited agitation toward the robotic pet, and some attempted to harm it [41,45]. In 1 study, staff attributed the participant's negative response to a recent change in psychotropic medications [45].

Practical Issues

Practical issues, which included cost, hygiene, and infection control, were raised. Although the low-cost of this innovation was cited as a reason for some researchers' choice of social robot for their studies [40,41,43,50], other researchers and care staff also raised concerns about their affordability [41,44,50]. The issue of hygiene and infection control, such as through shared use in care facilities, was also brought up by staff and researchers in 2 studies as potential challenges for longer-term use [41,46]. The authors of 1 study suggested that the robotic pets should be kept off residents' lap during mealtimes to address the issue of hygiene and that purchasing individual robots for each resident might simplify the issue of infection control [46].

Discussion

Principal Findings

This is the first scoping review to identify and synthesize the evidence on the delivery and impact of low-cost, familiarly and realistically designed robotic pets for older adults and people with dementia. The majority of the included studies in this review were conducted in long-term care facilities and in participants' homes, and most employed the JfA robotic cat.

Overall, the positive impacts of the JfA robotic pets related to several psychosocial domains. Positive impacts included improved mood and affect, communication, social interaction, and companionship; these benefits resonate with findings in reviews that investigated the effectiveness of other social robots and robotic pets for older adults and people with dementia [13,14,16]. However, the impacts on other domains, including loneliness, resilience, and purpose in life, were less investigated; in this review, only 1 study that focused on cognitively healthy older adults reported on such outcomes [50]. This corresponded with findings from a review paper that investigated the use of social robots for older people [52] and found that only 3 studies reported outcomes relating to loneliness among healthy older adults. Similar to studies using other robotic animals, the interactivity of the JfA robotic cat and dogs have been described to facilitate users' communication and interaction with the pet and with other people. Paradoxically, the interactive features of the JfA robopets caused distress among a few participants with dementia. Such issues have been reported previously, where users were disturbed by sounds produced by another robotic pet [18,53-55]. Moving forward, there is a need for robot developers to consider the customizability of the robopets' interactive features in accordance with users' preferences.

The issue of affordability has been reported to impede the use of robotic pets in the real world [18,21,22,24]. The low-cost of the JfA robotic pets appeared to have an influence on intervention delivery and the conduct of research; with the exception of 1 study, all participants in this review received their own robotic pet for individual use. This is in contrast to findings from a systematic review, which found that higher-cost robotic pets have been shared among users and used more frequently in group settings [13]. The affordability of the JfA robotic pets was also cited by researchers as one of the influencing factors in the choice of robotic pet for their studies [40,41,43,50]. Cost appeared to have played a role in influencing the research method in one study, where individual robopets were provided to 216 participants to enable a statistical significant analysis of their impacts [50]. This strategy may be more challenging to implement with more expensive robots [16]. In addition, it is worth noting that there is a relatively sizeable body of anecdotal evidence, largely stemming from individuals' reports of their experiences with this technology [56-59]. This might also be attributed to their affordability, which might have enabled more users to gain access to this technology as compared to other social robots that are more expensive. For example, although Paro is one of the most researched social robots, it has substantially less user-generated reports of its impacts. This could be because Paro is primary used in institutions [17], likely due to its cost, which renders it to be less accessible for individual users' purchase. Individual ownership of the robotic pets may be viewed as a promising way to mitigate the pertinent issue of infection control, especially in light of the ongoing COVID-19 pandemic. A recent publication by Bradwell et al [60] reported that the acceptable levels of microbes on robopets, including one with antibacterial fur covering [17], exceeded an acceptable threshold after 20 minutes of use. Frequent and shared use of these robopets between different users can further increase the potential of infection transmission [27,28]. Hence, since the lower cost of the JfA robopets increases the affordability of individual purchases for each user, the corresponding risk of direct or indirect contact transmission of infections related to shared use may be ameliorated.

Issues related to use of the JfA robopets were identified. Like other interventions involving social robots, there were issues associated with use of this intervention. Some participants with dementia did not benefit from their use or demonstrated negative responses toward the robopets. For this population, the ethical challenge of deception also emerged [10], as some participants misperceived them as real animals or showed attachment toward them. These issues are not unique to the JfA robotic cat and dog, as they have been reported in other studies using other robotic pets [23,33,61]. The significance of these issues should not be discounted, as those who were more attached or misperceived the robopets belonged to a vulnerable population. However, from the standpoint of the capability approach, all humans, including people with disabilities, should be given the opportunity to achieve a threshold level of core capabilities to uphold the principle of social justice [62]. Therefore, in consideration that the pet robot may facilitate a user's capacities that would be otherwise undermined, such as facilitating social interaction, this can be viewed as enabling technology with greater benefits than risks [63]. In addition, formal and informal caregivers should also explicitly consider upholding this principle, particularly when delivering the robotic cat. When introducing this technology to users, they should introduce it as a robotic pet and refrain from referring to it as a real animal [63]. The understanding of potential issues such as jealousy and attachment may also guide future implementation and inform future robot development to ensure robustness of the technology.

Users' responses toward the JfA robopets appear to be related to their profile (ie, preference for or experience with animals). Participants who did not respond or had negative responses to the JfA robopets were reported to not like animals. This aligned with findings from other studies that highlighted that multilevel stakeholders including people with dementia [17], family members [18], and staff [22] who liked animals had positive perceptions and reactions to robotic pets. Therefore, before considering the use of the JfA robopets to address the psychosocial needs of older adults or people with dementia, care providers should consider users' preferences for animals, as well as their preferred type of robotic animals, to maximize the appropriateness and meaningfulness of the intervention.

Strengths and Limitations

There are a number of strengths underpinning this work. First, the methodological framework used throughout the scoping review process was transparent and rigorous. The screening and data extraction process involved two independent reviewers, which reduced the risk of reviewer bias or article selection bias. Both reviewers met at regular intervals and discussed and resolved all discrepancies. Second, this paper discusses the pragmatic aspects relating to intervention delivery and the conduct of research using the JfA robotic pets, which can serve as useful considerations for researchers or users who are keen to further explore the use of this technology. However, there are limitations of this review. Articles that were published in other languages were not searched or included in this review. As non-English studies were excluded from this review, relevant studies may have been missed.

Conclusions

This scoping review has mapped out current evidence on the use of and impact of realistic and familiarly designed low-cost robotic pets for older adults and people with dementia. Our review contributes to the evidence base that is necessary for more widespread awareness about the potential utility of these low-cost robotic pets to address the psychosocial needs of older adults and people with dementia, as both the positive impacts and issues related to their use largely resonate with research conducted with several other robotic animals. The affordability of these robopets appear to have an influence on intervention delivery. They also appear to have the ability to uphold the distributive justice of innovation dissemination; these are especially relevant in light of the COVID-19 pandemic, where there is an increased emphasis on infection control and equal access. However, more rigorous effectiveness trials are required to confirm their positive impacts. Future studies should also consider comparing the intervention effects of the JfA robotic pets with other robotic pets. It is also important to ascertain the design preferences of older adults and people with dementia to facilitate the development of future user-centered interventions using robotic pets.

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Authors' Contributions

WQK conceptualized the review approach and developed the review questions and review design. FXHA and WQK were involved in the screening and selection process, quality appraisal, and data extraction. WQK initiated the draft of the manuscript, and

FCHA had meaningful contributions to its drafting and editing. DC read the draft and provided critical feedback on the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[PDF File (Adobe PDF File), 123 KB - rehab_v8i1e25340_app1.pdf]

Multimedia Appendix 2
PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist.
[PDF File (Adobe PDF File), 83 KB - rehab_v8i1e25340_app2.pdf]

Multimedia Appendix 3
Quality appraisal.
[PDF File (Adobe PDF File), 137 KB - rehab_v8i1e25340_app3.pdf]

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Abbreviations

AACODS scale: Authority, Accuracy, Coverage, Objectivity, Date, Significance scale
ITN: Innovative Training Network
JfA: Joy for All
NIH: National Institutes of Health
PCC: Population, Concept, and Context
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR: Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews
VR-12: Veteran's RAND
UCLA loneliness scale: University of California, Los Angeles loneliness scale

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Original Paper

Association Between Therapeutic Alliance and Outcomes Following Telephone-Delivered Exercise by a Physical Therapist for People With Knee Osteoarthritis: Secondary Analyses From a Randomized Controlled Trial

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Abstract

Background: The therapeutic alliance between patients and physical therapists has been shown to influence clinical outcomes in patients with chronic low back pain when consulting in-person. However, no studies have examined whether the therapeutic alliance developed between patients with knee osteoarthritis and physical therapists during telephonic consultations influences clinical outcomes.

Objective: This study aims to investigate whether the therapeutic alliance between patients with knee osteoarthritis and physical therapists measured after the second consultation is associated with outcomes following telephone-delivered exercise and advice.

Methods: Secondary analysis of 87 patients in the intervention arm of a randomized controlled trial allocated to receive 5 to 10 telephone consultations with one of 8 physical therapists over a period of 6 months, involving education and prescription of a strengthening and physical activity program. Separate regression models investigated the association between patient and therapist ratings of therapeutic alliance (measured after the second consultation using the Working Alliance Inventory Short Form) and outcomes (pain, function, self-efficacy, quality of life, global change, adherence to prescribed exercise, physical activity) at 6 and 12 months, with relevant covariates included.

Results: There was some evidence of a weak association between patient ratings of the alliance and some outcomes at 6 months (improvements in average knee pain: regression coefficient −0.10, 95% CI −0.16 to −0.03; self-efficacy: 0.16, 0.04-0.28; global improvement in function: odds ratio 1.26, 95% CI 1.04-1.39, and overall improvement: odds ratio 1.26, 95% CI 1.06-1.51; but also with worsening in fear of movement: regression coefficient −0.13, 95% CI −0.23 to −0.04). In addition, there was some evidence of a weak association between patient ratings of the alliance and some outcomes at 12 months (improvements in self-efficacy: regression coefficient 0.15, 95% CI 0.03-0.27; global improvement in both function, odds ratio 1.19, 95% CI 0.03-1.37; and pain, odds ratio 1.14, 95% CI 1.01-1.30; and overall improvement: odds ratio 1.21, 95% CI 1.02-1.42). The data suggest that associations between therapist ratings of therapeutic alliance and outcomes were not strong, except for improved quality of life at 12 months (regression coefficient 0.01, 95% CI 0.0003-0.01).

Conclusions: Higher patient ratings, but not higher therapist ratings, of the therapeutic alliance were weakly associated with improvements in some clinical outcomes and with worsening in one outcome. Although the findings suggest that patients who perceive a stronger alliance with their therapist may achieve better clinical outcomes, the observed relationships were generally weak and unlikely to be clinically significant. The limitations include the fact that measures of therapeutic alliance have not been validated for use in musculoskeletal physical therapy settings. There was a risk of type 1 error; however, findings were interpreted on the basis of clinical significance rather than statistical significance alone.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12616000054415; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=369204

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KEYWORDS

osteoarthritis; physiotherapy; physical therapy; tele-rehabilitation; telephone; therapeutic alliance; exercise; knee; pain

Introduction

Background

Knee osteoarthritis (OA) is highly prevalent and leading cause of functional limitation in older adults [1,2]. Given that there is no cure for OA, long-term self-management of the condition aims to reduce joint pain and improve physical function and quality of life. All current clinical guidelines recommend education, exercise, and if appropriate, weight loss [3-6]. Physical therapists are one of the most common providers of exercise management for people with OA [7] and traditionally, consultations occur in-person at a physical therapy clinic. However, there is a growing body of literature to support the safety and effectiveness of tele-rehabilitation, where physical therapists and patients consult remotely using telecommunication technologies, such as video conferencing or telephone [8-10]. Accordingly, tele-rehabilitation, as the mode of delivery of physical therapy services, is increasingly being advocated and implemented in Australia [11], the United Kingdom [12], and the United States [13,14].

An important aspect of health care is the strength of the relationship developed between the patient and the health professional. This relationship, known as the therapeutic alliance, is conceptualized as a sense of collaboration, warmth, and support between a patient and clinician [15], and it focuses on 3 elements of the relationship: (1) agreement on goals; (2) agreement on tasks; and (3) personal bond. Extensive research in psychotherapy settings (eg, patients recovering from schizophrenia, poor mental health, drug use) has demonstrated that a strong therapeutic alliance between patients and their therapists can positively influence satisfaction with care, quality of life, psychological well-being, symptom improvement, and treatment adherence [16-19]. There is emerging evidence that therapeutic alliance is also important in musculoskeletal rehabilitation. Two recent systematic reviews found evidence that a therapeutic alliance in people with chronic musculoskeletal pain (eg, chronic low back pain) was associated with clinical outcomes from treatment, including improvement in pain and function [20,21]. In contrast, another systematic review reported that the small number of studies available, failed to provide evidence of a strong relationship between therapeutic alliance and improvement in pain [22]. None of the studies cited in any of these three reviews evaluated the therapeutic alliance during tele-rehabilitation consultations. In addition, evidence suggests that therapeutic alliance is associated with better adherence to prescribed exercise. A cross-sectional study of 87 participants with musculoskeletal injuries found that the strongest predictor of adherence to home-based rehabilitation exercises was the therapeutic alliance between patients and the physical therapists treating them during in-person consultations [23].

Rationale for This Study

Most existing studies evaluating relationships between therapeutic alliance and outcomes of physical therapy practice have focused on in-person consultations between patients and therapists. Thus, it is not clear if findings from such studies can be generalized to telephone-delivered models of physical therapy care, where patients and physical therapists have no physical or visual contact. Our research provides some evidence from qualitative studies that physical therapists and patients with OA perceive a strong alliance when consulting via video [24] and telephone [25,26]. In addition, we found that both patient and physical therapist ratings of the therapeutic alliance using a validated measure [27] were high, when consulting via telephone and generally in agreement with each other [28]. However, the relationship between therapeutic alliance and clinical outcomes from telephone-delivered physical therapy care remains unexplored. Thus, the aim of this study was to investigate whether the therapeutic alliance between patients and physical therapists is associated with self-reported clinical outcomes (including pain, function, fear of movement, quality of life, exercise adherence, treatment satisfaction, physical activity) at 6 and 12 months following telephone-delivered exercise and advice for people with knee OA.

Methods

Design

This exploratory study used data collected from physical therapists and patients in the intervention arm of a randomized controlled trial (RCT; Australian New Zealand Clinical Trials Registry (ANZCTRN) 12616000054415), which evaluated the effectiveness of incorporating physical therapist-delivered exercise advice and support into an existing musculoskeletal telephonic service delivered by nurses [10,29]. The funders played no role in the design, conduct, or reporting of this study. All participants provided written informed consent, and the institutional ethics committee approved the study.

Patients

The intervention arm of the RCT included 87 randomized patients with knee OA. Inclusion criteria were meeting the National Institute for Health and Care Excellence OA clinical criteria (aged 45 years or over, with activity-related joint pain and morning stiffness ≤30 min) [5], an average knee pain of ≥4 on an 11-point numeric rating scale, and a history of knee pain for at least three months. The exclusion criteria have been published elsewhere [29]. Patients for the RCT were recruited from rural, regional, and metropolitan areas of Australia using advertisements on social media, on the radio, and in newspapers, through community organizations, and using previous volunteer databases.

Physical Therapists

A total of 8 physical therapists were recruited in Victoria, Australia, to deliver the intervention for the trial. Selection criteria included a physical therapy qualification, at least two years of musculoskeletal professional experience, and current Australian registration to practice. Before the commencement of the trial, the physical therapists underwent a 2.5-day training program in the delivery of person-centered care and behavior change (delivered by HealthChange Australia) [30,31]. This involved the use of a set of practice principles to foster effective communication, techniques to identify and address barriers to behavior change, and a framework to guide decision making.

Intervention

Details of the RCT have been published [29], including trial findings [10]. Patients in the intervention arm of the trial initially received a telephone call from a nurse as part of an existing musculoskeletal help line, where they received general information and advice about OA. Patients then received between 5 and 10 telephonic consultations from one of the eight physical therapists over a 6-month period (the same physical therapist provided all the consultations for each of their patients). During the initial consultation (approximately 40 min in length), the physical therapists helped increase patient knowledge and understanding of knee OA and the benefits of exercise. They worked with patients to devise goals and action plans that involved structured home-based strengthening exercise programs and/or physical activity plan. During follow-up consultations (approximately 20 min in length; the precise number of consultations was negotiated between the patients and their physical therapists), the physical therapists adjusted the program as necessary, while providing support using person-centered practice principles and behavior change techniques to help build patient confidence in their ability to undertake and adhere to an exercise program.

Patients were provided with a study folder containing information about OA and management, exercise instructions and access to a study website containing video demonstrations of each exercise. Patients were provided with three exercise resistance bands for home exercises.

Outcome Measures

Outcome measures (collected at baseline, 6, and 12 months) in the RCT that were included in this secondary analysis were as follows:

1. Overall average knee pain in the past week (measured with a numeric rating scale ranging from 0 indicating no pain to 10, indicating the worst pain possible).
2. Physical function (measured using the Western Ontario and McMaster Universities Osteoarthritis Index [32] with scores ranging from 0 to 68, with lower scores indicating better function).
3. Self-efficacy (measured using the Arthritis Self-Efficacy Scale [33], total scores ranging from 3 to 30, with higher scores indicating greater self-efficacy).
4. Quality of life (using the assessment of quality of life [AQoL] instrument [34], with scores from -0.04 to 1.00, higher scores indicating better quality of life).
5. Global changes at 6 and 12 months (overall, pain, and function) via 7-point scales (terminal descriptors *much worse* to *much better*), as well as change in physical activity (descriptors *much less* to *much more*). Scores were dichotomized into 1 (improved or increased; those indicating *moderately better* or *more* or *much better* or *more*) and 0 (not improved or increased; those indicating *much worse*, *moderately worse*, *slightly worse*, or *no change*).
6. Satisfaction with care collected at 6 and 12 months via a 7-point scale (terminal descriptors *extremely unsatisfied* to *extremely satisfied*). Scores were dichotomized into *1* (satisfied; those indicating *moderately satisfied* or *extremely satisfied*) and *0* (not satisfied; those indicating *extremely unsatisfied*, *moderately unsatisfied*, *slightly unsatisfied*, or *neither satisfied* or *unsatisfied*).
7. Physical therapist-rated patient adherence to home exercise program collected at 6-months via an 11-point scale (terminal descriptors 0=*not at all* to 10=*completely as instructed*), only collected at 6 months.
8. Self-rated adherence to (a) prescribed exercises and (b) physical activity plan via an 11-point scale (terminal descriptors 0=*not at all* to 10=*completely as instructed*) rated at 6 and 12 months.

Therapeutic Alliance Measures

Therapeutic alliance was measured using the Working Alliance Inventory-Short Form (WAI) [27,35], a commonly used valid and reliable measure of the alliance [27], which contains 12 statements relating to perceived trust and agreement between the therapist and the client (eg, “My patient/physical therapist and I agree about the things they/I will need to do in therapy to help improve my situation”). Statements were rated using a 7-point scale ranging from *never* feeling (or thinking) that way, to *always* feeling (or thinking) that way. The WAI has 3 subscales: (1) task (agreement on management methods being used; items 1, 2, 8, and 12); (2) bond (feelings of appreciation and trust; items 3, 5, 7, and 9), and (3) goal (agreement on aims and objectives of treatment; items 4, 6, 10, and 11), which are summed together to give a total score ranging from 12 to 84 (higher scores indicate a stronger alliance) [27,35].

As recommended [27], both patients and physical therapists completed the WAI separately, after their second consultation (approximately week 4 of the intervention). Although therapeutic alliance was also measured in the RCT at the end of the 6-month intervention, there was no significant change in total scores over time [28]. Thus, only scores obtained after the second consultation were used in this exploratory study.

Data Analysis

Means and SDs of the patient and physical therapist characteristics and therapeutic alliance ratings were calculated. Separate regression models were used to investigate whether the therapeutic alliance was associated with each outcome. For each continuous outcome, linear regression models for the 6 and 12-month outcomes (change from baseline) were fit, with random effects for each patient to account for the two measurements. The baseline outcome measurement, where available, was included in the model, as were terms for patient (sex, age, self-efficacy at baseline, treatment expectations) and physical therapist characteristics (years of experience, previous experience delivering care remotely) that could potentially influence both the therapeutic alliance measure and outcomes at 6 and 12 months. The effect of therapeutic alliance on outcomes at 6 and 12 months was estimated by including terms for the outcome measurement time point, therapeutic alliance score, and an interaction between the two. Global change scores were dichotomized and analyzed using mixed-effects logistic regression models. Separate models were fit for the patient and physical therapist ratings of the alliance. As data for physical therapist ratings of adherence were only collected at 6 months, a standard linear regression model was fit. Analysis was performed using Stata (StataCorp, version 15.1).

Results

Characteristics of Patients With Knee OA

Most of the 87 patients (Table 1) were female (55/87, 63%) and lived in the metropolitan areas of Australia (48/87, 55%). The mean age of the patients was 62.4 years (SD 9.1), and at baseline, their mean knee pain was 6.0 (SD 1.5) on an 11-point numeric rating scale. Patients had a mean of 6.3 (SD 1.8) telephonic consultations during the trial and rated their therapeutic alliance a mean of 75.3 (SD 7.4) out of a maximum of 84.

Table 1. Characteristics of people with knee osteoarthritis (n=87).

Characteristic	Value
Female sex, n (%)	55 (63)
Age (years), mean (SD)	62.4 (9.1)
BMI (kg/m^2), mean (SD)	31.1 (6.8)
Location[a], n (%)	
Metropolitan	48 (55)
Nonmetropolitan	39 (45)
Employment status, n (%)	
Working full- or part-time	37 (43)
Unemployed or retired	50 (57)
Education, n (%)	
Less than 3 years of high school	5 (6)
3 years or more of high school	19 (23)
Some tertiary training	21 (24)
Graduated from university or polytechnic	24 (29)
Any postgraduate study	15 (18)
Number of calls with physical therapist, mean (SD)	6.3 (1.8)
Therapeutic alliance (WAI[b]) at week 4, mean (SD)	75.3 (7.4)
Knee pain (NRS[c]) at baseline, mean (SD)	6.0 (1.5)
Physical function (WOMAC[d]) at baseline, mean (SD)	29.3 (10.1)
Self-efficacy (ASES[e]) at baseline, mean (SD)	20.2 (4.0)
Quality of life (AQoL[f]) at baseline, mean (SD)	0.7 (0.2)
Fear of movement (BFMS[g]) at baseline, mean (SD)	12.9 (3.5)
Treatment expectations, n (%)	
No effect	0 (0)
Minimal improvement	8 (9)
Moderate improvement	46 (53)
Large improvement	32 (37)
Complete recovery	1 (1)

[a]Defined according to the Australian Statistical Geography Standard Remoteness Structure [36].
[b]WAI: Working Alliance Inventory; scores range from 12 to 84, where higher scores indicate a stronger alliance.
[c]NRS: numeric rating scale; ranges from 0 to 10, where lower scores indicate less pain.
[d]WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; ranges from 0 to 68, where lower scores indicate better function.
[e]ASES: Arthritis Self-Efficacy Scale: scores range from 3 to 30, where higher scores indicate greater self-efficacy.
[f]AQoL: Assessment of quality of life instrument, ranges from −0.04 to 1.0, where higher scores indicate better quality of life.
[g]BFMS: Brief Fear of Movement Scale; ranges from 0 to 24, where higher scores indicate lower fear of movement.

Characteristics of Physical Therapists

Half of the 8 physical therapists (Table 2) were male and 63% (5/8) worked exclusively in private physical therapy settings. Collectively, physical therapists had a mean of 13.8 (SD 8.2) years of clinical experience, and none had experience delivering care via telephone, although 25% (2/8) had experience doing so via Skype. Physical therapists consulted with a mean of 10.5 (SD 2.1) trial patients each, and rated the therapeutic alliance as a mean of 71.0 (SD 5.5) out of a maximum of 84.

Table 2. Characteristics of physical therapists (n=8).

Characteristic	Value
Female, n (%)	50 (50)
Age (years), mean (SD)	35.4 (8.2)
Clinical experience (years), mean (SD)	13.8 (8.2)
Number of patients consulted with in the trial, mean (SD)	10.5 (2.1)
Work setting, n (%)	
Both private and public	2 (25)
Private	5 (63)
Public	1 (12)
Previous experience delivering care remotely, n (%)	
None	6 (75)
Yes (via Skype)	2 (25)
Yes (via telephone)	0 (0)
Postgraduate training in knee osteoarthritis, n (%)	
Yes	3 (37)
No	5 (63)
Postgraduate training in exercise, n (%)	
Yes	7 (88)
No	1 (12)
Postgraduate training in behavior change[a], n (%)	
Yes	3 (37)
No	5 (63)
Therapeutic alliance (WAI[b]) at week 4, mean (SD)	71.0 (5.5)

[a]Excluding trial-specific training in person-centered principles and behavior change techniques.

[b]WAI: Working Alliance Inventory; scores range from 12 to 84, where higher scores indicate a stronger alliance.

Association of Patient-Rated Therapeutic Alliance With Outcomes

Associations between patient ratings of therapeutic alliance and continuous and binary outcomes at 6 and 12 months are displayed in Tables 3 and 4, respectively. Data suggest that patient-rated therapeutic alliance was associated with some outcomes at 6 months. Regression coefficients show that a one-unit increase in the therapeutic alliance score was associated with (1) a −0.10 (95% CI −0.16 to −0.03) unit improvement in overall average knee pain measured via a numeric rating scale; (2) a −0.13 (95% CI −0.23 to −0.04) unit worsening in fear of movement; (3) a 0.16 (95% CI 0.04 to 0.28) unit improvement in self-efficacy; (4) increased odds of global improvement in physical function (odds ratio [OR] 1.21, 95% CI 1.04-1.39), and (5) increased odds of a global improvement overall (OR 1.26, 95% CI 1.06 to 1.51).

Data suggest that patient-rated therapeutic alliance was associated with some outcomes at 12 months. A one-unit increase in the therapeutic alliance score was associated with (1) a 0.15 (95% CI 0.03 to 0.27) unit improvement in self-efficacy; (2) increased odds of a global improvement in pain (OR 1.14, 95% CI 1.01 to 1.30); (3) increased odds of a global improvement in physical function (OR 1.19, 95% CI .03 to 1.37), and (4) increased odds of a global improvement overall (OR 1.21, 95% CI 1.02 to 1.42).

Table 3. Associations between patient and physical therapist ratings of the therapeutic alliance and changes in continuous outcomes at 6 and 12 months.[a]

Outcome	6 months		12 months	
	Regression coefficient[b] (95% CI)	*P* value	Regression coefficient[b] (95% CI)	*P* value
Patient rating of therapeutic alliance				
Overall average knee pain (NRS[c])	−0.10 (−0.16 to −0.03)	<.01	−0.06 (−0.13 to 0.00)	.06
Physical function (WOMAC[d] C)	−0.10 (−0.40 to 0.20)	.52	−0.13 (−0.43 to 0.18)	.42
Fear of movement (BFMS[e])	−0.13 (−0.23 to −0.04)	<.01	−0.08 (−0.18 to 0.01)	.08
Health-related quality of life (AQoL[f])	0.01 (0.01 to −0.01)	.43	0.01 (−0.01 to 0.01)	.42
Self-efficacy (total; ASES[g])	0.16 (0.04 to 0.28)	.01	0.15 (0.03 to 0.27)	.02
Overall self-rated adherence to prescribed exercise	0.09 (−0.02 to 0.20)	.11	0.04 (−0.07 to 0.15)	.46
Self-rated adherence to prescribed physical activity	0.08 (−0.02 to 0.18)	.10	0.07 (−0.03 to 0.17)	.15
Physical therapist-rated patient adherence	0.02 (−0.04 to 0.09)	.49	—[h]	—
Physical therapist rating of therapeutic alliance				
Overall average knee pain (NRS)	−0.02 (−0.11 to 0.06)	.55	−0.06 (−0.14 to 0.02)	.15
Physical function (WOMAC C)	−0.14 (−0.50 to 0.23)	.47	−0.03 (−0.40 to 0.35)	.89
Fear of movement (BFMS)	−0.07 (−0.20 to 0.06)	.28	−0.08 (−0.21 to 0.04)	.20
Health-related quality of life (AQoL)	0.01 (−0.01 to 0.01)	.25	0.01 (0.0003 to 0.01)	.04
Self-efficacy (total; ASES)	0.06 (−0.11 to 0.23)	.50	0.04 (−0.13 to 0.22)	.65
Overall self-rated adherence to prescribed exercise	0.03 (−0.11 to 0.18)	.65	−0.03 (−0.17 to 0.11)	.67
Self-rated adherence to prescribed physical activity	0.03 (−0.10 to 0.16)	.67	−0.01 (−0.14 to 0.12)	.90
Physical therapist-rated patient adherence	0.05 (−0.03 to 0.13)	.24	—	—

[a]Calculated as follow-up (6 or 12 months) minus baseline.

[b]Regression coefficients are not standardized. Regression models were adjusted and baseline outcome measures, patient variables (gender, age, self-efficacy at baseline, treatment expectations), and physical therapist variables (years of experience, previous experience delivering care remotely) were included as covariates.

[c]NRS: numeric rating scale; ranges from 0 to 10. Negative coefficients indicate that a stronger therapeutic alliance is associated with reduced pain over time.

[d]WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; ranges from 0 to 68. Negative coefficients indicate that a stronger therapeutic alliance is associated with reduced functional impairment over time.

[e]BFMS: Brief Fear of Movement Scale; ranges from 0 to 24. Positive coefficients indicate that a stronger therapeutic alliance is associated with an improvement in fear of movement over time.

[f]AQoL: Assessment of quality of life instrument, ranges from −0.04 to 1.0. Positive coefficients indicate that a stronger therapeutic alliance is associated with improvement in quality of life over time.

[g]ASES: Arthritis Self-Efficacy Scale: scores range from 3 to 30. Positive coefficients indicate that a stronger therapeutic alliance is associated with improvement in self-efficacy over time.

[h]—: Outcome measure not collected at 12 months.

Table 4. Associations between patient and physical therapist ratings of the therapeutic alliance and binary outcomes at 6 and 12 months.[a]

Outcome	6 months		12 months	
	OR[b] (95% CI)	*P* value	OR[b] (95% CI)	*P* value
Patient rating of therapeutic alliance				
Improved pain	1.12 (0.99 to 1.26)	.08	1.14 (1.01 to 1.30)	.03
Improved physical function	1.21 (1.04 to 1.39)	.01	1.19 (1.03 to 1.37)	.02
Improved overall	1.26 (1.06 to 1.51)	.01	1.21 (1.02 to 1.42)	.03
Satisfied with care received	1.12 (0.95 to 1.33)	.17	1.10 (0.96 to 1.25)	.18
Increased physical activity levels	1.09 (0.96 to 1.24)	.18	1.11 (0.97 to 1.26)	.12
Physical therapist rating of therapeutic alliance				
Improved pain	1.07 (0.93 to 1.24)	.33	1.10 (0.95 to 1.28)	.21
Improved physical function	1.13 (0.95 to 1.33)	.17	1.04 (0.89 to 1.22)	.63
Improved overall	1.13 (0.94 to 1.36)	.18	1.09 (0.92 to 1.31)	.32
Satisfied with care received	1.16 (0.94 to 1.43)	.16	0.89 (0.73 to 1.09)	.26
Increased physical activity levels	1.04 (0.90 to 1.20)	.57	1.06 (0.92 to 1.23)	.39

[a]Regression models were adjusted and baseline outcome measures, patient variables (gender, age, self-efficacy at baseline, and treatment expectations), and physical therapist variables (years of experience and previous experience delivering care remotely) were included as covariates.

[b]OR: odds ratio; ORs >1 indicate greater odds of reporting improvement in outcome or satisfaction with care with a stronger therapeutic alliance.

Association of Physical Therapist Ratings of the Therapeutic Alliance With Outcomes

Associations between physical therapist ratings of the therapeutic alliance and continuous and binary outcomes at 6 and 12 months are displayed in Tables 3 and 4, respectively. There was no evidence of an association between the physical therapist–rated therapeutic alliance and any outcomes at 6 months; only one outcome at 12 months was associated. A one-unit increase in therapeutic alliance was associated with a regression coefficient of 0.01 (95% CI 0.0003 to 0.01) unit improvement in health-related quality of life.

Discussion

Principal Findings

The aim of this study was to investigate whether the therapeutic alliance between patients and physical therapists during telephonic consultations was associated with outcomes following exercise and advice for people with knee OA. The findings suggest that patient-rated therapeutic alliance was weakly associated with some outcomes at 6 and 12 months, including improvements in pain, self-efficacy, global function, and overall global improvement, in addition to a worsening in fear of movement. The data indicated that associations between physical therapist-rated therapeutic alliance and outcomes were not meaningful. The observed relationships were generally weak and thus unlikely to be clinically significant.

Comparison With Earlier Work

This is the first study to investigate the relationship between therapeutic alliance and clinical outcomes following telephone-delivered physical therapy care in adults with OA. Existing reviews focusing on traditional, in-person consultations among those with musculoskeletal conditions have found that a stronger therapeutic alliance between the patient and their physical therapist is associated with improved outcomes, including better adherence to physical-therapist–prescribed exercise and physical activity [37], improved global effects (pain, physical function, disability) [21], and greater treatment satisfaction [37,38]. We also found some evidence of an association with improved global effects; however, our data did not indicate a strong association between therapeutic alliance and exercise adherence or treatment satisfaction. The reason remains unclear. However, we measured adherence and satisfaction using self-reported questionnaires and analyzed associations with a valid and reliable measure of therapeutic alliance. Other studies included in a review by Babatunde et al, [37] have qualitatively explored the relationship between therapeutic alliance and adherence, or used unvalidated custom-developed measures of alliance, which makes comparisons with our findings difficult. In addition, we found that a higher therapeutic alliance was associated with greater improvements in self-efficacy over time. To our knowledge, no previous studies have examined the association between therapeutic alliance and changes in self-efficacy. Intuitively, this finding makes sense, in that greater perceived agreement on tasks and goals and a greater perceived bond with therapists is related to improvements in confidence and belief in one's ability. Unexpectedly, we found that a higher patient-perceived therapeutic alliance was associated with worsening of fear of movement at 6 months, but at 12 months, the direction of the association was uncertain. In the overarching clinical trial, fear of movement worsened over time in both the intervention and control groups, with no differences in change between groups [10]. To our knowledge, no other studies have examined the association between therapeutic alliance and change in fear of movement after treatment; thus, further research is required to confirm this finding.

Our findings are broadly similar to those of previous research exploring therapeutic alliance in tele-rehabilitation consultations with clinicians outside of the physical therapy profession. One study of 22 adolescents (mean age 15 years) with idiopathic arthritis who received care via 12 telephonic consultations from trained nonprofessional health coaches over 12 weeks found that therapeutic alliance was correlated with improved treatment outcomes, including decreased pain [39]. However, the authors only reported correlation coefficients, which makes comparisons with the magnitude of association observed in our study difficult. Other populations of people with psychological disorders (eg, post-traumatic stress disorder, anxiety, depression, cancer stress) have found that therapeutic alliances during therapist-led remotely delivered (ie, via video or telephone) cognitive behavioral therapy is associated with improvements in outcomes (eg, reduced symptoms of depression and anxiety, increased compliance) at 5 to 18 weeks [40-42]. However, given paucity of evidence, particularly in remotely delivered physical therapy, further research is required.

Although we observed associations between therapeutic alliance and outcomes, the coefficients were very small and confidence intervals contained values that were close to zero. Thus, the clinical significance of our observed relationships is unclear. A single unit increase in therapeutic alliance score (measured on a scale of 12 to 84, with an SD of 7.4) corresponded to a very small, 0.10-unit improvement in overall average knee pain (measured on an 11-point numeric rating scale) at 6 months. This magnitude of change is similar to that observed by Ferreira et al [43], who investigated associations between therapeutic alliance and clinical outcomes following 12 in-person consultations with physical therapists over 8 weeks for patients with low back pain. This suggests that consulting via telephone does not change the relationship between therapeutic alliance and outcomes when compared with being in-person. Ferreira et al [43] found that a 1-SD increase in therapeutic alliance score (measured using a different version of the WAI to the one used in our study) corresponded to a 0.6-unit improvement in pain (measured on an 11-point numeric rating scale). For context, the minimal clinically important difference for pain following interventions for people with OA is an absolute change of 2.0 units on a numeric rating scale [44], which suggests that therapeutic alliance may not have a clinically significant impact on pain. In quality of life, a 1-SD increase in physical therapist-rated therapeutic alliance score in our study corresponds to a 0.055-unit improvement in quality of life, approximating the estimated minimal clinically important difference of 0.06 on the AQoL [45]. Minimal clinically important differences for other outcome measures that we found were associated with therapeutic alliance (including self-efficacy and fear of movement) are unknown [46], and as such, the clinical significance of associations with these outcomes is unclear.

Our patient and physical therapist ratings of the therapeutic alliance were high [28], and the small SD suggests that there was no significant variability in scores. This does not appear to be unique to our sample, as other studies investigating therapeutic alliances in physical therapy or tele-rehabilitation have also observed high scores with low variability in their sample [39,43]. A variety of tools have been used to evaluate therapeutic alliance [37]; however, none have been validated for use in musculoskeletal physical therapy settings. These existing tools may not necessarily capture domains of care that are important in physical therapy contexts [47] and have been found to demonstrate a ceiling effect [48]. Therefore, the development of measures that are validated in musculoskeletal physical therapy settings is important.

Our study is relevant to clinicians and researchers. The findings suggest that the strength of the therapeutic alliance with the physical therapist as perceived by the patient is associated with some clinical outcomes after telephonic consultations focused on exercise management. Thus, physical therapists should be mindful about the therapeutic alliance they build with their patients. To enhance the therapeutic alliance, it has been recommended that clinicians focus on fostering person-centered interactions with patients, including offering emotional support and facilitating patient involvement in decision-making [49-51]. It is also important to acknowledge, however, that we currently do not understand the clinical importance of the observed associations between therapeutic alliance and outcomes, and it is also not clear which strategies are best to increase therapeutic alliance. Further research is required to determine what specific components of care or clinician skills may need to be modified to enhance therapeutic alliance, and whether it is practical for physical therapists or other clinicians to adapt such skills in clinical practice. In addition, further research is required to investigate whether clinician experience with or training in remotely delivered care influences therapeutic alliance during telephonic consultations. Studies that include manipulation of therapeutic alliance may provide more insight into its importance in clinical practice. For example, Fuentes et al [52] randomized 117 people with chronic low back pain to enhanced and limit therapeutic alliance groups, where physical therapists either did not engage in conversation with patients and left the room during interferential current therapy (limited alliance group) or engaged in active listening and used empathetic language and encouragement (enhanced alliance group). They found that those allocated to the enhanced therapeutic alliance groups reported significantly greater improvements in pressure pain threshold and pain than those in the limited alliance group immediately after the treatment session.

Future research should consider evaluating relationships between therapeutic alliance and clinical outcomes in real-world clinical practice, as both alliance and clinical outcomes may be more varied than observed within the context of a clinical trial. Importantly, we found that physical therapist ratings of therapeutic alliance were generally not related to clinical outcomes, suggesting that their own perceptions of the alliance may not be as important as those of the patient. Our study was the first to investigate the relationship between therapeutic alliance and clinical outcomes following telephone-delivered physical therapy care in adults with OA, and thus further research is required to compare therapeutic alliance during tele-rehabilitation and traditional in-person consultations, and how it moderates treatment outcomes.

Limitations

Our study has some limitations. As with any study, there is a risk of type 1 error. However, in accordance with recommendations from the American Statistical Association [53], we did not interpret our results on the basis of statistical significance alone, instead considering the clinical significance of the findings. Before commencement of the trial, all trial physical therapists underwent training in person-centered care and behavior change techniques [30]. Our findings may not be generalizable to other physical therapists in the community who have not undergone such training. Most (5/8, 63%) of our physical therapists worked in private health care settings, where patients typically incur out-of-pocket costs for services. This broadly reflects the physical therapy workforce in Australia, where more than 60% of therapists work in private settings [54]. Thus, our findings may not be generalizable to other countries where physical therapists may work in alternate health care settings. We used the WAI to measure the therapeutic alliance between patients and physical therapists; however, this tool has not been validated for use in musculoskeletal physical therapy practice, and similar measures of therapeutic alliance have been found to demonstrate a ceiling effect [48]. Finally, a limitation of our study is that our dependent variables (clinical outcomes) were measured via participant-reported outcome measures. It is unclear if our findings may have differed had we used objectively measured outcomes (such as performance tests of physical function) which is an area where future research may be warranted.

Conclusions

In conclusion, higher patient ratings but not higher physical therapist ratings of the therapeutic alliance were weakly associated with improvements in some clinical outcomes. Although these findings suggest that patients who perceive a stronger alliance with their physical therapist may achieve some better clinical outcomes, the observed relationships were generally weak and unlikely to be clinically significant. Limitations include the fact that measures of therapeutic alliance have not been validated for use in musculoskeletal physical therapy settings. There was a risk of type 1 error; however, findings were interpreted based on clinical significance rather than statistical significance alone.

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Authors' Contributions

The authors declare the following contributions to the preparation of the manuscript: study conception and design (BL, KB, and RH), inclusion and data collection (PC), data analysis (JK), and interpretation of data (all authors); drafting of the manuscript (BL); critical revision of the manuscript (all authors). All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AQoL: assessment of quality of life
NHMRC: National Health and Medical Research Council
OA: osteoarthritis
OR: odds ratio
RCT: randomized controlled trial
WAI: Working Alliance Inventory

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Original Paper

Using a Web-Based App to Deliver Rehabilitation Strategies to Persons With Chronic Conditions: Development and Usability Study

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Abstract

Background: The global rise in the incidence of chronic conditions and aging is associated with increased disability. Physiotherapists and occupational therapists can mitigate the resulting burden on the health care system with their expertise in optimizing function. Rehabilitation self-management strategies can assist people with chronic conditions to accept, adjust, and manage different aspects of their daily functioning. Interventions delivered using technology have the potential to increase the accessibility, availability, and affordability of rehabilitation self-management support and services.

Objective: This study aims to describe the development and usability evaluation of iamable, a web-based app created to provide rehabilitation self-management support for people with chronic conditions.

Methods: The development and evaluation of iamable were undertaken in several phases. We used user-centered design principles and an iterative process that included consultations with rehabilitation experts; developed a prototype; and conducted usability tests, heuristic evaluations, and a focus group analysis.

Results: The iamable app was developed to provide rehabilitation self-management strategies in the areas of exercise, fall prevention, fatigue management, pain management, physical activity, and stress management. We engaged adults aged ≥45 years with at least one chronic condition (N=11) in usability testing. They identified navigation and the understanding of instructions as the primary issues for end users. During the heuristic evaluation, clinicians (N=6) recommended that some areas of app content should be more succinct and that help should be more readily available. The focus group provided input to help guide clinical simulation testing, including strategies for selecting patients and overcoming barriers to implementation.

Conclusions: We engaged end users and clinicians in the development and evaluation of the iamable app in an effort to create a web-based tool that was useful to therapists and their patients. By addressing usability issues, we were able to ensure that patients had access to rehabilitation strategies that could be used to help them better manage their health. Our app also provides therapists with a platform that they can trust to empower their patients to be more active in the management of chronic conditions. This paper provides a resource that can be used by others to develop and evaluate web-based health apps.

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KEYWORDS

rehabilitation; physiotherapy; occupational therapy; self-management; function; web-based application; usability; user-centered design

Introduction

Background

The global rise in the incidence of noncommunicable chronic diseases will cause an associated rise in the prevalence of disability and will be responsible for 75% of all deaths by 2030, thereby creating the most significant public health problem of the 21st century [1,2]. There is an opportunity to manage this current health care crisis through the introduction of multisector rehabilitation strategies. Physiotherapists and occupational therapists are rehabilitation professionals with expertise in promoting physical function and preventing disability, particularly in the presence of comorbid health conditions. Rehabilitation assists people with chronic conditions to accept, adjust, and manage different aspects of functioning and share similar processes that are advocated in self-management. It has been suggested that by incorporating self-management support, rehabilitation providers could provide a more effective approach to rehabilitation and chronic disease management [3-5].

Self-management is defined as an individual's ability to manage the symptoms, treatment, physical and psychological consequences, and lifestyle changes inherent in living with a chronic condition [6]. It is usually undertaken collaboratively with the support of a health care provider. Rehabilitation principles can be incorporated into self-management support for people with chronic conditions to optimize their physical function. Most chronic conditions and disabilities are long-standing, and it is often challenging to keep people with chronic conditions engaged in long-term self-management [7]. Technology could be one way to promote ongoing engagement with rehabilitation clinicians who support self-management because it has the potential to increase the accessibility and availability of rehabilitation services. Web-based apps can ensure that patients have remote access to rehabilitative care when in-person interactions are not possible. In addition, leveraging technology may facilitate more effective self-management of chronic diseases, which may lead to improved health outcomes [8,9]. A recent systematic review that examined the effectiveness of mobile self-management apps in the long-term management of chronic conditions showed that 6 of the 9 apps developed for diabetes, chronic lung disease, and cardiovascular disease demonstrated a statistically significant improvement in the primary measure of clinical outcomes [10].

To foster the effectiveness of digital health apps, it is important to ensure their usability. A recent scoping review [11] describes the current methods used in the usability testing of eHealth apps. The methods used included questionnaires (n=105), task completion (n=57), think aloud (n=45), interviews (n=37), heuristic testing (n=18), and focus groups (n=13). Most of the studies used 1 (n=45) or 2 (n=46) testing methods. Automated mechanisms such as eye tracking were not reported as a method of assessment to test usability, and the System Usability Scale (SUS) was the most frequently used questionnaire (n=44). Multimodal usability evaluation was used most frequently, used in 67.2% (88/131) of the studies where intended users were patients and/or caregivers. The authors conclude that there is only a small proportion of reported evaluations of digital health apps in peer-reviewed publications, although the number of apps has increased substantially [9]. Further research is needed to determine the best testing methods for the usability of eHealth apps, considering their target users and their health conditions [11].

Objective

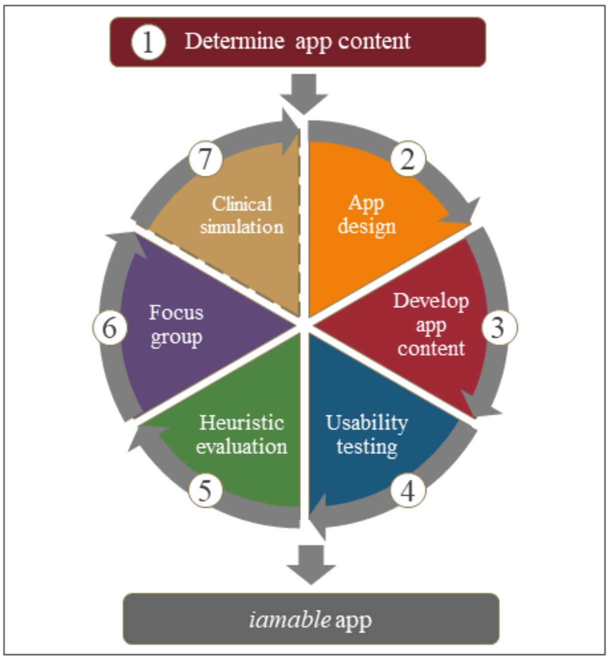
This paper describes the development and usability evaluation of iamable, an app that uses rehabilitation strategies to promote self-management of chronic conditions. Specifically, we describe the iterative process of developing the app and conducting usability and heuristic testing. The purpose of this work is to determine whether users (people with chronic conditions) can navigate through a web-based app and access information to facilitate rehabilitation self-management. This project received ethics approval from the Hamilton Integrated Research Ethics Board (Project number: 5160).

Methods

Overview

The iamable app was developed and evaluated in stages, with the findings from each stage used to refine the final product. Our phased approach used user-centered design principles similar to those of Peute et al [12]. We adopted methods from the Website Developmental Model for the Health Care Consumer framework, which included (1) an information needs analysis and mock-up design, (2) website prototype development, and (3) heuristic evaluation and think-aloud analysis. This phased approach was developed further. It is illustrated as an iterative process in Figure 1. This paper reports on stages 1 to 6.

Figure 1. Process of iamable app development and evaluation.



Determining App Content

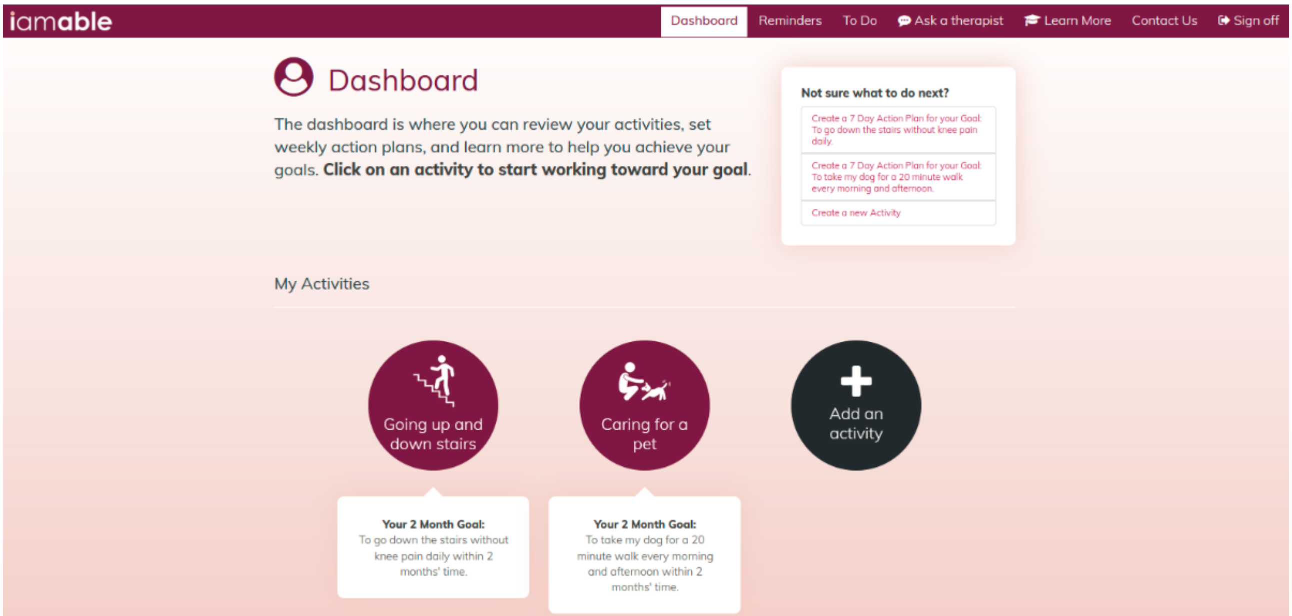
We undertook a consultation process with physiotherapists and occupational therapistswho were either clinical or research experts in the self-management of chronic conditions to prioritize the topics for module development that formed the content for the app. In creating the self-management modules, we used the concept of clinical concordance to develop rehabilitation strategies used by either physiotherapists or occupational therapistsor both professionals to address issues faced by people with chronic conditions (who frequently have comorbid conditions). Clinical concordance is an approach that uses the concepts of clinical discordance (where conditions are not linked by pathogenesis or management) and concordance (conditions represent an overall pathophysiological risk profile) [13]. The unique contributions of physiotherapists and occupational therapiststo self-management interventions target mobility, functional activity, and participation levels [5]. Often, the rehabilitation strategies suggested by physiotherapists and occupational therapistshave a high level of therapeutic concordance in that they can be applied (sometimes with some modification) to multiple conditions where there may be clinical discordance, but the functional outcomes are similar.

Briefly, the consultation was a web-enabled consensus process, whereby specific self-management strategies that could be used to manage mobility, functional activity, and participation issues associated with chronic conditions were identified by the participants. The 6 self-management strategies identified were physical activity, fall prevention, fatigue management, pain management, stress management, and exercise. The concept behind self-management is that people with chronic conditions all experience to a greater or lesser extent some homogenous symptoms, including fatigue, pain, and stress; therefore, the app was designed to provide people with rehabilitation-focused strategies they could use to break the symptom cycle [14].

App Design

We began by identifying the goals of the project with the design team from Media Production Services at McMaster University. Our primary objective was to develop a web-based app that would benefit both patients and clinicians. We wanted to provide patients with access to a trusted source of health information and rehabilitation strategies that they could use to optimize their function and participation in daily life. We also wanted patients to have a tool that would help them self-monitor their health and communicate with their therapist to better manage their chronic condition. In addition, we wanted to create a resource that busy rehabilitation clinicians could use to support the self-management efforts of their patients. With the design team, we identified the target users as patients receiving rehabilitation services in primary care and discussed web design features that would appeal to this population. We worked together to create wireframes (illustrations of basic page layouts) and detailed mock-ups to visualize the user experience and the information architecture of the app. We used the Drupal Content Management System [15], which allowed us flexibility in our design. The app was built to be mobile and responsive, with a focus on tablet and computer use. We focused on maximizing white space with minimalistic design and colors to limit confusion and provide obvious focus points on the page and chose a simple san-serif font face and larger font sizes where possible with increased contrast to support target audiences from an older demographic. We then worked with the design team to develop a prototype and engaged 2 end users and 2 clinicians to review the mock-ups and provide feedback. They were able to comment on the general appearance of the user interface (UI) and provide input regarding basic navigation (moving between screens) and workflow processes (completing forms). Figure 2 shows a sample screenshot of the finalized design for the iamable UI (Multimedia Appendix 1 provides additional screenshots of the UI).

Figure 2. Sample screenshot of the iamable user interface.



Developing App Content

The content of the iamable app was developed using concepts from social cognitive theory, including goal setting and self-monitoring [16]. Users were prompted to identify an activity that was important to them that they were having difficulty performing because of their health problem and to create a long-term goal for that activity. They were asked to identify gaps in their knowledge and explore the information contained in the self-management modules. The development of the modules (pain management, exercising with a chronic condition, physical activity and chronic conditions, stress management, fatigue management, and fall prevention) was undertaken by rehabilitation experts in their respective fields, who used systematic reviews and clinical practice guidelines to convey strategies and recommendations to help users manage their condition(s). Each evidence-informed module was developed in the same format so that users of the app would (1) complete self-assessments to receive feedback about their level of risk for health outcomes and receive advice tailored to their needs, (2) have access to evidence-based self-management strategies, (3) engage in action planning based on activities with which they self-identified, and (4) have the option to consult with a physiotherapist or occupational therapist via secure messaging. All content was reviewed by the research team before it was finalized and before the usability evaluation.

Usability Testing

Usability testing was conducted with adults aged ≥45 years (N=11) recruited from a database of previous research participants who consented to future contact and through an advertisement distributed to the network of the Hamilton Council on Aging. All potential participants were screened by telephone to determine if they met the following inclusion criteria: (1) the presence of at least one chronic condition and (2) computer proficiency. To be eligible to participate, people were required to respond “somewhat easily” or “very easily” to all questions on the Computer Proficiency Questionnaire-12 (CPQ-12) [17]. Participants were also asked to estimate their daily technology use (Multimedia Appendix 2 [17] provides a copy of CPQ-12).

Usability testing was performed in the Advanced Human-Computer Interaction (HCI) Lab, located in the DeGroote School of Business on McMaster University’s main campus in Hamilton, Ontario. The HCI Lab consisted of a participant room and a control room, with one-way mirrors between the rooms to allow for the monitoring of subjects and their interactions. Audiovisual recordings of the test sessions were obtained from 4 video cameras at multiple angles and a recording of the website screen overlaid with eye tracking (Tobii Eye-tracker, Tobii AB; Multimedia Appendix 3 provides a detailed usability test plan).

We used the concurrent think-aloud method, which is one of the most frequently used tests of usability in health care research [18]. Participants were required to verbalize their actions and thoughts, as they completed representative tasks using the app. Users were asked to perform the following tasks: (1) sign in to the app; (2) complete step 1: select 1 activity that you are having difficulty with because of your health problem (The app allows users to select up to 3 activities in step 1. We asked test users to select 1 activity for the usability testing session); (3) step 2: rate your ability to perform the activity on a 10-point scale and set a goal; (4) select the activity goal that you would like to work toward; (5) select one of the self-management modules you identified that would help you reach your goal; (6) complete self-assessment; (7) on the basis of the results of self-assessment, select a topic such as “medications” in the Fall Prevention module to learn more about medications and fall risk; (8) create a 7-day action plan; and (9) ask your therapist a question (send your therapist a message). Participants completed a training task to practice the think-aloud method [19] before the testing session began, and the interviewer provided feedback on the participant's performance. Participants were prompted to continue talking if they were silent for more than 10-15 seconds. Each testing session took approximately 1.5 hours.

Participants completed the SUS at the conclusion of the test session. The SUS is a tool that quickly and easily evaluates a user's subjective rating of a product's usability [20]. It consists of 10 statements that are scored on a 5-point Likert scale (1=strongly disagree and 5=strongly agree). Estimates of reliability range from 0.83 to 0.97 [21]. Scores for the SUS can range from 0 to 100, where higher scores indicate better usability (Multimedia Appendix 4 [20] provides an adapted copy of the SUS).

Audio recordings of the usability test sessions were transcribed to create log files, which were then marked up by a research coordinator who reviewed the video recordings and added annotations about usability issues identified by the user. The transcripts were coded to identify specific types of usability issues, as proposed by Kushniruk et al [22] (Multimedia Appendix 5 [22] provides details of the video coding scheme). Qualitative comments were extracted from the log files during the coding procedures if they were illustrative and representative of the usability issue.

Heuristic Evaluation

The next phase of the usability assessment involved a heuristic evaluation, which is a usability inspection method used to identify usability problems in the UI design. Evaluators examined the interface and assessed the degree to which it complied with established usability principles (the heuristics) [23]. A total of 8 heuristics for evaluation focused on identifying specific usability problems, and 4 heuristics focused on identifying issues related to health literacy. The criteria were adapted from the work of Nielsen et al [18,23-25]. We recruited clinicians with experience using digital health apps and rehabilitation self-management interventions (N=6) to perform an independent evaluation of the iamable app based on these 12 criteria. The clinicians included a convenience sample of 3 physiotherapists and 3 occupational therapists(female: n=5; male: n=1; clinical experience: mean 14 years; range 3-31 years) who worked in primary care and/or whose practice involved the management of people with chronic conditions who might use the app. The clinicians practiced in both urban and rural primary care settings, and several clinicians provided care to marginalized populations.

Clinicians were asked to log in to the iamable app remotely and complete six tasks: (1) identify an activity; (2) rate the activity and set a goal; (3) navigate to the self-management module, complete the self-assessment, and review the 2 module topics assigned; and (4) create an action plan. Each clinician evaluated 2 of the self-management modules, so that each module was evaluated by 1 physiotherapist and 1 occupational therapist. They systematically progressed through the screens required to complete the task. When they encountered a usability issue, they recorded it on the heuristic evaluation form, applied a severity rating (1=mild, 2=moderate, and 3=severe), captured a screenshot of the page on which they encountered the problem, and provided comments or recommendations to resolve the issue (Multimedia Appendix 6 provides a copy of the heuristic evaluation form). We allowed approximately 1.5 hours for completion of these tasks.

Clinicians submitted their completed evaluation forms electronically. Heuristic violations were summed and tabulated according to severity, and clinicians' recommendations were summarized by the research team.

Focus Group

We held a focus group using videoconferencing 1 week after the completion of the heuristic evaluation to gather the clinicians' general impressions of the app and its clinical utility. Specifically, the questions they were asked were as follows: What are the strengths of the app? What are the areas that could be improved? Which patients do you think might benefit from using the app? Which patients would you recommend it to? How do you envisage using the app in your clinical practice?

Results

Usability Testing

Table 1 presents the demographic characteristics of the participants. The mean age of the participants was 69.3 years (SD 10.1 years; range 48-84 years), and the majority were retired (8/11, 73%) and used technology for 1-5 hours daily. The chronic conditions they reported included arthritis (7/11, 64%), hypertension (5/11, 45%), diabetes (3/11, 27%), asthma (3/11, 27%), chronic obstructive pulmonary disease (2/11, 18%), heart disease (1/11, 9%), and other (5/11, 45%; included chronic neck or back pain, chronic kidney disease, anxiety, and depression).

Table 2 provides an example of task duration. Users were asked to complete the self-assessment, and duration was measured as the length of time it took users to read the instructions and click the self-assessment button on the module page. The duration varied considerably between users, ranging from 21 to 264 seconds (average task duration for females: 79.8 seconds; average task duration for males: 108 seconds), indicating that users follow instructions and navigate the app with differing levels of efficiency.

Table 1. Participant characteristics (N=11).

Characteristic	Values
Age (years), mean (SD)	69.3 (10.1)
Sex, n (%)	
Male	6 (55)
Female	5 (45)
Marital status, n (%)	
Married	8 (73)
Divorced	2 (18)
Widowed	1 (9)
Employment, n (%)	
Working part-time	2 (18)
Retired	8 (73)
On disability	1 (9)
Ethnicity, n (%)	
European	11 (100)
Financial situation, n (%)	
Have just enough to get along	3 (27)
Are comfortable	8 (73)
Number of chronic diseases, n (%)	
1	3 (27)
2	3 (27)
3	3 (27)
4	2 (18)
Daily technology use (hours), n (%)	
<1	1 (9)
1-3	4 (36)
3-5	4 (36)
>5	2 (18)

Table 2. Example of task duration.

User	Age (year)	Sex	Number of chronic conditions	Task duration (seconds)
1	84	Female	4	48
4	77	Female	1	141
6	70	Female	4	42
10	56	Female	1	33
11	65	Female	3	135
2	72	Male	2	171
3	77	Male	2	34
5	72	Male	2	68
7	73	Male	1	264
8	48	Male	3	90
9	72	Male	3	21

In total, 7 usability issues emerged from the think-aloud transcripts. They include navigation, understanding instructions, layout, understanding terminology, workflow issues, accuracy and correctness, and consistency. The usability issues for each of the 9 tasks are illustrated in Figure 3. The most common usability issue across tasks was related to navigation. Users described difficulty in determining what to do next, uncertainty about which content was clickable, and confusion about the labels on certain buttons and tabs. The task with the greatest number of usability issues was task 6: complete self-assessment. The most common usability issue when asked to complete the self-assessment was related to layout, with some users unable to locate the self-assessment button on the page, whereas others had difficulty finding their self-assessment results. Other usability issues with this task included difficulties with navigation, understanding instructions, workflow, and accuracy. Examples of usability issues by task were extracted from the audio recordings of the think-aloud sessions and are presented in Tables 3 and 4.

Figure 3. Summary of usability issues by task. Task 1: log in; task 2: select activity; task 3: rate activity and set goal; task 4: open activity: task 5: select self-management module; task 6: complete self-assessment; task 7: select module topic; task 8: create action plan; task 9: message therapist.

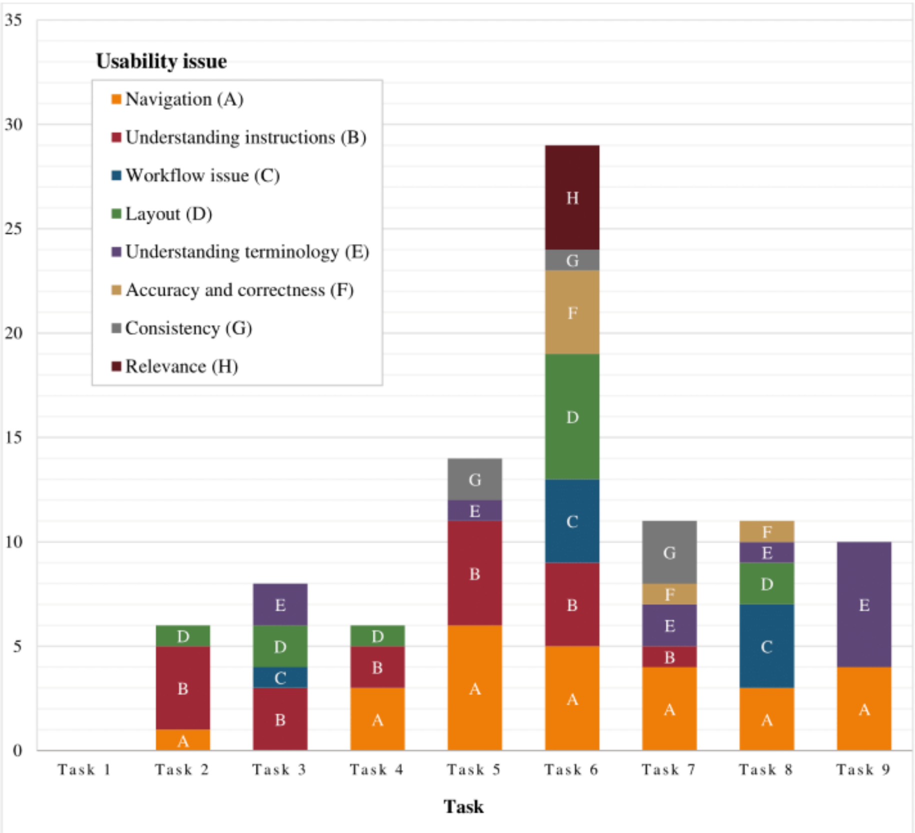


Table 3. Think-aloud results for tasks 2-6.

Task	Usability issue	Description	Example
Task 2: Select activity	Understanding instructions	Users had difficulty understanding that they should select an activity that they were having difficulty with because of their health.	• "Like gardening, I'm not that thrilled about gardening and I'm not very good at it. Would that be considered one, or no?" (User 7) • "It's asking for an activity you are having difficulty doing because of your health." (RC[a]) • "Oh, I'm sorry. I didn't even think of that. Ok, because of my health." (User 7)
Task 3: Rate activity and set goal	Understanding instructions	Users had difficulty determining how many modules they should select.	• "So, you want me to pick just one?" (User 5) • "No, you can pick as many as you would like." (RC)
Task 4: Open activity	Navigation	Users did not realize that they needed to click on the icon to open the activity.	• "So, we've done that...I don't see a 'next' to click on, so what should we do about that? How do we move on?" (User 1)
Task 5: Select self-management module	Navigation	Users had difficulty locating the self-management modules on the page.	• "That's this, right? That's what this is?" (User 3) • "So, that's to create an action plan…" (RC) • "Oh, over here. Oh, ok. So that's the module." (User 3)
Task 5: Select self-management module	Understanding instructions	Users had difficulty with the instructions because they had the option to explore the topics or complete the self-assessment.	• "So I'm not really sure here." (User 5) • "So based on the information you read..." (RC) • "Complete the self-assessment, it says. So I guess they want me to do this, right?" (User 5)
Task 6: Complete self-assessment	Navigation	Users suggested that the recommendation provided by the system after completing the self-assessment did not provide adequate direction to help navigate to the next task.	• "So, should I go back to self-assessment? This is the same page as before, right? I don't understand where I go from here." (User 7)
Task 6: Complete self-assessment	Understanding instructions	Users had difficulty following the instruction to complete the self-assessment. Some were drawn to the "Not sure what to do next" box and the instruction to create an action plan instead.	• "Ok, 'Start by completing the self-assessment. Based on your answers, you will receive a recommendation to guide you in selecting the topics below that will help you the most.' Ok, so this is what I've got to do, create a 7 Day Action Plan for your goal." (User 11)
Task 6: Complete self-assessment	Layout	Users had difficulty finding the self-assessment button.	• "But if the instruction says 'Start by completing the self-assessment', can you see on the page where that might be?" (RC) • "Right here. So [the button] is not in a place that I would have thought to look. It's in a place where I think to not pay attention." (User 11)
Task 6: Complete self-assessment	Workflow	Users suggested that questions on the self-assessment were unclear.	• "This is a little confusing...there could be an easier way to get the answers." (User 7)
Task 6: Complete self-assessment	Accuracy	Users identified that one of the self-assessments was not scoring correctly, providing some users with the wrong result.	• "Yeah, that's kind of worrying when I read that...I'm thinking, how can I be sedentary when I'm doing something 7 days a week." (User 2)

[a]RC: research coordinator.

Table 4. Think-aloud results for tasks 7-9.

Task	Usability issue	Description	Example
Task 7: Select module topic	Navigation	Users were unsure how to navigate to topics (this task required the user to click on a topic to open it).	• "Ok, so I don't understand what I'm doing next...because am I going to open one of these by clicking?" (User 11)
Task 7: Select module topic	Consistency	Users expressed difficulty because the topic buttons did not appear to be hyperlinks.	• "Ok, well the first thing is...is that a link? When you look at that, you think that it is just text...so that changes the way that I was thinking." (User 2)
Task 8: Create action plan	Navigation	Users were confused by the delete action plan button, not sure what to do after creating an action plan.	• "I don't want to delete this. So where else do I want to go? I can either delete it, or I create a 7-Day Action Plan which I already did. I don't know where to go now. Unless you want to delete this goal." (User 7)
Task 7: Select module topic	Workflow issue	Users anticipated a menu of action plans to choose from rather than having to create one of their own.	• "So, would this answer not have...would I not have been led to this, from maybe, from the results of the previous step? Would I not have been given some suggested actions at this point?" (User 9)
Task 9: Message therapist	Navigation	Users were not certain that the ask button should be used to contact the therapist.	• "Ask...that means ask a therapist? Ok...so you type the question and she'll get back to you online?" (User 1)
Task 9: Message therapist	Understanding terminology	Users were confused about the save and send buttons when attempting to send a message to the therapist.	• "So I'm saving it rather than sending it...But I will click send because that's the only thing I can think of to get it off to the therapist." (User 11)

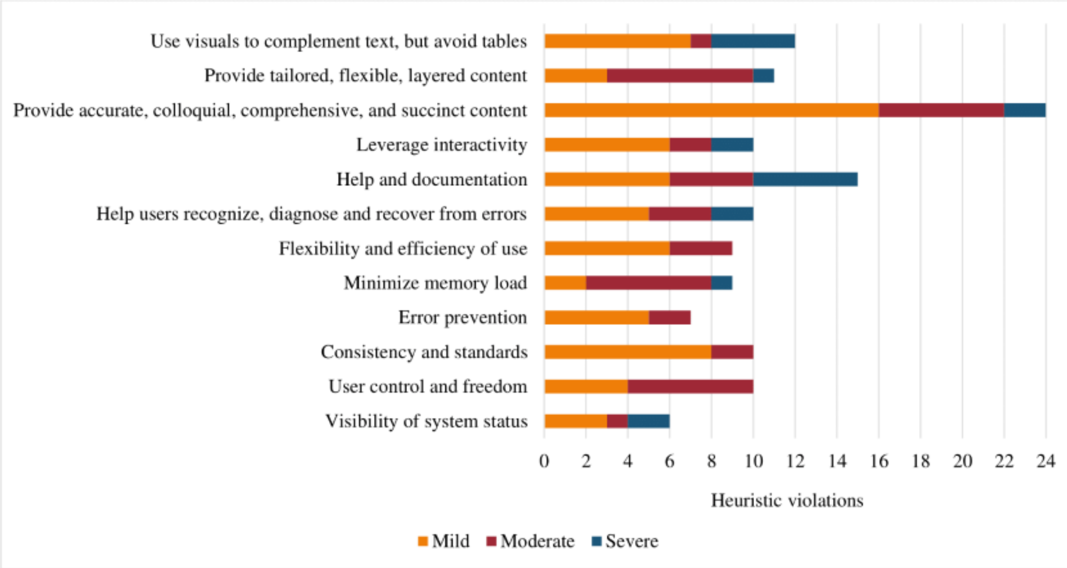
We were not able to fully test the messaging function in the app, as the test user accounts were not linked to therapist accounts. In clinical practice, the user will be able to post a question to the therapist, who will, in turn, receive notification about the message and enter the app to provide a response. Users will be reminded that they can expect to receive a response from their therapist within 2 working days; if they have an urgent issue that requires an immediate response, they will be told to contact their therapist directly.

The SUS provided a single score that estimated the overall usability of the iamable app. The mean score of the iamable app (N=11) was 71.14 (SD 19.67). Products that are acceptable have SUS scores above 70, with superior products scoring in the high 70s to the high 80s [26].

Heuristic Evaluation

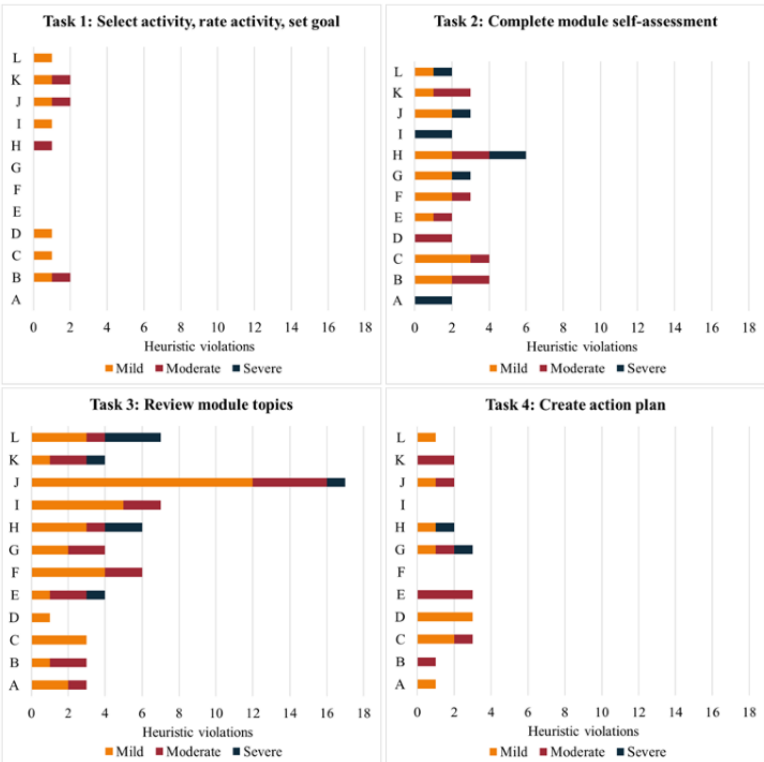
Figure 4 shows the results of the heuristic evaluation performed by the 6 clinicians. Specifically, it shows the overall frequency of heuristic violations identified by clinicians for all tasks that they were required to complete. Violations were rated according to severity: 1=mild, 2=moderate, and 3=severe. The heuristic that resulted in the highest number of violations (n=24) across all 4 tasks was "provide accurate, colloquial, comprehensive, succinct content." The heuristic that resulted in the fewest violations (N=6) was the "visibility of system status," where the user is informed as to the state of the system at any given moment (Multimedia Appendix 7 provides a frequency table summarizing all heuristic violations).

Figure 4. Results of heuristic testing. The graph depicts the overall frequency of heuristic violations.



The raters identified 36 heuristic violations for task 2 (complete module self-assessment) with mostly mild to moderate severity ratings (Figure 5). Violations for the heuristic "help and documentation" indicated that there was no help button or frequently asked question (FAQ) option, and the raters felt that a video or timer should be added to facilitate the self-assessment task (in the fall prevention module). The raters identified severe violations for the heuristic "visibility of system status" because the instructions to complete the self-assessment remained on the screen and the self-assessment button remained active even after the self-assessment was completed. The other severe violation related to the heuristic "leverage interactivity," where the clinician felt the recommendation following the self-assessment was not sufficiently tailored (exercise module; Multimedia Appendix 8 provides additional details).

Figure 5. Heuristic violations by task. "A" refers to the visibility of system status. "B" refers to user control and freedom. "C" refers to consistency and standards. "D" refers to error prevention. "E" refers to minimized memory loads. "F" refers to the flexibility and efficiency of use. "G" refers to helping users recognize, diagnose, and recover from errors. "H" refers to help and documentation. "I" refers to leveraging interactivity. "J" refers to providing accurate, colloquial, comprehensive, and succinct content. "K" refers to providing tailored, flexible, and layered content. "L" refers to using visuals to complement text but avoiding tables.



Task 3 (review module topics) generated the greatest number of heuristic violations (n=65) from the raters, the majority of which were mild (Figure 5). The heuristic "provide accurate, colloquial, comprehensive and succinct content" was identified as a mild violation by all raters for each of the modules they reviewed. Feedback from raters included the need for a more lay-friendly language to avoid using language that labels users (ie, faller vs nonfaller), to provide examples or links to explain more difficult concepts (ie, cognition and corticosteroids), to shorten videos and text in some areas, and to provide emphasis to ensure that users do not take certain actions (ie, stop taking a medication) without first consulting with their physician. Raters identified several severe violations, including (1) the heuristic "use visuals to complement text" where a trip hazard was not identified in a home hazards video (fall prevention module) and the video was not uploaded (stress management module), (2) the heuristic "minimize memory load" because there is no way for users to track their progress through the module (ie, an indicator that a topic had been read or completed), and (3) the heuristic "help and documentation" because there is no topic-specific help or FAQs (Multimedia Appendix 8 provides additional details).

Raters detected 21 mild or moderate heuristic violations for task 4 (creating an action plan; Figure 5). Raters noted severe violations in relation to the heuristic "help and documentation" (n=1) because there was no help option available and the heuristic "system provides a clear and easy to understand way of recovering from an error" (n=1) after the system did not save the action plan after prompting that the confidence level was too low (Multimedia Appendix 8 provides additional details).

Focus Group

Strengths of the App

Clinicians identified several positive features of the app. They reported that the videos were particularly helpful, especially because the content was simplified and summarized for the user. For example, they stated that the self-management modules explained concepts using simple, nontechnical language, and when it was not possible to replace technical terms, a simple definition was provided in brackets.

They appreciated the interactive nature of the app, which enabled the user to set goals, receive tailored information, and check their progress. An example they gave of the tailoring was if a user scored high on the pain catastrophizing scale (the pain self-assessment), they were directed to complete the topics focusing on thoughts, emotions, and pain. They endorsed the self-assessments associated with each module and noted that the information from these would be helpful to both the user and the clinician to have an assessment of baseline functioning and track progress toward goals.

Areas for Improvement

Although the clinicians were very positive about the videos, they commented that some were too long, estimating that the maximum time that a video would sustain a user's attention would be 2 minutes. They suggested that it would be helpful if there was a way for users to mark their progress within the app, so that if they returned, they would know where to resume (ie, by providing a bookmark, by changing the color of the font, or by identifying favorite content). They suggested that more consistent use of the "add to my reminders" feature would help users identify and prioritize tasks that they needed to undertake to help them complete their action plans and reach their goals. They felt that the app might increase engagement in exercise and self-management and adherence in the management of their chronic condition.

Some therapists felt the recommendation following the self-assessment in the exercise module provided the same information irrespective of the score and that it would be helpful if the exercise prescription was better tailored to the user's fitness level.

Several clinicians noted technical issues when using the app on their phone or tablet, where certain buttons did not function, and it was difficult to read the content without having to manually resize the text.

Suitability for Patient Groups

Primary care was recommended as the setting in which the app would be the most useful. Clinicians agreed that they would want to introduce the app to patients in a 1:1 consultation to ensure that patients had the ability to use it successfully before engaging with it independently. They reported that there were no contraindications for any patient group, although the level of digital and health literacy required to use the app might prove too advanced for some of the populations seen in primary care, such as new immigrants or people who were homeless. Clinicians thought that an app such as iamable might be especially appealing to users who had social anxiety. They commented that users in rural and remote areas would find the app very helpful because they could use it in a clinical setting and then have it as support to work on their goals from home. Clinicians agreed that the app would help keep patients engaged in their rehabilitation between visits. Finally, the clinicians suggested translating the content of the app to other languages.

Discussion

Principal Findings

This study describes the successful development of an app to support the self-management of people with chronic conditions and address symptoms that could be managed using rehabilitation strategies. The approach we used to evaluate the usability of the iamable app included task completion, think-aloud, interviews, heuristic testing, and focus groups, a process similar to that of Peute and endorsed by Maramba [11,12]. iamable is the first app developed and systematically evaluated by rehabilitation professionals that addresses the holistic management of people with chronic conditions using rehabilitation strategies. The 6 areas of self-management targeted by the app align with the self-management skills outlined by Lorig for breaking the symptom cycle [14]. The premise of the relationship between these symptoms is that, irrespective of the disease, people with chronic conditions often experience common issues. The modules included within the app are evidence based, and the strategies recommended to address these issues have been developed using best practice guidelines (ie, prescribing multicomponent home-based exercise and promoting home safety assessments to reduce the risk of falls [27] and providing pain neuroscience education to help patients manage chronic pain [28]). The app requires users to identify the gaps in their knowledge and select modules accordingly. The design of the iamable app was iterative and involved consultation with users from the early stages of development, with revisions and changes based on their feedback and input. Our multistage approach to usability evaluation enabled us to make modifications serially and remediate user problems before the next stage of testing.

Common Issues Identified by Usability Testing

The two most frequent issues encountered by users during usability testing were navigation and the understanding of instructions within the app. These issues are well documented in the literature and may result from reduced vision, hearing loss, or psychomotor impairment [29]. Barriers related to navigation and instructions on websites and health apps have been reported in other older adult populations, suggesting the need for special considerations and adaptations to improve these and other fundamental aspects of app design [30,31]. Our results are not surprising because older people in the United States and Europe report that they are less likely to engage with web-based apps because of the perceived complexity of internet use [32,33]. Older people are less likely than younger people to perceive websites as user friendly [34]. In an effort to improve the usability of the iamable app, we addressed issues with navigation and understanding instructions that were identified during usability testing. Modifications made to improve navigation included making buttons clearly clickable; using more consistent use of hyperlink colors; modifying button size, color, and location to draw the user's attention; and relabeling buttons to clarify their meaning. Color and size sensitivity reduce with age, especially blue-green differentiation [29]. To clarify the instructions, we added text such as "select all that apply" and "start by completing the self-assessment" to improve usability. These changes will further provide accommodations to older users with diminished abilities in attention, learning, and memory, which manifest in determining where to go next [29].

A study by Bangor et al [26] found that there was a small, significant correlation between age and SUS scores (SUS scores decreased with increasing age) but no effect of gender. In our sample, we observed a sex difference where women had higher SUS scores compared with men (women: mean 78.5, SD 17.6; men: mean 65.0, SD 20.7) despite having similar levels of comorbidity and education and slightly older mean age (women: mean 70.4 years, SD 10.8 years; men: mean 68.3 years, SD 10.4 years). A mean SUS score of 71.14 (SD 19.67) suggested that the usability of the iamable app is acceptable. An SUS score of 71.4 (SD 11.6) corresponds with a rating of "good" using an adjective rating scale [26]. The SUS was administered to participants at one point in time only; therefore, it is reasonable to assume that with the revisions made to the app following usability testing, SUS scores would likely have improved if the survey had been readministered.

For the sample task in which we calculated task duration (ie, complete the self-assessment), there were no differences by age or number of chronic conditions. In addition, when the outlier was removed, there were no sex differences in task completion time.

Most Common Heuristic Violations

The top heuristic violations identified by the clinicians were related to the provision of accurate, colloquial, comprehensive, succinct content and help and documentation. The heuristic "provide accurate, colloquial, comprehensive, succinct content" targets health literacy and is intended to ensure that written information is brief, relevant, and in the users' vernacular. Our goal was to engage users in the app content in a way that motivates them to create goals and complete action plans. To do this, we endeavored to create content that was both brief and to the point, actionable, and engaging [12]. It is also suitable for users with a range of literacy skills to reflect the types of patients that therapists would see in clinical practice. In response to clinician feedback, the iamable app content was revised to add images to complement text, make the text more concise, simplify instructions, and emphasize safety considerations. In addition, the heuristic "help and documentation" directly impacts the usability and is intended to ensure that help is available to users when needed. In response to comments from clinicians, we clarified for users that they should use the "Ask a Therapist" feature for self-management support and added a "Contact Us" page so that users could access technical assistance when required.

Focus Group

The focus group with the clinicians provided us with additional information about the app and recommendations for further changes and development that we would not have gathered through heuristic testing alone. Clinicians agreed that some patients would be able to use the app independently. A systematic review reported that self-management apps have been used successfully both with and without clinician input [10], but older people are more likely to engage in learning and adopt the use of technology if they live with someone or have assistance [35]. In response to concerns about ease of navigation, we are exploring ways to make it easier for users to find where they left off during previous sessions using the app. The focus group also provided us with information to help guide the final stage of the iamable evaluation, the clinical simulation. Participants were able to provide advice about overcoming barriers to implementation from the perspective of both the clinician and the patient. Potential barriers for clinicians included increased workload to support patients using the app and the need to obtain permission from clinic administrators. Patient barriers might include cost, literacy, language, connectivity, and availability or accessibility issues, which are similar to other reports in the literature [10].

Limitations

There were some limitations to this study. The sample recruited for usability testing was not ethnically diverse. All participants were of European heritage and were English speaking. To ensure that the iamable app is accessible to a diverse range of users, a future study that includes a more heterogeneous sample is warranted. Furthermore, we were unable to use eye tracking data to substantiate our results. For reasons related to cost and analyst availability, we were not able to analyze the eye tracking data that we collected. Eye tracking provides an automated method for objectively evaluating usability. Eye tracking analysis would have resulted in a more comprehensive usability evaluation of the iamable app. Combining eye tracking with qualitative data can provide a more holistic understanding of usability issues. For example, Cho et al [36] used eye tracking metrics (time to first fixation, time spent, revisits, and total number of fixations) to compare groups with and without task difficulty to help identify barriers to task performance.

For usability testing, we required that our sample have a high level of computer proficiency, which likely meant that they had access to technology. Overall, 73% (8/11) of our sample reported that they used their computers and mobile devices on average for 1-5 hours per day. With future testing, it will be important to include older people with less access to technology to ensure usability for those with low digital literacy. Finally, we made many revisions to the app in response to the results of usability testing and feedback from the heuristic evaluation but did not repeat either assessment to determine whether these changes resolved the identified issues.

The final stage of our usability evaluation will be a clinical simulation where we will enlist therapist-patient dyads (n=26) from primary care sites where occupational therapists and physiotherapists engage in rehabilitation self-management. As was recommended in the focus group, the plan will be to have therapists introduce the iamable app in a face-to-face or virtual session with the patient and then to provide support as needed over the course of the trial. This will enable us to determine more specifically the role the app might play in a primary care environment, how the therapists will use the app with patients who have different chronic conditions, and how useful the app is for patients who are currently receiving rehabilitation. This final stage of the usability evaluation is considered important by the study team because the app has not yet been tested as an interactive therapeutic resource where the therapist and patient engage collaboratively in chronic disease self-management.

Conclusions

In conclusion, we have produced an app that closely matches the expectations of both the patient and clinician end users, and although there are usability issues identified from our testing, the app was rated highly on the validity of its evidence-based content. The information contained in the app can provide self-management support to people with chronic conditions with or without the support of a therapist because some users may not be receiving care from a rehabilitation practitioner. The app has the potential to both reinforce information provided during a rehabilitation intervention and provide rehabilitation strategies to users who can engage in self-management independently. It may strengthen the patient's relationship with the therapist, increase engagement, and enable the patient to proactively address concerns related to their rehabilitation [37]. A systematic review reported that self-management apps have been used successfully both with and without clinician input. Although clinicians noted that they would introduce the app to their patients, some patients would be able to use it independently without prior instruction [10]. Adoption of the iamable app may face barriers to use such as cost, literacy, language, connectivity, availability and accessibility issues, similar to other health apps reported in the literature [10].

To guide the development of the iamable app, we incorporated user-centered design principles [12]. We used an iterative process that included consultation with rehabilitation experts to determine app content, app design, usability testing, and heuristic evaluation plus a focus group. This paper provides a resource that can be used by others to develop and evaluate web-based health apps that can benefit both patients and clinicians.

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Authors' Contributions

JR is the principal investigator. JR and LL led the conception and design of the study, the web-enabled consensus exercise, and the focus group. JR, LL, SS, JM, and JT contributed their expertise in developing app content. CD, SW, and JT provided feedback about the app from a clinician's perspective. SS coordinated usability testing and heuristic evaluation. JR and SS wrote the manuscript with input from LL, DC, JM, CD, JT, SW, JG, and AS. All authors read and approved the final manuscript. Other members of the research team included Sarah Sanford, Evelyne Durocher, and Meredith Vanstone.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots of the iamable user interface.
[PDF File (Adobe PDF File), 422 KB - rehab_v8i1e19519_app1.pdf]

Multimedia Appendix 2
Computer Proficiency Questionnaire.
[DOCX File , 22 KB - rehab_v8i1e19519_app2.docx]

Multimedia Appendix 3
Usability test plan.
[DOCX File , 20 KB - rehab_v8i1e19519_app3.docx]

Multimedia Appendix 4
System Usability Scale.
[DOCX File , 20 KB - rehab_v8i1e19519_app4.docx]

Multimedia Appendix 5
Video coding scheme.
[DOCX File , 21 KB - rehab_v8i1e19519_app5.docx]

Multimedia Appendix 6
Heuristic evaluation form.
[DOCX File , 22 KB - rehab_v8i1e19519_app6.docx]

Multimedia Appendix 7
Frequency of heuristic violations.
[DOCX File , 22 KB - rehab_v8i1e19519_app7.docx]

Multimedia Appendix 8
Examples of heuristic violations by task.
[DOCX File , 24 KB - rehab_v8i1e19519_app8.docx]

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Abbreviations

AGE-WELL: Aging Gracefully Across Environments Using Technology to Support Wellness, Engagement and Long Life
CPQ-12: Computer Proficiency Questionnaire-12
FAQ: frequently asked question
HCI: Human-Computer Interaction
MIRA: McMaster Institute for Research on Aging
SUS: System Usability Scale

UI: user interface

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Review

Health-Enabling Technologies to Assist Patients With Musculoskeletal Shoulder Disorders When Exercising at Home: Scoping Review

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Abstract

Background: Health-enabling technologies (HETs) are information and communication technologies that promote individual health and well-being. An important application of HETs is telerehabilitation for patients with musculoskeletal shoulder disorders. Currently, there is no overview of HETs that assist patients with musculoskeletal shoulder disorders when exercising at home.

Objective: This scoping review provides a broad overview of HETs that assist patients with musculoskeletal shoulder disorders when exercising at home. It focuses on concepts and components of HETs, exercise program strategies, development phases, and reported outcomes.

Methods: The search strategy used Medical Subject Headings and text words related to the terms *upper extremity*, *exercises*, and *information and communication technologies*. The MEDLINE, Embase, IEEE Xplore, CINAHL, PEDro, and Scopus databases were searched. Two reviewers independently screened titles and abstracts and then full texts against predefined inclusion and exclusion criteria. A systematic narrative synthesis was performed. Overall, 8988 records published between 1997 and 2019 were screened. Finally, 70 articles introducing 56 HETs were included.

Results: Identified HETs range from simple videoconferencing systems to mobile apps with video instructions to complex sensor-based technologies. Various *software*, *sensor hardware*, and *hardware* for output are in use. The most common *hardware* for output are PC displays (in 34 HETs). Microsoft Kinect cameras in connection with related *software* are frequently used as *sensor hardware* (in 27 HETs). The identified HETs provide direct or indirect *instruction*, *monitoring*, *correction*, *assessment*, *information*, or a *reminder to exercise*. Common parameters for exercise instructions are a patient's *range of motion* (in 43 HETs), *starting and final position* (in 32 HETs), and *exercise intensity* (in 20 HETs). In total, 48 HETs provide visual instructions for the exercises; 29 HETs report on *telerehabilitation* aspects; 34 HETs only report on prototypes; and 15 HETs are evaluated for technical feasibility, acceptance, or usability, using different assessment instruments. Efficacy or effectiveness is demonstrated for only 8 HETs. In total, 18 articles report on patients' evaluations. An interdisciplinary contribution to the development of technologies is found in 17 HETs.

Conclusions: There are various HETs, ranging from simple videoconferencing systems to complex sensor-based technologies for telerehabilitation, that assist patients with musculoskeletal shoulder disorders when exercising at home. Most HETs are not ready for practical use. Comparability is complicated by varying prototype status, different measurement instruments, missing telerehabilitation aspects, and few efficacy studies. Consequently, choosing an HET for daily use is difficult for health care professionals and decision makers. Prototype testing, usability, and acceptance tests with the later target group under real-life conditions as well as efficacy or effectiveness studies with patient-relevant core outcomes for every promising HET are required. Furthermore, health care professionals and patients should be more involved in the product design cycle to consider relevant practical aspects.

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KEYWORDS

shoulder; upper extremity; musculoskeletal diseases; exercises; physical therapy; telerehabilitation; technology-assisted therapy; assistive technologies; mobile phone

Introduction

Background

Health-enabling technologies (HETs) promote individual health and well-being via sensors and communication technologies [1,2]. They are information and communication technologies, particularly for the health sector. One field of HET application is telerehabilitation, a subcategory of telehealth care and telemedicine. Telerehabilitation provides and supports rehabilitation measures at a distance and connects health care professionals and patients [3,4]. An aging population, the shortage of health care professionals, especially in rural areas, and special situations with contact restrictions such as the coronavirus pandemic show the importance of telerehabilitation [5,6] and the potential of HETs for telerehabilitation [5,7]. This also applies to HETs that assist patients with musculoskeletal shoulder disorders in their home-based exercises and exercises outside of physiotherapy. Shoulder disorders are among the most frequently reported musculoskeletal problems and lead to considerable socioeconomic costs [8,9]. To maintain or improve the success of therapy, patients with musculoskeletal shoulder disorders usually perform exercises at home to complement their rehabilitation treatment (eg, physiotherapy) [10].

Although there are a few reviews on information and communication technologies to assist exercise therapy for patients with neurological diseases [11-13], an overview of technologies for patients with musculoskeletal shoulder disorders is missing. Such an overview could show the current state of HET development, the need for development, and indications for clinical use.

Objectives

Against this background, the overall aim of this review is to identify and analyze the concepts and components of HETs, strategies of exercise programs, development phases, and reported outcomes for HETs that assist patients with musculoskeletal shoulder disorders who exercise at home. The following research questions were addressed:

1. Overview:
   a. Target group: Which groups do the HETs target?
   b. Objectives: What are the reported objectives of the HETs?
2. Forms of HET assistance:
   a. Instruction: How do HETs assist patients with instructions on how to perform exercises?
   b. Monitoring: How do HETs monitor exercise quality and quantity?
   c. Correction: How do HETs correct patients' exercise performance?
   d. Assessment: How do HETs assist patients in terms of assessment?
   e. Provision of information: To what extent do HETs provide additional information beyond direct assistance during the exercises?
   f. Reminder: How do HETs assist patients in terms of reminding them to exercise?
   g. Visualization: What forms of exercise visualization do HETs provide?
   h. Telerehabilitation: To what extent do HETs use telerehabilitation aspects?
3. Strategies used by exercise programs:
   a. Structure: How are HET-assisted exercises structured in terms of therapeutic goals, number of different exercises, frequency of exercise execution, and phases of the exercise program?
   b. Adaptation: How can the exercises and the exercise programs in HETs be adapted?
4. HET components:
   a. Sensor hardware: What sensor hardware is used to capture (motion) data?
   b. Hardware: What hardware is used as output device for patients?
   c. Software: Is the software off-the-shelf or self-developed?
5. Development and evaluation:
   a. Interdisciplinary development: To what extent were HETs developed in interdisciplinary cooperation?
   b. System status and project phase: What is the current system status or project phase and which phases have been reported?
   c. Evaluation: Which (clinical) outcomes are reported?

Methods

Eligibility Criteria

This scoping review was conducted following the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews) [14]. Inclusion criteria were defined according to the PICO (Patient or Population, Intervention, Comparison, Outcome) framework [15]. Patients were defined as patients with musculoskeletal shoulder disorders. Intervention was described as technology-assisted exercises outside of therapy sessions, specifically technology-assisted, home-based shoulder exercises. Comparators or any specific outcomes were not specified as this scoping review aims to provide a general overview. Articles on other populations (eg, adults with neurological disorders) and articles on other interventions (home-based exercises not assisted by information and communication technologies or with movement analyses unrelated to exercising) were excluded. Robots, exoskeletons, and orthoses intervening in the exercise flow in a special way were also excluded because of the lack of comparability with other technologies. Articles on studies with and without follow-up were included, and there were no restrictions by type of setting as long as the HETs were suitable for application at patients' homes. Peer-reviewed articles in all languages were included. Articles in languages other than English or German were classified and translated by external experts.

Information Sources

MEDLINE (PubMed interface), Embase (OVID interface), IEEE Xplore, CINAHL (Cumulative Index to Nursing and Allied Health Literature), PEDro, and Scopus databases were searched. The year 1997 was chosen as the starting point for the search because before this, the use of information and communication technologies, assistive technologies, and HETs to assist patients with their exercises was rare. The search was conducted on July 16, 2019. To maximize the coverage of literature, the reference lists of included articles and relevant reviews identified through the search were complementarily scanned by following the *pearl growing method*.

Search Strategy

The search strategy was developed according to the PICO framework using Medical Subject Headings (MeSH) and text words related to the terms *upper extremity*, *exercises*, and *information and communication technologies*. The specific search strategies were developed by a medical computer scientist and a physiotherapist in consultation with the review team and 2 librarians experienced in systematic literature searches. The MEDLINE strategy was adapted to the syntax and subject headings of the other databases. The search terms are included in Multimedia Appendix 1.

Selection, Categorization, and Data Extraction

Literature search results from each database were imported into the literature management program *Citavi* (*Citavi 5*, *Swiss Academic Software*). Duplicates were removed by PubMed ID, Digital Object Identifier, and International Standard Book Number (ISBN).

Two reviewers (LE and B Steiner) independently screened the titles and abstracts against predefined inclusion and exclusion criteria. Full texts were obtained for all titles that met the inclusion criteria or where there were uncertainties. The 2 reviewers screened all full texts for final inclusion. Disagreements in both screening processes were resolved through discussion. Persisting disagreements were resolved through discussion with a third party from the review team (B Saalfeld or KW). The reasons for excluding articles were recorded and categorized according to the fulfilled exclusion criteria (only the first matching criterion). Overlapping or accompanying articles describing the same HET were included and specified in a summary table. Only the main article was included in the overview.

To ensure consistency between the 2 reviewers, a pilot data extraction was conducted on 5 randomly selected articles of the included full-text articles. The 2 reviewers independently extracted data from these 5 articles. Disagreements on categorization were resolved through discussion. Persisting disagreements were resolved through discussion with a third party from the review team (B Saalfeld or KW). One reviewer (LE) then extracted the data from all other eligible full-text articles based on the consensus reached during discussion of the 5 articles.

Synthesis of Results

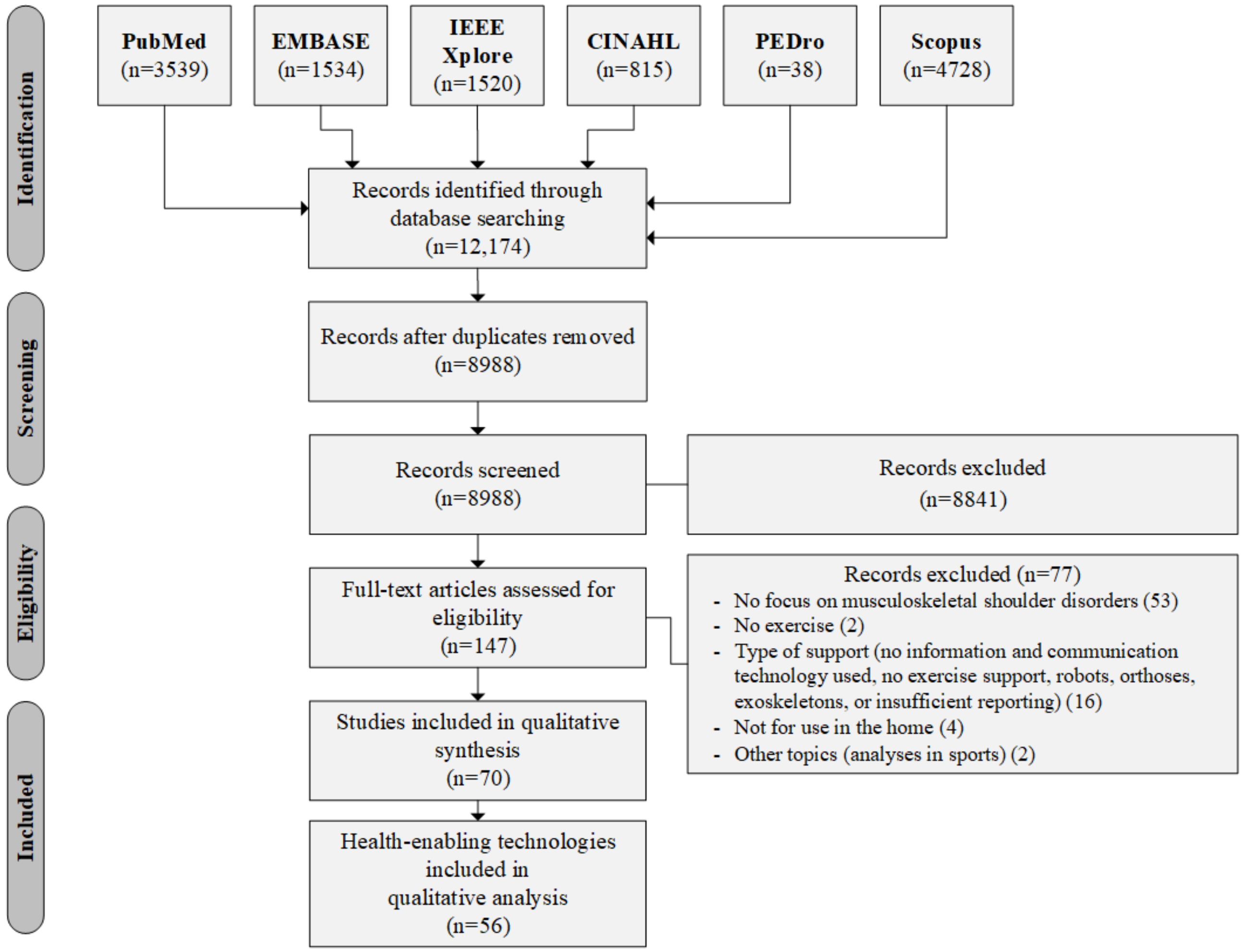
A systematic narrative synthesis was performed with information presented in texts and tables to explain the characteristics, categories, and findings of the included articles. A coding frame with categories and subcategories was built in a mix of concept-driven and data-driven approaches (deductively-inductively) [16]. The main categories *form of HET assistance*, *exercise program strategy*, *HET components*, *system/project phase*, and *reported outcomes* were defined as concept-driven after literature research and unstructured expert interviews. The 2 categories *interdisciplinary development* and *adaptation*, along with further subcategories, were derived from the texts using a data-driven approach in the form of a growing list. All coded categories and subcategories can be found in the Results section and in Multimedia Appendix 2. For better identification, main categories and subcategories in the text are written in italics.

Results

Overview

The *PRISMA flow diagram* in Figure 1 (adapted from [17]) provides an overview of the literature search. Multimedia Appendix 2 contains the complete table of articles and analysis categories. A total of 70 articles introducing 56 HETs were included in this review. The 70 identified articles differ according to the target group and their overall objectives.

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



All identified articles and related HETs, grouped by telerehabilitation aspects, are shown in a table in Multimedia Appendix 3 [18-87].

Target Group

All 56 articles describe HETs that can help patients with musculoskeletal shoulder disorders when exercising at home (Table 1). Of these, 18 articles refer to a specific target group for their use [20,23,26,36,37,45,47-50,52,54,58,62,68,71,73,77].

In 11 articles, the HET is recommended for several target groups [19,30,31,42,53,55,60,75,76,81,83]. Cubukcu and Yüzgec [55], for example, address patients with shoulder joint, muscle, and tendon damage. In 5 articles, the focus is on patients with musculoskeletal shoulder problems and patients with neurological disorders (eg, stroke) [42,76,80,81,83]. In total, 27 articles do not directly name the proposed target group [29,34,38,40,43,44,46,51,52,55-57,59,61,65-67,69,70,72,74,78,80,82,84-87].

Table 1. Target groups connected to musculoskeletal shoulder disorders in descending order of frequency.

Target group	Frequency, n (%)	References to health-enabling technologies
Frozen shoulder	18 (32)	[23,31,36,37,42,45,47-49,54,58,60,62,66,70,76,81,83]
Shoulder impingement syndrome	11 (20)	[24,31,50,55,60,68,70,71,73,75,81]
Rotator cuff tear	8 (14)	[20,31,55,60,70,75,80,81]
Humerus fracture	7 (13)	[26,31,53,55,60,70,81]
Rheumatoid arthritis	6 (11)	[31,55,60,70,77,81]
Arthrosis	5 (9)	[31,55,60,70,81]

Objectives

Assistance with home exercises and *monitoring exercises* are the most reported HET objectives (34/56, 61%). *Simple instructions* are reported for 12 HETs. Only one HET aims at patients' *reintegration into employment* [32].

A total of 14 articles describe a specific period of use. This period ranges from 3 weeks [69] to 12 weeks [24,54] to 6 months [20]. The reason given for these periods is the underlying study design, inappropriate therapeutic follow-up time, or the duration of the rehabilitation phase.

Forms of HET Assistance

The HETs assist patients with their exercises by instructing, monitoring, correcting, assisting with assessments, providing additional information, and reminding them about exercising (Table 2).

The *instruction*, *monitoring*, and *correction* of exercises, as well as the *provision of additional information*, is carried out directly or indirectly. Direct HETs instruct patients on specific movements, give feedback on movement performance or provide additional information (eg, how to modify daily activities [20]). Indirect assistance occurs in 2 different ways or in a combination of both. Either therapists assist directly using HETs (eg, watching videos of patients [29] and receiving accumulated data for interpretation [23]) or HETs instruct, monitor, or correct patients' movements indirectly by playing games [31].

Other ideas for supporting patients while exercising at home are described in the discussions of the identified articles but have not yet been realized. These ideas are mentioned in Table 2 under "Implementation planned."

Table 2. Assistance options in descending order of frequency.

Availability HET[a] assistance	Available (%) (direct (%) + indirect (%))	Implementation planned, n (%)
Instruction	50 (89) (19 (34)+31 (55))	0 (0)
Monitoring	40 (71) (34 (61)+6 (11))	4 (7)
Correction	36 (64) (9 (16)+27 (48))	4 (7)
Assessment	26 (46) (26 (46)+0 (0))	4 (7)
Additional Information	7 (13) (5 (9)+2 (4))	0 (0)
Reminder	4 (7) (4 (7)+0 (0))	0 (0)

[a]HET: health-enabling technology.

Instruction

Usually, patients need instructions on how to perform exercises correctly. This subsection focuses on (1) whether it is specified who gives the instruction, (2) in which form and with which movement parameters, (3) the timing, and (4) which visual, auditory, or tactile types of assistance are used in the exercise programs.

In total, 47 articles report instructions given by HETs, whereas 3 articles report guidance by therapists alone [26,29,51]. In 6 articles, HETs and therapists instruct exercises together [19,23,24,43,53,59]. Pastora-Bernal et al [24], for example, provide training videos with exercise instructions, and the therapist enhances this via videoconferencing. With the *iJoint App*, the therapist guides the patient while the app provides information about target angles, actual angles, number of repetitions, and beeps when a target angle is reached [23]. A total of 25 HETs indirectly instruct exercises using games.

Both direct and indirect exercise instructions are mostly given using *range of motion* (ROM; 43/50, 86%). Other parameters related to movement execution are *starting and final position* (32/50, 64%), *smoothness of movement* (5/50, 10%), *speed* (18/50, 36%), *strength* [53], and *correct posture* [59]. Furthermore, 26 articles address a *training framework* for exercise instruction, that is, a kind of strategic planning of the exercise is described. At least one training science component of an exercise program must be named to fulfill this category. This can be the intensity of the exercises, for example, the *intensity* (20/50, 40%) and the *scope* (12/50, 24%) are most frequently mentioned. Only 2 articles report on *frequency* [23,58] or *density* [58,61] with regard to correct exercise performance.

All exercise instructions are given *synchronously*, that is, the patient is instructed before performing the exercise or while exercising. The *Shoulder Physiotherapy Application*, for example, provides visual instructions using skeletal images and text messages about correct exercise execution [55]. Two articles describe both *synchronous* and *asynchronous exercise instructions* via videos and written feedback [20,24]. The asynchronous part of the exercise instruction is done later via a supplementary paper-based document with an overview of the exercises [24] or written feedback with exercise instructions via email [20].

The type of assistance ranges from *visual* to *auditory* to *tactile* instructions for the exercises. Most articles describe visual assistance using *symbols* (n=33), *messages* or *texts* (n=25), *avatars* (n=22), *videos* (n=14), *schemes* or *models* (n=11), *skeleton images* (n=2), and *photos* (n=1) in different combinations. For example, the *Kinect-based telerehabilitation system* (*KiReS*) depicts the current and target status of movement with two 3D avatars and shows repetitions, series, next posture, and motivational messages. A 3-level color scale indicates whether a patient has reached a posture [19]. Pekyavas and Ergun [71] and Rizzo et al [73] use the Wii games of boxing and bowling with visual, auditory, and tactile exercise guidance.

Monitoring

Some HETs can monitor the quality and quantity of the performed exercises. Monitoring makes it possible to either give direct feedback to the exercising patient or inform the therapist about the patient's current state or long-term development. The degree of detail in monitoring ranges from simply recording the information that training took place on a certain day [58] to indicating how many repetitions of an exercise were completed [56] to storing aggregated data on ROM and the recognition of compensatory movements [31]. In addition, 34 HETs monitor exercises directly, whereas 6 use indirect monitoring (Table 2); 2 articles report indirect monitoring solely by physiotherapists during videoconferencing

[26,28]; 4 articles report on therapists who monitor exercises using HETs, and 10 report on both HETs and therapists who monitor the exercises. This is done, for example, by physicians and therapists evaluating recorded videos [20]. *Passive registration* of exercise execution means that monitoring starts automatically when HET-assisted exercising starts. This is described in 34 articles, whereas in 5 other articles, patients must activate the control (eg, recording ROM) to compare and track improvements [48]. A HET named *PARC*, for example, shows records of the scores and repetitions for the prescribed exercises. Physiotherapists can view exercise videos and results based on ROM measurement [43].

Correction

The category *correction of exercises* indicates that the patient's exercise performance is corrected in some way. This category also specifies by whom corrections are given, in which form, and with which parameter feedback is given. The timing of correction and parameters concerning the correction of movements are stated in the last paragraph of this subsection. In total, 9 HETs provide direct correction of the exercises, the other 27 HETs correct the exercises indirectly, and 4 HETs plan to fulfill this function (Table 2).

There are instances in which therapists correct exercises while an HET serves as an aid, as is the case in a videoconferencing system [20,26,29,43]. Simultaneous correction by HETs and therapists also occur [23,45,46,51,65,73]. One example of how correction by an HET is implemented is the use of red and green buttons to indicate right and wrong movements. Popup messages provide additional explanations of correct movements [70].

The most common form of feedback is *visual feedback* (25/36, 69%). The articles report the following subcategories of visual feedback in descending order of frequency: *messages/text*, *symbols*, *schemes*, *video*, *avatar*, and *skeleton imaging*. *Auditory feedback* is characterized in 13 articles as either *sounds* or *verbal explanations*. Furthermore, 3 HETs provide *tactile/haptic feedback*, two of which use Wii games [71,73]. One single HET provides both visual, auditory and haptic feedback. It displays symbols that change color in a web application, gives auditory feedback ("keep on" or "sit straight"), and includes a module on a vest that vibrates to indicate incorrect posture [57].

Almost all HETs offering exercise corrections provide *synchronous correction* (33/36, 92%). Two HETs exclusively use *asynchronous correction* via written feedback [20] and changes in game settings by therapists for indirect correction of patients' movement performance [20,43]. Parameters for the correction of movement execution are *ROM* (n=28), *starting and final position* (n=25), *speed* (n=9), and *smoothness of motion* (n=4).

Assessment

The category *assessment* is concerned with all kinds of assessments from movement measurements to questionnaires provided by HETs. The forms of *data collection* (*passive* or *active*), *timing*, and *content* are categorized (Multimedia Appendix 2). A total of 26 HETs provide assessment functions. All HETs perform assessments passively, usually during each exercise session. Active recording (eg, by pressing a monitor button) is also possible [44,58]. Most HETs evaluate the *ROM* (25/26, 96%). Four of the technologies enable therapists to supplement the assessment with patient-reported outcomes regarding *pain*, *strength*, or *function* [19,31,42] or to calibrate the neutral position and range of allowed movements [59]. Patient-reported outcomes are actively provided and entered by patients [19,31,42]. In Anton et al [19], therapists are also able to create individual questions.

Provision of Information

The category *provision of information* includes all additional information beyond direct support for exercise execution. In total, 7 articles report on this topic. Of these, 2 articles describe a given structure for *videoconferences* to do so. Structural elements include a question period [26] and a three-way meeting with patients, outpatient physiotherapists, and physiotherapists at the hospital [29]. A total of 5 HETs provide information as a *tutorial* that shows *how to use the HET* [62], *how to use the wearable devices* [37], "*information on different care activities and how to modify daily activities*" [20], "*on-screen tips about the importance of exercising*" [70], and *a display screen showing "a brief definition of frozen shoulder, [...] common treatment options, pain medication, and mobilization exercises*" [58].

Reminder to Exercise

A total of 4 HETs remind patients to exercise. One article reports a *calendar reminder* and a status report for exercises for each training session [58]. The other 3 articles do not specify the implementation of this function [23,37,54].

Visualization

Exercises are visualized in different ways: *2D or 3D graphics* and *aggregated information* mostly visualize guidance or exercise performance (eg, by *ROM values*, *speed in graphs*, and *real-time videos* [46]). Aggregated information can take the form of graphs or scores in a game. The subcategories *augmented reality*, *augmented virtuality*, and *virtual reality* can be thought of on a continuum between physical reality and virtual environment according to Milgram et al [88]. No subcategories for physical reality were created. The other 3 subcategories were created in a data-driven manner. To be classified as virtual reality, both the visualization of the exercises and feedback during the exercises must take place in a virtual environment. Augmented reality indicates that the virtual and physical environment are mixed. If, in this mix, a Red Green Blue (RGB) image is visualized in a virtual environment, then it is classified as augmented virtuality and, as such, a subcategory of augmented reality. In total, 15 HETs use *virtual reality*, 15 use *augmented reality*, and 5 use *augmented virtuality*. Sveistrup et al [83], for example, show an RGB image of the patient in front of a soccer net in a virtual soccer environment where the patient has to stop balls from scoring.

Telerehabilitation

The category *telerehabilitation* deals with the rehabilitation measure of exercise assistance at a distance. The connection between patients and therapists and the communication between them with the help of HETs is considered in terms of the aim of *communication*, *initiation of contacts*, *timing and communication channel*, and *content of messages*. Message content is subcategorized in *movement execution*, *framework for training*, *display of training*, *assessment*, and *aggregated information*.

Table 3 gives an overview of HETs using (20/56, 36%) or planning to use (7/56, 13%) telerehabilitation with mobile apps and game components or one of the two to assist patients in performing their exercises.

Table 3. Health-enabling technologies with telerehabilitation combined with apps and game components.

Number of subject	HET[a], n (%)	HET using apps, n (%)	HET using game components, n (%)
Telerehabilitation	20 (36)	18 (32)	14 (25)
Telerehabilitation planned for the future	7 (13)	3 (5)	3 (5)
No telerehabilitation	29 (52)	17 (30)	17 (30)

[a]HET: health-enabling technology.

Telerehabilitation contacts are usually initiated by therapists to check exercise results. For example, therapists log on to a therapist portal to view patients' exercise parameters in graphs and videos [46]. In total, 18 HETs use *web interfaces* as a communication channel. Additional communication channels include *video chats* [26,30], *video messages* [20,46], *text messages* [50], and *emails* including video recordings of exercises customized for a patient, images, and parameters of each exercise [24]. Eriksson et al [29] report on a classic *videoconference−based* telerehabilitation. The timing of telerehabilitation contact is mostly not stated. In total, 5 articles report *periodic* telerehabilitation meetings (eg, twice a week [20]). The *MoMo* app provides telerehabilitation contacts *on demand* [37].

The *content of messages* is largely consistent with the categories and subcategories described above for instruction, monitoring, and correction. Information on *ROM* (n=11), *starting and final position* (n=10), *speed* (n=8), and *smoothness of motion* (n=5), as well as *assessment results* (n=10), *aggregated information* (n=9), *videos* (n=7), *avatar images* (n=4), *patient images* (n=4), and *photos* (n=1) are displayed. *Aggregated information* concerns *execution of exercises* (n=8), *exercise frequency* (n=7), *number of repetitions* (n=7), and *execution quality* (n=5). This can take the form of a patient's avatar movements from different rounds, target angle, arm side, date, time, number of repetitions, and ROM results in graphs [36]. *Intensity* (n=9), *scope* (n=9), and *frequency* (n=4) represent the *exercise program framework*.

Strategies of Exercise Programs

Structure

This section describes HET-assisted exercises and exercise programs. Typical therapeutic goals of exercising for patients with shoulder disorders are reported. The most common goal is to *maintain or improve shoulder mobility* (30/56, 54%). This is followed by *strengthening* (14/56, 25%) and *pain relief* (13/56, 23%). Less frequently reported goals of technology-assisted exercises are *initiation of scapulothoracic rhythm* [24,31,57,73], *humeral head centering* [24,31,73], *postural control* [26,37,57], *increasing blood circulation* within the affected area for faster recovery [53], *motor learning* [82], and *increasing functional ability and occupational performance* [77]. In total, 23 articles did not specify any goal for the implemented exercises.

Depending on the intended use and therapeutic goal, an exercise program can be designed differently in terms of the number of exercises, frequency of exercise, and exercise duration. The category *number of assisted exercises* represents the number of different supported exercises. This number is given for 18 HETs and ranges from 2 [31] to 9 [42]. Carbonaro et al [31], for example, describe 2 exercises to externally rotate the shoulder and abduct to 80° with an elastic band. Inertial measurement units identify compensatory movements during these exercises. Rahman et al [42] defined 9 different exercises (eg, shoulder flexion and shoulder extension) for mobilization with starting and final position and integrated them into the game *Pluck the Fruits*. An app instructs wiping movements for shoulder mobilization in patients with a frozen shoulder along with 3 other exercises in Stütz et al [58]. The counting of the exercises in this category follows the authors' definition of the exercises.

Duration per exercise (program) performance ranges from 5 [54] to 60 min [77]. The *exercise frequency per week* ranges from twice a week [47] to 14 times a week [26] with a recommended exercise frequency of once [58] to 3 times per day [54]. As justification for these recommendations, almost all articles mention aspects of study design. Only Chiensriwimol et al [36] explain that the treatment of a frozen shoulder requires an exercise duration of 12 to 18 months with daily exercises.

Training therapeutic exercise programs for mobilization and strengthening can be roughly divided into *warm-up phase*, *main phase*, and *cool-down phase*. Only 5 of the 56 articles report on an exercise program with a *warm-up phase* and *main phase* [26,71,73,77,83]. Two of them also mention a *cool-down phase* [71,73], and one refers to a phase in which patients can ask therapists questions [26].

Adaptation

Adaptation of exercises or exercise programs describes the possibility of adapting exercises or exercise programs to fit patient-specific characteristics, needs, or training progress. This is possible in 36 HETs. The most common criterion for adaptation is the *ROM* (28/36, 78%). In total, 24 HETs adjust the settings directly to the patient's ROM, and 4 articles report on therapists using ROM to adapt to exercises. Other criteria are the *individual patient* (20/36, 56%), *exercise duration* (4/36, 11%), *age and gender* [34], *patient's proportions* [55], *patient's disease* [19], and *patient's home environment* [29]. However, adjustment to patients is usually not described in detail. For example, Du et al [66] report adjusting the game settings and difficulty levels to fit each patient's condition and demands without explaining how this is done. In total, 14 articles report on the adaptation of exercises during the course of therapy, and 22 articles report on the adaptation of exercises at the beginning of therapy.

Most often, therapists decide on the adjustment (28/36, 78%). Seldom do HETs adjust exercises independently (eg, adapt game levels according to a patient's ROM [37]). Good interaction between the therapist and HET is visible in *KiReS* and *iJoint App*. *KiReS* supports therapists' exercise decisions by assessing the rehabilitation phase based on the *TrhOnt* ontology [19]. The *iJoint App* calibrates settings via ROM, whereas physiotherapists undertake adjustments to fit a patient's progress [36]. In total, 2 HETs allow patients to make additional adjustments and choose levels of difficulty [26,46].

HET Components

Various HET components, such as *sensor hardware*, *hardware for output*, and *software*, are used to assist patients in their exercises. A total of 47 HETs are *transportable*, 9 are *body wearable*, and 6 are transportable technologies with wearable components. Fixed installed HETs are not among the identified HETs. One reason for this is that only HETs suitable for use in patients' homes are included.

Sensor Hardware

The depth-image camera Kinect from Microsoft is the most frequently used sensor hardware. In total, 27 articles report on HETs based on *depth-image cameras* and all of them use the Kinect. For 23 HETs, the version is not specified, and one uses *Kinect for Xbox 360* (Kinect v1) [19] and 3 use the newer version *Kinect for Windows* (Kinect v2) [38,51,69]. *Inertial Measurement Units* (IMU) are part of 15 HETs, and 14 HETs use *accelerometers*, 12 *gyroscopes*, and 10 *magnetometers*. Some HETs use multiple sensors. For example, Yeh et al [45] combined joint angle measurements from IMU and Kinect v1 in their HET *cloud motion-sensing rehabilitation system*. In addition, 7 articles describe the use of sensors in smartphones. In three of them, an accelerometer, a gyroscope, and a magnetometer are used [23,36,58]. Smartphone cameras are also considered sensors in smartphones. A total of 4 HETs use the *smartphone camera* and 5 HETs have a *conventional color camera*; 2 articles report on the *Wii Nunchuck Controller* and on the *Wii Remote* [71,73]. In addition, 7 other *controllers* are used including other gaming controllers [30,62,77], a mouse [26], a red glove for a virtual reality system [83], a force feedback device [82], and a standard shoulder wheel [33,34]. The shoulder wheel has a control module for converting wheel rotation into control signals for 6 exergames. In one of the games, for example, arrows are fired at a target with the shoulder wheel at the correct angle [33,34].

Hardware for Output

In total, 34 HETs use *PC displays*, 11 use *smartphones*, and 8 use *televisions* as hardware for output; 6 *bigger screens* (>40) or *projectors* [26,34,37,40,47,67] and 3 *head-mounted displays* [26,46,60] are also reported. Furthermore, 6 articles do not specify the hardware [38,49,66,69,72,75]; however, these 6 articles describe interfaces for games that require visual control by the patient.

In addition, 3 *haptic devices* [57,60,82], 2 *audio-biofeedback modules* [23,35], and 3 *LEDs* controlled by an analog-digital converter with a *microcontroller* [53] are used for output.

For most technologies, the output channel is *visual*. In total, 22 articles report on *auditory* and 5 on *haptic* channels [57,60,71,73,82]. Underreporting of auditory output channels is possible because not all articles on games indicate their likely use of auditory channels. For example, Powell and Powell [72] describe the sound of falling fruit for the game of fruit picking, whereas Rahman et al [42] do not mention this for a similar game.

Software

In total, 9 HETs use *off-the-shelf software* [26,29,44,71,73,75,77,80,83], whereas the basis for all other technologies is *self-developed software*. Two technologies use both off-the-shelf and self-developed software [26,44]. One article about a telerehabilitation platform does not specify the software used or developed [20]. Software development is described in varying detail. This ranges from a detailed description of each developmental step [85] to a simple presentation of the programming language and game engine [38] to no description at all [57].

Development and Evaluation

Interdisciplinary Development

An interdisciplinary contribution to the development of HET is mentioned in 17 articles. This includes the *development* of the technology by computer scientists or engineers and therapists or physicians, *consultation* of therapists or physicians during the development, or at least the involvement of therapists or physicians in the *evaluation*. Patients evaluated 18 HETs. In 2 articles, patients were involved in the development above and beyond this evaluation [37,74]. Chung and Chen [37] conducted a 2-month observation of the therapy process and interviewed therapists, physicians, and patients. Shi and Peng [74] performed a user requirements analysis with patients using the *house of quality method*.

In 7 other articles, an interdisciplinary development can be assumed but is not described explicitly [24,45,47,49,54,56,72]. For example, the analysis of therapeutic goals and actions is stated, but an interaction and collaboration with health care professionals and patients is not described [72].

Compared with other articles, the 17 that had interdisciplinary cooperation show an above average proportion of *provision of information* by HETs (4/5), *reminder to exercise* by HETs (4/4), *adaptation of exercises* to an individual patient (4/5), and *correction* under the telerehabilitation aspect (6/7). A relatively small proportion of these are seen in the corrections by HETs (3/9) and among the articles that do not specify a goal for the presented exercises (5/24).

System and Project Phase

The category *system or project phase* is based on the study phases of trials for drugs and medical devices. The included articles report tests in *phases 0, 1, 2, and 3*. None of the studies on long-term effects dealt with *phase 4*. In the following summary, an HET can be counted in multiple phases. Whenever it is reported in the corresponding articles, the already completed phases and the current project phase are recorded. Da Gama et al [65], for example, report *phase 0* and *phase 2*.

Phase 0 is concerned with the testing of prototypes and prototypical tests; 48 articles are in *phase 0*, 34 of them end in *phase 0*, 13 articles present *initial prototypes*, 33 present *system prototypes* in which the later function is fully implemented, and 24 articles test the HET prototype under *laboratory conditions for feasibility, acceptance, usability, or safety.*

In *phase 1*, an HET is tested for *feasibility*, *acceptance*, *usability*, or *safety* in the setting (a patient's home or a rehabilitation facility) or under everyday conditions. In total, 15 articles are concerned with *phase 1*. In 7 articles, study staff supported the tests, whereas the other 8 articles did not provide personal support. *Phase 1* is the last phase to be reported in 7 articles.

Phase 2 involves proof of concept and the exclusion of risks and side effects. A *first effectiveness or efficacy study* is also possible in *phase 2*. The first phase 2 testing of an HET occurred in 2011. An initially suspected increase in the later study phases over time was not found (Figure 2). *Phase 2* is reported in 8 articles, where it is also the last phase; 4 articles report on the *proof of concept*, 6 on a *first effectiveness or efficacy study*, and 1 on the *exclusion of risks and side effects* [73].

Figure 2. Overview of current and completed system and project phases per year.

Significant effectiveness or efficacy is evaluated in *phase 3*. This is the case in 5 articles. For outcomes, see the section *Evaluation*. Figure 2 shows an overview of the current and completed system and project phases per year. The data for 2019 may be biased because articles were only included until July 2019.

Evaluation

Feasibility, *usability*, *acceptance*, or *effectiveness or efficacy* were tested in 49 HETs. This evaluation ranges from self-designed interviews and questionnaires [20] to the use of validated survey instruments (eg, *System Usability Scale* in [58]). Four articles report the absence of *(serious) adverse events* [26,54,73,77]. The other articles do not mention *adverse events*.

Feasibility tests of partial components or individual algorithms are reported (22/49, 45%), as well as tests of the entire technology (30/49, 61%). Only Pastora-Bernal et al [24] and Eriksson et al [29] describe embedding in the care process under everyday conditions.

Usability tests were conducted for 15 technologies. *Healthy volunteers* [20,42,48,57,70], *patients* [19,29,48,49,54,58,65,69,74], and in a few cases *therapists* [36,59,65] were interviewed or filled out a questionnaire. Mostly, relatively small samples of 3 to a maximum of 20 patients and 5 to a maximum of 11 therapists were queried. Only Choi et al [54] tested usability with the *Usefulness, Satisfaction, and Ease of Use* questionnaire in 42 patients. Two articles describe preliminary usability results with 1 patient [30] or tested only an interface prototype [37]

Acceptance is examined for 14 HETs in patients and 3 HETs in therapists [51,59] or physicians [42]. The level of detail in the description of user groups and sample size varies widely. For example, acceptance is tested in 1 physician [42], 12 therapists [51], 50 patients [81], or 100 users with and without impairments [72].

In total, 8 articles show significant improvements after training with assistance from the respective HET in one or more of the following categories: *mobility/flexibility* [20,29,47,49,65,73,77], *pain* [20,49,71,73,77], *strength* [20,77], *quality of life* [29,73], *activity performance* [49,71,77], *participation* [77], and *postural control* [57]. The study designs differ considerably, as do most survey instruments. Only ROM measurements were analyzed in 7 of the 8 articles. Eriksson et al [29] report a significant improvement in ROM and health-related quality of life in a nonrandomized controlled trial with 10 patients in the intervention group and 12 patients in the control group over 2 months. In their noncontrolled study in 11 patients over 6 months, Macias-Hernandez et al [20] show a significant improvement in pain on the *Visual Analogue Scale* and in muscle strength and function with the *Constant Murley Score*.

Discussion

Principal Findings

Overview

The *target group* is mainly described as typical patients with musculoskeletal shoulder disorders. It is surprising that about half of the articles offering exercise assistance do not specify their target group. A total of 5 HETs assist both neurological patients and patients with musculoskeletal shoulder problems. This is conceivable as long as the exercise goals are identical (eg, to improve mobility); however, it should be noted that the need for assistance and support can vary considerably.

Most HETs have been developed for single parts of the therapy process involving exercises, as can be seen from the reported objectives. Only Pastora-Bernal et al [24] and Eriksson et al [29] describe embedding them in the care process. Beyond this, Anton et al [19] already provide support in the selection of exercises and recommended the use of their HET, *KiReS*, in addition to regular therapy sessions.

The study design is stated as the reason for the very different periods of use. Substantive reasoning that includes the course of healing, guidelines, or expected rehabilitation phases is missing.

Some HETs offer patients a complete and balanced exercise program that follows scientific training aspects, although the program is usually not individualized. Most technologies, however, fall far short of this and cover, at most, single components and goals, such as maintaining shoulder mobility in a specific direction of movement.

Forms of HET Assistance

The concepts underlying the assistance provided by HETs are subcategorized into *instruction*, *monitoring*, and *correction* with the subsubcategories *direct and indirect instruction, monitoring, and correction*. In physiotherapeutic treatment with exercises, *instruction*, *monitoring*, and *correction* are closely interwoven in the sense of an iterative adaptation [89]. This becomes evident to some extent in telerehabilitation with a direct connection to therapists. During a videoconference session, instruction, monitoring, and correction occur all at once. Even without direct videoconferencing, the therapist checks the training results via the aggregated information provided by the HET or via the recorded training video. This is then the basis upon which therapists give feedback for exercise correction, select a new exercise, or adjust the exercise instructions. This is done by changing the settings in games, creating and providing exercise videos, or by giving written feedback.

Instructions and *correction* via feedback from HETs through games are also frequently interwoven. Whenever a user is instructed with feedback to move within a certain range for success or failure, indirect *instruction* and *correction* via feedback are inseparable. This is similar to the procedure in physiotherapeutic processes with exercise treatment and adjustment, where the patient has to fulfill conditions with external attention focus. External focus leads to better motor skill learning than exercising with an internal attention focus [90]. The corresponding HETs have the potential to offer this procedure in the patient's home environment at a high frequency, with many repetitions and with constant adaptation to the performance and ability of the patient. However, this interplay of *exercise instruction*, *monitoring*, and *correction* by HET is not described in detail. The adaptation of game tasks or game levels to simple motion parameters permits this conclusion. In the game "pluck the fruits," for example, patients are instructed to achieve a certain ROM to pluck a fruit and advance to the next level. The HET indirectly corrects incorrect exercise execution by not allowing the fruit to be plucked, monitors exercise progress via ROM, and increases the ROM at the next level [42].

Exercise assistance solely from HETs is most often provided in the *instruction* of exercises, followed by *monitoring*, *assessment*, and *correction*. Simple, easily measurable, and presentable parameters such as *ROM*, *starting and final position* of the shoulder, and the *frequency* via the *number of repetitions* are by far the most frequently described parameters. Only rarely are parameters of movement quality used, such as *posture control*, *speed*, *harmony*, or *smoothness of movement*, which are also important for good exercise performance [91]. Beyond the pure ROM, it is important to avoid certain compensatory movements or to perform exercises with a smooth movement. This can serve to achieve a greater training effect, address certain muscle groups, or prevent negative consequences of the exercise. In addition, the quality of movement can be recorded in detail and reported back to the patient to improve exercise performance. This also makes it even more difficult to trick the system, for example, by replacing large movements with small fast movements.

Overall, some key components of motor learning are used for assistance by HETs but are not defined by the authors and developers. These are, for example, "observational learning" (eg, video-based instructions), "trial and error learning" (eg, in games with a task-oriented approach with feedback), and "errorless learning" (eg, the therapist adjusts the difficulty in the game via ROM) [92].

Only 3 HETs provide information on the relevance of exercises and changes in everyday life [20,58,70]. Even if it can be assumed that information and the motivation to exercise come from elsewhere, the integration of technology in these exercises to support and maintain motivation and adherence would be conceivable. It is therefore surprising that this aspect is not considered in many articles.

Assessments are usually represented by *ROM*. Very few technologies offer the possibility of patient-reported outcomes concerning *pain*, *strength*, and *function* [19,31,42]. *KiReS* offers an outstanding patient-specific approach in which therapists can create individually adapted questions [19]. Additional HETs with such functions would be desirable for patient-specific exercise therapy.

Telerehabilitation aspects are described in 27 of the 56 articles. This appears to be few and can be justified by the early development states. A total of 7 articles report *telerehabilitation aspects* as planned but not yet implemented. However, not all HETs seem to be designed for telerehabilitation, but rather for exercise assistance without connection to health care professionals. To what extent this is harmless and therapeutically useful is questionable as only 4 articles consider *adverse events*. Moreover, the vast majority of technologies do not offer a balanced exercise program for the shoulder. Balanced in this context is an exercise program that is adapted to the patient's individual functional problem or is at least a complete exercise program that follows scientific training aspects. The individual adaptation of exercises to a patient is only partial and rarely done directly by HETs. In contrast to the physiotherapeutic treatment with repetitive adjustment [89], customization of exercises usually occurs at the beginning. The most common criterion for this is the *ROM*. More complex adjustments are only made in HETs with telerehabilitation. Usually, it is the responsibility of therapists who change the settings of an HET or teach patients to use the technology. This may protect patients at the current stage of HET development from physical damage as a result of incorrect exercising.

HET Components

Although some articles describe the *sensor hardware*, *hardware for output*, and *software* in detail, several do not. A lot of information is missing in the articles without detailed description, making traceability and comparability with other approaches impossible. For example, 28 of the 32 articles do not specify the version of the Kinect camera used. However, such information is important for drawing conclusions on the accuracy of joint position calculations [93,94].

The same applies to the lack of specification of the sensors used, whether they are body-worn sensors or sensors in the smartphone. This is also evident in some functions. Concerning the reminder function, for example, how it has been implemented remains open in most articles.

Microsoft's Kinect depth-image camera seems to be particularly well suited to assist patients with musculoskeletal shoulder disorders in their exercises [95]. It was by far the most common sensor hardware, followed by IMUs and conventional color cameras. With regard to the detection accuracy of joint positions, the Kinect camera may be inferior to some marker-based, body-worn sensors. However, the Kinect's advantage is a contactless measurement of the shoulder joint angle with acceptable accuracy, even though factors such as loosely fitting clothing can influence the accuracy [96].

Most the software is self-developed. This allows the adaptation of HETs to patients' needs and becomes all the more apparent when more patients are involved in the development process. Development processes with or without user involvement are reported in varying degrees of detail. Rarely found was a reference to a strict development scheme (eg, a development according to the Medical Device Regulation [97]). This may be due to the current state of development. Nevertheless, development according to legal requirements and subsequent quality assurance for use in therapy would be advisable.

Development and Evaluation

Many technologies are not yet sufficiently developed. Instead, the focus is on the description and testing of technical components. Most of the articles are in "phase 0," and only 5 articles report on *phase 3*. A systematic completion of all phases, comparable to drug and medical device studies with the resulting comparability and quality assurance, cannot be observed.

Interdisciplinary HETs focus more often on patient-relevant goals and correct exercises with the therapist in charge. Additional functions such as *reminders* or the *provision of information* were almost exclusively the result of interdisciplinary developments. It can be assumed that the patients' or therapists' experiences are responsible for this. *Interdisciplinary development* seems to be a reasonable approach to consider all relevant aspects and to develop sustainable practical solutions.

The results on *feasibility*, *acceptance*, and *usability* of the presented HETs are mainly positive. However, several articles report small sample sizes or tests with healthy persons. Therefore, it is often unclear to what extent these results are transferable to patients and practice.

Different measuring instruments and study designs are used. *Feasibility* is mostly tested under laboratory conditions. Using different study designs and measurement tools, 5 articles in *phase 3* and 3 articles in *phase 2* show significant improvements in at least one shoulder-relevant outcome parameter. In contrast, 6 articles reported insignificant results. For these studies, which had small sample sizes and were tested for superiority or without a control group, the technologies cannot automatically be considered unsuitable. Standardized comparable parameters would be necessary for meta-analyses in the presence of further randomized controlled trials.

Limitations

The deliberately broad database search resulted in a high number of records. In several attempts to specify search terms, this led to a reduction in the number of records and a loss of relevant articles. As a consequence, the decision was made to screen a large number of records for this scoping review. Nevertheless, it is only a broad overview of the scientific literature. A supplementary market analysis of HETs that assist patients with musculoskeletal shoulder disorders in their exercises has not been conducted.

Following a pilot data extraction, 1 reviewer performed the content analysis of the full texts. A content analysis of all full texts by 2 reviewers separately may have led to more reliable results.

This scoping review serves exclusively as a broad overview of HETs that assist patients with musculoskeletal shoulder diseases in their home-based exercises. Quality assessments of the studies and a meta-analysis were not done amid the different study designs with predominantly small sample sizes. Therefore, this review does not provide systematically substantiated answers in this respect. The aim was to identify and analyze the development and use of HETs describing their approaches and their stage of development. A narrower limitation and subdivision, for example, according to development status or hardware use, would be useful as a next step. A deeper analysis and presentation within subgroups would be possible.

Conclusions

This scoping review provides an overview of HETs that assist patients with musculoskeletal shoulder disorders in their exercises at home. The spectrum of identified HETs ranges from simple videoconferencing systems, exergames, and apps without telerehabilitation aspects to complex sensor-based technologies for telerehabilitation. HETs assist patients *directly* or *indirectly* (eg, with exercises hidden in a game). Various *sensor hardware*, *hardware for output*, and *software* are used for *instruction*, *correction*, or *monitoring* of exercises and *assessments*. The *Microsoft Kinect camera* and *ROM* are most frequently used and well proven. Other parameters of *movement quality* (eg, *posture control* or *smoothness*) are rarely used but are also important for good exercise performance and movement learning. Few articles describe a technology-based *exercise reminder* or the *provision of information* (eg, how to modify daily activities according to the shoulder condition or explain the importance of exercises).

Although some HETs offer patients a balanced exercise program, although usually not individually, most HETs fall short of doing this. The support of evidence-based exercises based on guidelines, recovery processes, or expected rehabilitation phases is missing here. Exercise *adaptation* to an individual patient is mostly done by therapists and rarely by HETs.

Most HETs are not yet sufficiently developed, but rather are in a prototype state. Few HETs achieved significant improvements in at least one shoulder-relevant outcome parameter. Various instruments and study designs are used to evaluate *acceptance*, *usability*, or *effectiveness or efficacy*, mostly in small samples. Interdisciplinary developed HETs more often define their target group, focus on patient-relevant goals, and offer additional functions such as reminders or extra information. Health care professionals and patients should therefore be involved in the product development cycle to consider all relevant aspects of sustainable practical HETs. This includes the embedding of an HET in the care process, prototype testing as well as usability and acceptance tests with the later target group under real-life conditions. A greater correspondence of study designs with control groups for effectiveness and efficacy studies, comparable standardized assessment instruments, and larger sample sizes would enable better comparability and, consequently, a sound selection of HETs for clinical use. Altogether, this review provides a first overview and thus a basis for pursuing more specific questions in the future about subgroups of HETs for selection or recommendation for clinical use as well as for further research and development.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Search queries.

[DOCX File , 19 KB - rehab_v8i1e21107_app1.docx]

Multimedia Appendix 2

Overview of results.

[XLSX File (Microsoft Excel File), 79 KB - rehab_v8i1e21107_app2.xlsx]

Multimedia Appendix 3

Overview of identified articles and related health-enabling technologies with telerehabilitation aspects.

[PDF File (Adobe PDF File), 278 KB - rehab_v8i1e21107_app3.pdf]

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Abbreviations

HET: health-enabling technology
IMU: inertial measurement unit
KiReS: Kinect-based telerehabilitation system
PICO: Patient or Population, Intervention, Comparison, Outcome
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analysis
RGB image: Red Green Blue image
ROM: range of motion

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Original Paper

Attitudes Toward the Use of Voice-Assisted Technologies Among People With Parkinson Disease: Findings From a Web-Based Survey

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Abstract

Background: Speech problems are common in people living with Parkinson disease (PD), limiting communication and ultimately affecting their quality of life. Voice-assisted technology in health and care settings has shown some potential in small-scale studies to address such problems, with a retrospective analysis of user reviews reporting anecdotal communication effects and promising usability features when using this technology for people with a range of disabilities. However, there is a need for research to establish users' perspectives on the potential contribution of voice-assisted technology for people with PD.

Objective: This study aims to explore the attitudes toward the use of voice-assisted technology for people with PD.

Methods: A survey was approved for dissemination by a national charity, Parkinson's UK, to be completed on the web by people living with the condition. The survey elicited respondent demographics, PD features, voice difficulties, digital skill capability, smart technology use, voice-assisted technology ownership and use, confidentiality, and privacy concerns. Data were analyzed using descriptive statistics and summative content analysis of free-text responses.

Results: Of 290 participants, 79.0% (n=229) indicated that they or others had noticed changes in their speech or voice because of the symptoms of their condition. Digital skills and awareness were reported on 11 digital skills such as the ability to *find a website you have visited before*. Most participants (n=209, 72.1%) reported being able to perform at least 10 of these 11 tasks. Similarly, of 70.7% (n=205) participants who owned a voice-assisted device, most of them (166/205, 80.9%) used it regularly, with 31.3% (52/166) reporting that they used the technology specifically to address the needs associated with their PD. Of these 166 users, 54.8% (n=91) sometimes, rarely, or never had to repeat themselves when using the technology. When asked about speech changes since they started using it, 25% (27/108) of participants noticed having to repeat themselves less and 14.8% (16/108) perceived their speech to be clearer. Of the 290 respondents, 90.7% (n=263) were not concerned, or only slightly concerned, about privacy and confidentiality.

Conclusions: Having been added to the homes of Western society, domestic voice assist devices are now available to assist those with communication problems. People with PD reported a high digital capability, albeit those who responded to a web-based survey. Most people have embraced voice-assisted technology, find it helpful and usable, and some have found benefit to their speech. Speech and language therapists may have a virtual ally that is already in the patient's home to support future therapy provision.

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KEYWORDS

Parkinson disease; mobile phone; telerehabilitation; eHealth

Introduction

Background

Globally, there are more than 6 million people diagnosed with Parkinson disease, and it is currently the fastest growing neurological disease worldwide [1]. Early presentation includes tremor, stiffness or rigidity, slow movement, impaired balance, poor coordination, and speech problems [2]. Although it usually affects people aged >50 years, it can also affect younger people [2].

Problems with speech occur in 90% of people with Parkinson disease [3] at some point in their condition and include monotonous tone, reduced pitch and loudness, variable rate, imprecise consonant production, and an unclear *breathy* voice [4,5]. These speech symptoms are caused by issues with neuromuscular control over the speech mechanism that can be classified under the umbrella term of *dysarthria* [6]. People with Parkinson disease have an abnormal perception of loudness levels to guide the correct production of volume in their speech [7] so that an individual will feel that they are shouting when speaking at a normal level. Recalibration of the internal perception of volume and effort is one of the goals of speech and language therapy (SLT) [8]. The impact of speech problems is wide, affecting activities of daily living, mood, and self-identity [3].

Early SLT intervention is important to address communication issues [8], but only a little more than half of all people with Parkinson disease have contact with a therapist (52% in the United Kingdom [9]; 59% in Australia [10]). Given the extremely high rates of this population who experience voice changes or are dissatisfied with how they communicate [11], this rate of access to SLT is alarmingly low. Lee Silverman Voice Treatment (LSVT) is the gold standard approach provided by SLT for improving vocal loudness in people with Parkinson disease (which is often the primary concern). Despite its benefits, LSVT is resource intensive, requiring significant personal and professional time investment and self-directed motivation to practice largely repetitive exercises [12]. Often, the intensity and effort required to finish a program of LSVT outweigh the perceived benefits. People with Parkinson disease report that practicing on their own can be difficult; they feel self-conscious, overburdened, and doubtful about the effectiveness of carryover from therapy sessions to everyday situations [13]. The limited access to SLT and resource intensity of clinical services warrants exploration of alternative methods to support people with Parkinson disease to communicate effectively.

Application of Technology

Technology can offer a range of opportunities to support people with Parkinson disease during this process of home-based practice by structuring activities, adding gamified elements to increase enjoyment, and providing positive reinforcement and feedback. For example, improved engagement and enjoyment in vocal loudness exercises conducted with a digital game was described by users [14]; an innovative crowd-sourcing approach was explored to provide real-time, human feedback on speech for people with Parkinson disease, who uploaded structured speech samples via an app [15]. Participants could then use a practice area in the app, based on feedback received, to direct their home-based practice (eg, focus on volume using a decibel meter, focus on pacing using a metronome). Further work showed promising results for the use of a head-worn wearable device (Google Glass) as a volume training tool at home and an assistance device in social settings with cues to increase volume [16]. The glasses displayed real-time feedback of volume using a thumbs up symbol for positive reinforcement when a preset target was achieved. When discussing Google Glass, people with Parkinson disease explicitly described the benefits of the voice interaction functionality to access technology. Even those with pronounced speech difficulties found success with voice interaction [17]. Although this work on technology-assisted SLT for people with Parkinson disease seems promising, it is only now emerging as an area of research, and studies to date only explore interventions with small numbers of participants. Through this work, we explored the opportunities for widely used, off-the-shelf voice-assisted technologies (VATs, which implement voice interaction) in supporting people with Parkinson disease.

Voice assistants are software agents installed in devices such as phones, computers, or tablets or on purpose-built speakers [18]. They are capable of interpreting human speech and, depending on the command they receive, can complete different tasks (eg, tell the time or the weather, send and read text messages, make phone calls, set alarms, play music, and control various connected devices) [18]. Currently, one in 5 homes in the United Kingdom owns a voice-assisted speaker, a figure that is predicted to rise significantly in the coming years [19]. As many as 53% of homes in the United States own one voice-assisted speaker [20]. As such, these VATs are growing in popularity and are becoming pervasive. The older population (aged ≥60 years) make up around 20% of smart speaker ownership, with almost 60% of these consumers using the device every day [21]. Amazon Alexa is the market leader across all age groups [21]. VAT offers hands-free access and naturalistic voice interaction, a beneficial means of interacting with the device for those with physical disabilities or lower levels of technology literacy [15]. As such, recent years have seen an emergence in research in the health and care space, which is exploring the role of VAT in supporting people within these demographics.

A living lab study was conducted with older adults aged between 64 and 89 years [22] to explore older people's interactions with a voice assistant (Google Home) and several connected smart home devices. Participants were asked to perform several relevant activities (eg, ask for information, control lights, fans, and a television [TV]) and were interviewed about their experiences. The authors noted high levels of acceptance with the smart home technologies among older adults and, in particular, described the value they found using voice command as an input, describing how participants enjoyed interacting at their own pace, without being *judged* or *hurried*. Similarly, the design of adaptive systems, using voice interface technology for people with physical disability, can enable flexible use of smart homes [23]. The VAT system was *self-learning* and adapted to each user's command preferences after being trained through a series of short sessions. This work shows promise in particular for participants with speech difficulties, as the system adapts to impaired speech patterns (eg, people with dysarthria taking more pauses between phrases).

Several studies have explicitly explored the opportunities of the leading VAT (Amazon Alexa) to support people with disabilities, largely focusing on analysis from public reviews (posted on the Amazon store). For example, 284 reviews were thematically analyzed from people discussing disability and found recurrent themes relating to feelings of empowerment, as well as reporting success from people with speech difficulties [24]. They concluded that although very promising, usability issues, such as unintended access to the technology from children and privacy concerns, can have serious implications for health applications in the home. They also recognized the need to consider disease state in technical skill development to reduce frustrations. Similarly, 346 Amazon reviews by people with cognitive, sensory, or physical disability were analyzed, finding high levels of acceptance among users, reports of users considering the device as a companion, and increased reported independence in the user [25]. The authors also explicitly discussed reviews from users with speech difficulties. A total of 13.6% (47/346) of the reviews were by someone with speech impairment, and 74% (23/31) of their comments were around positive experiences with the technology, indicating success with being understood by Amazon Alexa. Interestingly, 2.0% (7/346) of users mentioned specifically that it helped them *talk slowly, clearly, and loudly*, which is highly relevant to our work with Parkinson disease (PD), where this is often the main aim of SLT. Similar findings were found in a study of the challenges and opportunities for the internet of things (IoT) for people with Parkinson disease [26]. Approximately 50% of the participants had already used Amazon Alexa in their homes, and similar reports from a participant with speech difficulties described speaking in a slower, clearer voice to enhance his ability to interact with Amazon Alexa [26]. This effect is interesting and potentially significant for speech improvement, justifying further investigation.

In addition, the extent to which people with dysarthria (the motor speech disorder experienced by people with Parkinson disease) interacted with 3 specific VATs (Apple Siri, Google Assistant, and Amazon Alexa) was investigated [27]. They used the TORGO database [28], consisting of available recordings of people with dysarthria, and found 50% to 60% accuracy of phrase recognition. What was not controlled for in this study was how well the VATs worked in correlation with the degree of dysarthric speech (ie, it worked better with a moderate level vs severe dysarthria or was the presence of any dysarthria, even a mild one, a cause for issue). In addition, the speech samples were standardized in nature and recorded in laboratories and thus did not represent the naturalistic interactions with the VATs that one would carry out in everyday life. Finally, the abovementioned study did not account for disease-specific origins of the dysarthria, which could in themselves have different factors that account for the intelligibility levels in the speech samples.

In summary, there is some evidence that VATs are already beginning to improve the lives of older people and people with disabilities and clear potential for the technology to support people with speech impairments. Furthermore, VATs may even be unexpectedly acting as a prompt for improving the speech of some users [24-26]. However, these studies provide only anecdotal evidence, highlighting the need to conduct systematic research to explore if and how people with different levels of speech impairment engage with VATs.

Study Aims

In this work, we investigate the opportunities for VAT to support SLT outcomes for people with Parkinson disease. We focused on exploring the ownership and acceptance of VATs among the Parkinson community and their usability for those with speech issues. In addition, to further explore possible barriers to the adoption of VAT to the wider Parkinson community, we also wanted to explore any privacy and security concerns that people with Parkinson disease might have surrounding these technologies. We aimed to answer 3 questions within the UK-based Parkinson community:

1. What is the level of basic digital skills?
2. What is the knowledge and experience of existing VAT?
3. What are the reported effects of VAT on speech and language?

In so doing, we aim to build a foundation of knowledge for further research, development, and implementation of VAT for people with Parkinson disease.

Methods

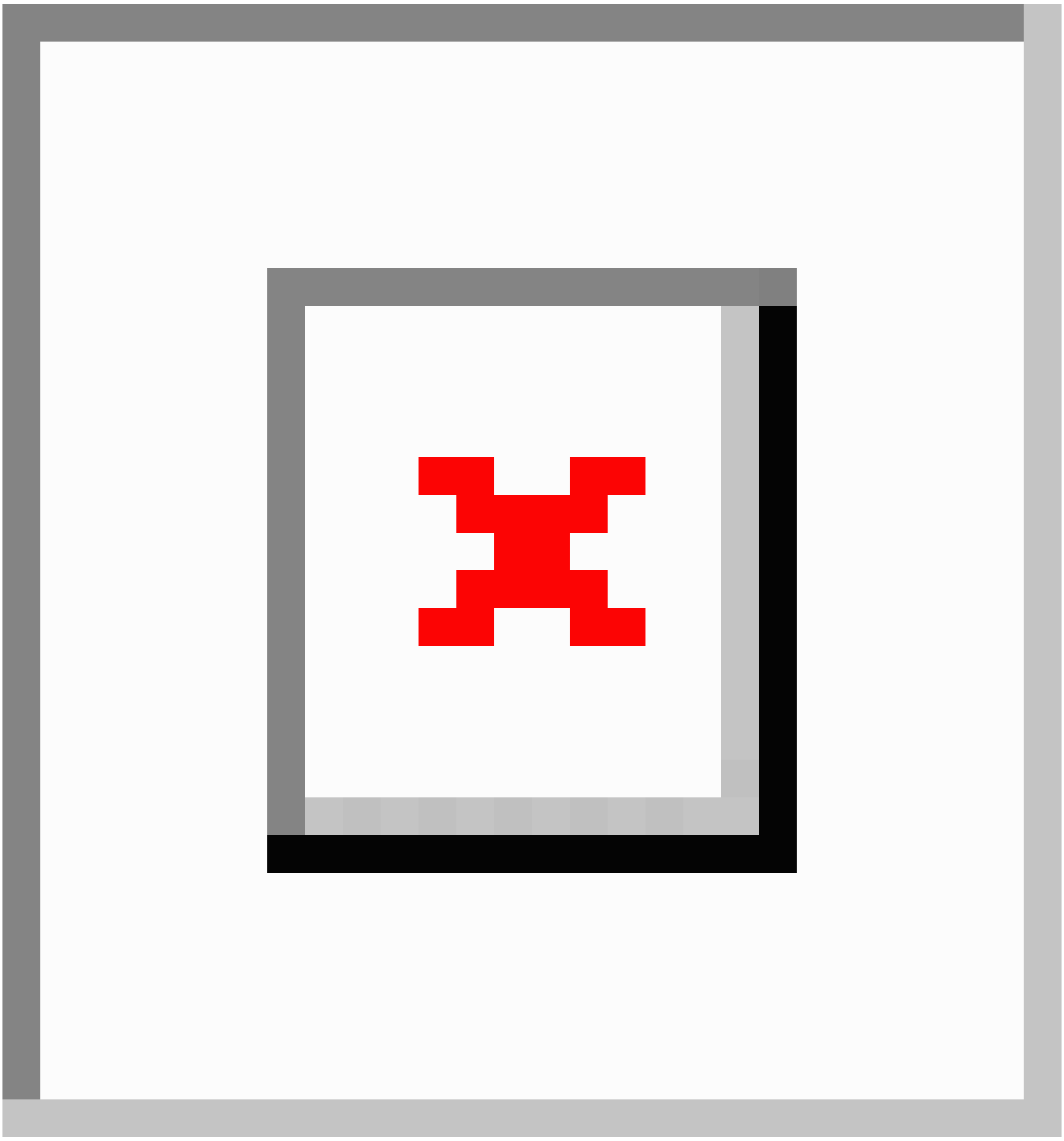
Survey Design

Using a descriptive, observational approach, we developed a survey using Qualtrics, a web-based platform. The survey was based on a review of the literature on Parkinson speech and voice difficulties and digital technology use [26,29,30]. It was pilot tested with six academic staff members at two UK universities. Following amendment, it was further piloted with 44 patient and public involvement (PPI) volunteers, accessed through Parkinson's UK. Volunteers were sent a link for the survey that they completed on the web, and they were asked to provide feedback on the survey with any suggestions for improvement. The PPI feedback resulted in amendments to the flow of the survey, removal and addition of questions, improving clarity, and improving format.

The final version of the survey consisted of 31 questions in four sections (Multimedia Appendix 1).

1. Six questions on demographics and PD features to elicit the profile of respondents.
2. Voice Handicap Index (VHI): we wanted to collect information on participants' voice symptoms and their impact on their lives. As such, we used a validated instrument, the VHI [29]. The VHI is a voice outcome measure that has been used widely in voice research with various clinical and healthy populations and specifically with people with PD. It is validated with good psychometric properties. It assesses the physical, functional, and emotional impact of voice difficulties.
3. Digital skills and awareness: digital skills were assessed through an adaptation of the Tech Partnership's Basic Digital Skills framework [30]. Reuse permission was also granted. This framework consists of asking respondents which of the 11 digital tasks they would be able to complete if they were asked. These digital skills cover areas including managing information, communicating, transforming, problem solving, and creating. For example, a Managing Information digital skill is Find a website I have visited before. This instrument collected details on digital ability.
4. Smart device usage: there were 3 questions about smart device usage, providing further details about digital access and familiarity. To find out about VAT specifically, there were 20 questions about usage, ownership, support for PD features, problems with usage, VAT impact on speech, and security concerns. Responses were in both free text and checkbox format. The survey used display logic to direct participants to relevant questions; therefore, different numbers of participants answered some questions (Figure 1).

Figure 1. Survey flow diagram. Starting at top left, the diagram shows elements of the survey with skip logic to avoid unnecessary questions such as Voice Handicap Index, which applies to respondents who notice a change (Q7). Numbers of respondents to each element are given. The final element elicits security concerns (bottom left).



Study Population and Recruitment

Following peer review, the study was approved by the Institute of Nursing and Health Research Ethics Committee at Ulster University. Participants were presented with details about the study on the welcome page. Participants were made aware that all data were anonymous and would be used in the research. Informed consent was obtained by providing participants with information about the study, its purpose, length of time to complete, data storage, and anonymity. Consent was indicated through the submission of responses. Parkinson's UK disseminated the survey by emailing it to their research support network from March 15 to April 30, 2019. We included people with Parkinson disease of any age and at any stage of the disease. The sample size was based on the number required to obtain 90% confidence and ±5% margin of error in estimating proportions: exact calculation, N=289.

Analysis

The study used a mixed methods approach. Quantitative data were analyzed using the statistical package IBM-SPSS (version 26) [31]. Descriptive statistics, such as frequency, standard deviation, and mean, were used. Summative content analysis was used for qualitative free-text responses [32]. Responses from each free-text question were collated into a spreadsheet and separately analyzed by 2 researchers to identify themes.

Any disagreements were resolved through discussion until a decision had been made on the final set of themes. Frequency counts were then provided, with the number of responses relating to each theme available for the analysis.

Results

Demographics and Digital Skills

The survey received responses from 320 respondents. Partially completed survey responses, which did not include completion of the final mandatory question, were excluded. This resulted in the exclusion of 30 respondents, providing a total of 290 fully completed surveys for analysis.

Of 290 respondents, 116 (40.0%) were female and 174 (60.0%) were male; the most represented age group was 65-74 years (121/290, 41.7%), followed by 55-64 years (96/290, 33.1%). Most respondents (237/290, 81.7%) were based in England, with 25 (8.6%) based in Scotland, 17 (5.9%) in Wales, and 11 (3.8%) in Northern Ireland. Respondents were asked to specify how many years it had been since their diagnosis. A total of 97.9% (284/290) of respondents had been diagnosed with PD for at least 1 year. The mean years since diagnosis was 6.35 (SD 5.55).

Respondents were asked to select which PD symptoms they experienced. Slow movement was the most commonly experienced symptom (227/290, 78.3%), followed by writing changes (223/290, 76.9%). Of particular relevance to this study was speech changes, which was the third most commonly reported symptom at 66.9% (194/290). In addition, 79.0% (229/290) of respondents indicated that they or others had noticed changes in their speech or voice because of their PD, and this group of 229 then were asked to complete the VHI. The VHI consists of 3 parts; each part provides 10 statements regarding speech difficulties and their impact on physical, functional, and emotional domains. Respondents were asked to respond to each statement with a score between 0 (never) and 4 (always), indicating how often they experienced each difficulty. Example statements are “My voice makes it difficult for people to hear me” and “My voice problem upsets me.” Higher scores indicate more severe vocal difficulties. Each section has a minimum possible score of 0 and a maximum possible score of 40. The minimum possible score for the entire VHI was 0, and the maximum possible score was 120. Table 1 provides an overview of the mean scores for each VHI section and for the overall VHI.

Table 1. Voice Handicap Index scores by domain.

Section	Score[a]
Function	
Mean (SD)	16.06 (7.67)
Range	37-0
Physical	
Mean (SD)	16.09 (6.78)
Range	34-0
Emotion	
Mean (SD)	14.04 (8.70)
Range	38-0
Total	
Mean (SD)	46.19 (21.08)
Range	108-1

[a]Voice Handicap Index scores: a higher score indicates more severe voice problems.

The scores for each statement were analyzed. In the Function section, the top-rated items were “People have difficulty understanding me in a noisy room” (mean 2.31, SD 0.94), “My voice makes it difficult for people to hear me” (mean 2.07, SD 0.78), and “People ask me to repeat myself when speaking face-to-face” (mean 2.00, SD 0.86). Of the 229 respondents, 3 scored 0 in this section. In the Physical section, the top-rated items were “The clarity of my voice is unpredictable” (mean 2.19, SD 0.91) and “The sound of my voice varies throughout the day” (mean 2.13, SD 0.89). In this section, 4 people scored 0, and they were not the same as the 3 respondents who scored 0 in the Function section. In the Emotions section, the top-rated item was “My voice problem upsets me” (mean 1.80, SD 1.18). In this section, 8 people scored 0; 2 of them scored 0 in part 2, and 1 scored 0 in part 1.

The Digital Skills questionnaire consisted of 11 items (eg, “use a search engine to look for information online”). Participants were asked to select a yes if they could complete the skill or no if they could not. Of the 290 participants who completed the questionnaire, 208 (71.7%) were able to complete at least 9 of 11 skills. The highest rated skill was “Use a search engine to look for information online”, as 97.6% (283/290) of respondents were able to complete it, closely followed by “Find a website you have visited before” (280/290, 96.6%) and “Send a personal message to another person via email or online messaging service” (275/290, 94.8%). “Create something new from existing online images, music or video" had the lowest number of participants indicating they would be able to complete it (132/290, 45.5%).

In summary, as many as 79.0% (229/290) of respondents indicated that they or others had noticed changes in their speech or voice because of PD. The respondents rated themselves as digitally competent, with 71.7% (208/290) being able to complete at least 9 of 11 digital skills.

Smart Device Usage

Respondents (n=290) reported how familiar they were using technology, such as smartphones, computers, tablets, and laptops. More than half (163/290, 56.2%) of the respondents indicated that they were very familiar, 38.6% (112/290) indicated that they were somewhat familiar, and only 5.2% (15/290) indicated that they were unfamiliar with the use of these devices. Respondents (n=290) were asked how often they use technologies such as smartphones, computers, tablets, and laptops. The vast majority (272/290, 93.8%) of respondents indicated daily usage, 1.4% (4/290) indicated weekly usage, 1.7% (5/290) monthly, and 3.1% (9/290) indicated that they never used these devices. A total of 91.7% (266/290) respondents indicated that they own a touchscreen device, such as a smartphone or tablet.

The respondents were asked about the ownership of VAT. A total of 29.3% (85/290) participants said that they did not own a VAT and were directed to the last 2 questions of the survey, as the rest of the survey was concerned with ownership. The remaining 70.7% (205/290) participants responded to questions about how long they owned their device and how they had gained one. The respondents owned their VAT for a mean of 23 months (range 0-84 months, SD 18.5), with 70.2% (144/205) owning it for 24 months or less.

Of those who own VAT (n=205), 49.3% (101/205) bought it for themselves and 17.1% (35/205) received it as a gift and 2.9% (6/205) were recommended VAT by a health care professional. Other sources (63/205, 30.7%) included preinstallation on a smart device (47/63, 74.6%), provided for work or study access (8/63, 12.5%), and other general comments (8/63, 12.5%).

Respondents who owned VAT (n=205) were asked what they had used the technology to do. For this question, participants could select more than one response. The most popular responses were to request information (n=131, 64.0%), to play music (n=92, 44.9%), and to set a reminder (n=67, 32.7%). The *other* category was selected by 30.2% (n=62), and free-text responses included dictating messages and text (n=36/62, 58.1%), creating a shopping list (4/62, 6.5%), setting a timer (3/62, 4.8%), controlling the home environment (3/62, 4.8%), answering questions (3/62, 4.8%), and miscellaneous (13/62, 21.0%). Of those who owned a VAT, 19.0% (39/205) had not used it, and they were directed to the last two questions in the survey, as the remaining questions were about use. Therefore, 166 respondents answered the next set of questions.

VAT for PD Support

A total of 166 respondents were asked if they had used VAT to help with their PD. A total of 31.3% (52/166) reported that voice assistants helped them with aspects of their PD. Most responses focused on using speech-to-text functions (33/52, 63.5%) to cope with symptoms such as *tremor, which makes typing difficult*. There were specific mentions about how VAT had helped respondents to practice their speech (7/52, 13.5%), for example, "Voice meter to practice voice levels*"* and "Low Volume speech. I have to concentrate to say 'Alexa' loud enough." Other respondents used the technology to set medication reminders (4/52, 7.7%) to access entertainment, such as listening to music (3/52, 5.8%), and to communicate with other people through calls (4/52, 7.7%).

When queried about the type of VAT the 166 respondents used, 45.8% (n=76) used only mobile VAT, 30.1% (n=50) used only a standalone device, and 24.1% (n=40) used both.

How Well Do Voice Assistants Work?

Table 2 provides an overview of how well voice assistants function for participants. Participants were asked how well the VAT works in general and specifically how well they feel the VAT understands their voice.

Participants were asked to explain their answers, with 86.7% (144/166) participants providing further explanation via a free-text box. A total of 36.1% (52/144) respondents of participants agreed that the device misinterpreted what they had asked, which could cause frustration; for example, "I find that it often misinterprets what I say so I spend a lot of time correcting it which is very frustrating." More common problems related to PD and specifically with speech were also mentioned (19/144, 13.2%), such as "Sometimes Amazon Alexa does not hear me—because of my Speech problem with Parkinson's"; "Due to stumbling over words, or stuttering, or low gravelly voice misunderstands me"; "Sometimes my voice is too quiet for Apple Siri." Several participants noted that intonation or accent (9/144, 6.3%) affected this technology; for example, "I have a Scottish accent and so some voice technology does not understand my accent." Other responses were related to the fact that participants did not use the technology frequently (13/144, 9%), that they were in an early *training phase* of using the technology (7/144, 4.9%), or that there were general technical issues (6/144, 4.2%).

Of the 166 respondents, 12.0% (20) who had used VAT reported other specific issues while using VAT. Misinterpretation of what participants had said was one of the main issues reported (6/20, 30.0%). For example, *misunderstood words and proper nouns*. Grammar was also cited as a problem for 15% (3/20) of participants, for example, "Always inserts capital letter. Correcting it is not easy." In addition, there were (6/20, 30.0%) responses that specifically discussed technical restrictions of the technology itself and how this could cause issues. Some of the participants (3/20, 15.0%), however, highlighted that some positive speaking behaviors might arise through issues with the technology, for example, *have to speak slowly and clearly*; *having to talk louder*; and *making my voice clear*. Another (1/20, 5.0%) reported concerns over the privacy of their personal information.

Table 2. How well voice-assisted technology works for participants and how well it elicits meaning in their speech (N=166).

How well VAT[a] works	Values, n (%)
How well does the VAT work for you?	
It always works for me	20 (12.0)
It works most of the time	72 (43.4)
It works about half of the time	17 (10.2)
It works some of the time	52 (31.3)
It never works for me	5 (3.0)
How well do you feel the VAT understands your voice?	
I never have to repeat myself	7 (4.2)
I rarely have to repeat myself	23 (13.9)
I sometimes have to repeat myself, but it works most of the time	61 (36.7)
OK, but I often have to repeat myself	44 (26.5)
I usually have to repeat myself	16 (9.6)
I always have to repeat myself	15 (9.0)

[a]VAT: voice-assisted technology.

Speech Changes as a Result of VAT

Respondents with PD were asked about changes in their speech as a result of using VAT. Table 3 provides an overview of responses from 166 who use VAT and from people with Parkinson disease who recorded speech changes as a symptom they experience. The most common response was “I have not noticed any change in my speech” (87/166, 52.4% overall; 71/166, 42.6% of people with Parkinson disease with speech changes), and the least common response was “Confidence in my speech has decreased” (11/166, 6.6% overall; 15/166, 9.3% of people with Parkinson disease with speech changes). As many as 25.3% (42/166) of participants who had identified speech changes reported that VAT asks them to repeat less.

Table 3. Changes to speech as a result of using voice-assisted technology by the overall population and by respondents who experience speech changes as a symptom of Parkinson disease.

Changes to your speech as a result of using your voice-assisted technology (percent that agree or strongly agree)	Overall (N=166), n (%)	With symptom: speech changes (n=108), n (%)
I have not noticed any change in my speech	87 (52.4)	46 (42.6)
The voice assistant asks me to repeat myself less than when I first started using the technology	39 (23.5)	27 (25.0)
I feel my voice is clearer	24 (14.5)	16 (14.8)
I feel my voice is louder	20 (12.0)	14 (13.0)
Confidence in my speech has increased	18 (10.8)	15 (13.9)
Other people ask me to repeat myself less than when I first started using the technology	14 (8.4)	11 (10.2)
Confidence in my speech has decreased	11 (6.6)	10 (9.3)

Privacy and Confidentiality Issues

All 290 participants responded to questions relating to privacy and confidentiality issues associated with the use of VAT. A minority of respondents (27/290, 9.3%) were very concerned, 34.5% (100/290) were slightly concerned, and 56.2% (163/290) were not concerned at all. Respondents who did have privacy and confidentiality concerns were invited to provide further information about these concerns, with 30.0% (87/290) responding in free text. Of these, the biggest concern from participants was related to the possibility that they could be *hacked* (23/87, 26%), such as “being spied on and hackers”. The second most discussed concern was related to the storage and misuse of personal data (20/87, 23%), for example, “the surveillance potential in these devices is alarming. Information could be used to my detriment—health insurance, for example.” Another theme that was widely commented on was the fact that devices were *always listening* and how this might be used for surveillance purposes (13/87, 15%): “If the voice control technology is permanently active then you have a ‘Big Brother’ situation.” Finally, there were general comments regarding privacy (9/87, 10%), for example, “TV documentaries have shown that Amazon can collect information on users of Amazon Alexa, so they have no privacy"; security (8/87, 9%); and confidentiality concerns (4/87, 5%).

In summary, 71% (205/290) of participants owned VAT, and 166 of them used their VAT device; of these 290 participants, 52 (31%) reported using VAT to help with their PD. Of the 166 participants, 54.8% (91) never or only sometimes had to repeat themselves when using VAT. When asked about speech changes since using VAT, as many as 25.0% (27/108) noticed that VAT asked them to repeat less when compared with when they started using it, and 14.8% (16/108) noticed that their speech was clearer. Of the 290 respondents, 90.7% (n=263) were not concerned or only slightly concerned about privacy and confidentiality.

Discussion

Principal Findings

The purpose of this study was to understand the attitudes and experiences of people with Parkinson disease toward VAT and to investigate their digital capabilities. Specifically, we were interested in any reported changes to speech and language through the use of VAT. We found that most respondents reported changes in their speech or voice because of PD, with almost 80% indicating this symptom. Interestingly, a large proportion (71%) of participants owned VAT, with almost one-third using VAT to help with PD symptoms. Of particular interest is that one-fourth of participants using VAT reported that it asks them to repeat less since they started using it.

The participants in this study could be considered representative of people with Parkinson disease, in agreement with other studies, by the proportion experiencing speech changes and the nature of their symptoms [11]. On average, they reported a moderate voice impairment as measured by the VHI [29], emphasizing the impact on the quality of life and supporting the need to explore solutions. The top-rated items in the VHI indicate issues with volume, clarity, and predictability of voice, all of which may be a challenge when communicating with VAT; however, recent studies have found that participants report putting in extra effort to optimize their speech when interacting with the device [24,26]. Future research is needed to fully explore the impact of VAT usage on speech in PD.

This survey explored digital skills and capabilities and found that most respondents were capable of completing most of the basic digital skills. The task that the least respondents indicated they could complete was creating something new from existing web-based images, music, or video. Nevertheless, a task of this nature is beyond the complexity of the VAT interaction. Overall, this level of basic digital skills, technology familiarity, usage, and ownership indicate a community in which the majority are actively embracing technology. Similarly, high rates of ownership and adoption of technology with older adults were found in a recent study [33]. This is a welcome result for technology developers, as this ultimately reduces the barriers to uptake of novel solutions for the Parkinson community, which our findings have indicated as digitally capable.

The results of this survey provide a positive outlook toward the knowledge and experience of existing VAT, with a high level of ownership and usage, showing a readiness to engage with new technology. Similar findings were found in a study exploring the IoT for support in people with Parkinson disease [26]. The accessibility features of voice activation for individuals who may be experiencing manual dexterity difficulties could contribute to this positive attitude among people with Parkinson disease [26]. However, we need to be cautious in our interpretation, as this self-selecting group may have responded because of their familiarity with VAT.

Respondents were asked how they obtained their VAT. A small proportion (2.9%) of respondents indicated that they were recommended by a health care professional, suggesting that an increased evidence base with regard to the potential benefits of VAT for people with Parkinson disease, combined with closer communication with health care professionals, may be required. Future research should consider the current knowledge and experience of speech and language therapists using VAT.

Almost one-third of our participants used VAT to help with their PD symptoms. A small number of studies reported that VAT helped them to successfully practice their speech by concentrating on increasing their volume or clarity as to be understood by the device, which is similar to findings from other recent papers [24-26]. It is important to recognize that there may be a misconception that VAT is not an option for people with Parkinson disease who experience speech changes, yet VAT offers some participants the encouragement to speak slower and louder. Perhaps, the opportunity for unlimited attempts, with clear indicators of success and the absence of frustration from a communication partner, makes this technology an attractive option. Such preliminary positive findings indicate the need for further research into how VAT can work for people with speech difficulties, as well as support and perhaps improve speech difficulties in people with Parkinson disease.

Participants using VAT were asked about speech changes as a result of using this technology. One-fourth of the respondents experiencing speech changes noted that the VAT asked them to repeat themselves less than when they began using the technology. This suggests that out-of-the-box VAT use may actually improve speech. Although we need to be cautious in this interpretation, it is possible that there are other reasons for being asked to repeat less: increased familiarity with the technology, increased awareness of the most reliable voice commands, and the VAT can improve voice recognition rather than speech improvement. This finding warrants further research.

One note of caution is that a few respondents with speech changes indicated a decrease in confidence in their speech since using VAT. It is not certain that this decline in confidence is a direct result of VAT rather than a progression of PD. However, this result highlights the possibility that repeated unsuccessful engagement with VAT may be detrimental to confidence and that use by people with Parkinson disease should be monitored, particularly in the early stages of use. Coyne et al [24] found that users were frustrated when VAT did not understand their voice because of speech impairments. Future work should ensure that speech recognition can be as accurate as possible for individual speakers with speech impairments to ensure that their confidence is strengthened and not eroded.

Nevertheless, a notable portion of respondents with speech changes indicated that they felt their voice was clearer (16/108, 14.8%) and louder (14/108, 13.0%), that their confidence in speech had increased (15/108, 13.9%), and that other people ask them to repeat themselves less than when they started using the technology (11/108, 10.2%). Although these changes were noticed by a minority of respondents, they do provide some promise that VAT may provide therapeutic benefit to people with Parkinson disease. It is interesting to consider the possibility that speech improvements reported by participants were experienced beyond the voice interaction with VAT. It is widely recognized that there are problems for people with Parkinson disease with maintenance and generalization of speech improvements from therapy tasks into everyday contexts [34]. The potential for VAT to improve social participation warrants further investigation.

Privacy and confidentiality concerns with VAT are a current topic of significant discussion within the media and academia [35]. The results from our survey indicate that the majority of respondents were not seriously concerned about privacy and confidentiality. However, more than one-third of respondents did have slight concerns, and 9.3% were very concerned. Specific concerns were around the potential for hacking, misuse of personal data, and surveillance potential. This prevalence of concern is similar to that found in another study, in which 7% of participants reported privacy concerns as a reason for not using such devices and concluded that these concerns influence the likelihood of using the device and trust in commercial companies [36]. Interestingly, research has found that individuals might be more likely to share data for the benefit of their care and others [26,37]. To maximize the uptake of these technologies and benefit from the immense potential offered to patients' health, further efforts must be made to reassure, promote clear privacy-friendly default settings in companies, and educate potential users about privacy and confidentiality concerns.

Limitations

The survey was advertised and distributed electronically. Therefore, it is logical to assume that respondents primarily consisted of self-selecting people with Parkinson disease who are already actively engaging with technology. Nevertheless, this method of distribution facilitated the collection of a higher number of responses than would have otherwise been possible. Another potential limitation of this study is that it is possible that people with Parkinson disease who are familiar with VAT may have been more likely to engage with the survey than those who have no experience with VAT. This is a limitation of any survey that focuses on a particular subject.

Conclusions

Many people with Parkinson disease recognize that they are experiencing voice and speech changes because of their condition. This group of participants reported some promising effects on their speech symptoms when using VAT; however, this needs further investigation. This is the first study to systematically explore the experiences of using VAT by people with speech difficulties. The next step will be to investigate speech and language therapists' current professional use of VAT and to consider their professional opinion of VAT as a potentially useful support for speech improvement. More research is needed to trial out-of-the-box VAT for speech and communication difficulties in people with Parkinson disease and explores the potential generalization effects that might occur in other nontechnology-mediated speaking contexts.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Full survey.
[PDF File (Adobe PDF File), 180 KB - rehab_v8i1e23006_app1.pdf]

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Abbreviations

IoT: internet of things
LSVT: Lee Silverman voice treatment
PD: Parkinson disease
PPI: patient and public involvement
SLT: speech and language therapy
TV: television
VAT: voice-assisted technology
VHI: Voice Handicap Index

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Original Paper

Adherence Patterns and Dose Response of Physiotherapy for Rotator Cuff Pathology: Longitudinal Cohort Study

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Abstract

Background: Physiotherapy is considered to be essential for the successful operative and nonoperative management of rotator cuff pathology; however, the extent to which patients adhere to assigned physiotherapy activities and how this impacts recovery is unknown.

Objective: The purpose of this study was to measure the rate and patterns of participation in physiotherapy for rotator cuff disorders, assess the dose response between physiotherapy activity and recovery, and explore patient factors predictive of physiotherapy participation.

Methods: We report a prospective longitudinal study of 42 patients undergoing physiotherapy for symptomatic rotator cuff pathology. The patients were issued a smartwatch that recorded inertial sensor data while they performed physiotherapy exercises both in the clinic and in the home setting. A machine learning approach was used to assess total physiotherapy participation from smartwatch inertial data. Primary outcomes were the Disabilities of the Arm Shoulder and Hand and numeric pain rating scale assessed every 4 weeks until 12 weeks follow-up. The relationships between participation, outcomes, and clinical patient variables were assessed in univariable analyses.

Results: Mean physiotherapy exercise participation in clinic and at home were 11 minutes per week and 33 minutes per week, respectively, with patients participating in physiotherapy on 41% of days assigned to treatment. Home physiotherapy participation decreased significantly over time (*P*=.03). There was a statistically significant and clinically meaningful relationship between cumulative physiotherapy participation and recovery demonstrated by pain scores at 8 weeks (*P*=.02) and 12 weeks (*P*=.05) and disability scores at 8 weeks (*P*=.04) and 12 weeks (*P*=.04). Low patient expectations and self-efficacy were associated with low rates of physiotherapy participation.

Conclusions: There was a low rate of participation in home shoulder physiotherapy exercise, and a statistically and clinically significant dose response of physiotherapy on treatment outcome in patients with rotator cuff pathology. The findings highlight the opportunity to develop novel methods and strategies to improve the participation in and efficacy of physiotherapy exercises for rotator cuff disorders.

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KEYWORDS

rehabilitation; treatment adherence and compliance; wearable electronic devices; machine learning; rotator cuff

Introduction

Rotator cuff pathology is a common cause of shoulder pain and disability [1,2] and is associated with significant utilization of health care resources [3] and societal economic costs [1]. Exercise-based physical therapy is an established first-line treatment for this condition [4-6] and is also an important element of rehabilitation following rotator cuff surgery [7,8]. Adherence to prescribed physical therapy exercise is considered to be essential for successful rehabilitation of both conservatively and operatively managed patients [9,10]. However, self-reported adherence to physical therapy is often poor (50%-70%) [9,11], particularly in the home setting [9,12,13] and in worker populations [10].

The concept of adherence, in the context of physiotherapy and rehabilitation, is multidimensional [14]. It includes behaviors such as attending clinical appointments, active participation in physiotherapist-supervised activities and home exercises, avoiding potentially harmful or contraindicated activities, and wearing protective or therapeutic devices. Adherence to the home component of physiotherapy exercise programs is important, as this activity calls for the greatest level of independent patient engagement in the rehabilitation process and typically represents most of the opportunity for physiotherapy exercise.

Objective measurement of adherence to home physiotherapy exercises remains an open problem [15]. Adherence diaries, in which patients self-report their independent exercises, are the recommended and most widely used measure of adherence to home exercise [15]. However, adherence diaries have significant limitations: The validity and reliability of the adherence diaries have not been established, they cannot measure or assess adherence to technique, and poor patient acceptability results in low rates of diary completion (60%-75%) [4,16,17].

The capacity to accurately and objectively measure home physiotherapy adherence would further our understanding of the rate and patterns of home physiotherapy adherence, the impact of adherence on recovery, patient motivations, and barriers to effective home physiotherapy engagement [12]. This understanding is a crucial first step to developing strategies to optimize home physiotherapy adherence.

Several technologies (chiefly wearable or video devices) have been developed and pilot tested for providing objective and complete assessments of adherence to home physiotherapy [13,18-26]. However, we are not aware of any that have been validated in a clinical population or used to obtain the necessary clinical insights. The common premise underlying a technical solution to adherence monitoring is using sensors to record patient home physiotherapy and having a computer algorithm classify activity type (and potentially evaluate technique).

Advances in the capabilities of wearable devices such as smartwatches and time-series machine learning methods present an opportunity to leverage robust and accessible technology for remote physiotherapy tracking. In our prior preclinical work [18], we demonstrated that shoulder physiotherapy exercise performed by healthy study participants can be accurately tracked using a smartwatch.

This paper presents the results of a study with the following objectives: (1) measure the rate and patterns of total (home and clinic) participation in rotator cuff physiotherapy, (2) assess the dose response between physiotherapy activity and recovery, and (3) explore patient factors predictive of physiotherapy participation.

Methods

Population

We performed a prospective longitudinal study of 42 patients with rotator cuff pathology. The inclusion criteria were (1) age ≥18 years, (2) diagnosis of unilateral rotator cuff tendinosis, shoulder impingement syndrome, or degenerative or traumatic rotator cuff tear, (3) planned conservative or operative management, (4) capacity to participate in home shoulder physiotherapy. The exclusion criteria were (1) upper extremity neurologic deficit, (2) bilateral symptomatic rotator cuff pathology, (3) failed surgical management of rotator cuff pathology.

The presence of rotator cuff pathology was determined clinically and confirmed with diagnostic imaging (magnetic resonance imaging or ultrasound).

Registrations

Sunnybrook Health Sciences Centre institutional research ethics board approval was obtained for this study, and a protocol paper was published [27]. This manuscript represents a preliminary analysis of 42 patients out of 120 patients planned according to the protocol [27].

Physiotherapy Treatment

Patients received 1-hour in-person shoulder physiotherapy sessions on a weekly basis and were assigned home exercises from a 19-exercise rotator cuff protocol by their treating physiotherapists (Multimedia Appendix 1). They were asked to complete their assigned exercises each day that they were not attending in-person physiotherapy. In addition to physiotherapy exercise, patients received other adjunct treatments at the discretion of their physiotherapist (heat, manual therapy, ultrasound, and electrotherapy). All physiotherapy services were funded either by the study or through worker's compensation claims.

Inertial Data Collection

Patients were provided with a Huawei 2 smartwatch (Huawei Technologies Co Ltd) to be worn on their affected extremity when performing prescribed shoulder physiotherapy exercise both at home and in the physiotherapy clinic. Inertial data (triaxial accelerometer, triaxial gyroscope, and triaxial magnetometer) data were recorded on the smartwatch at sampling rate of 50 Hz while being worn, then uploaded to a cloud storage server using a custom app. Inertial data were labeled during supervised physiotherapy for exercise type and number of repetitions.

Primary Outcomes

A numeric pain rating scale (NPRS) [28,29] and the Disabilities of the Arm, Shoulder and Hand (DASH) score [30-32] were collected to measure the relationship between total (home and in-clinic) physiotherapy participation and patient recovery. These validated clinical outcome measures were assessed at baseline, 4 weeks, 8 weeks, and 12 weeks.

The NPRS pain scores were assessed using a 3-item survey with the following questions: (1) What is your pain at rest? (2) What is your pain with activity? (3) Over the past week, how bad has your pain been on average?

Predictors of Adherence

To explore potential predictors of physiotherapy adherence [12,33-38], the following data were collected for each patient at recruitment: age, sex, BMI, baseline pain level (NPRS), baseline physical activity level (total hours per week of resistance and aerobic exercise), work status (working or not working), education, current income, ENRICHD Social Support Inventory score (perceived social support) [39], 2-item Pain Self-Efficacy Questionnaire (patient self-efficacy) [40], Patient Expectation Questionnaire score [41], and Hospital Anxiety and Depression Scale score [42]. This represents a subset of adherence predictors from those described in our protocol [27] with high response rate (>80%) and sufficient distribution among categorical variables.

Machine Learning Algorithms

A supervised learning framework was used to train and validate a fully convolutional neural network (FCN) classifier [43,44] for detecting and differentiating physiotherapy exercise activity from the inertial data collected on the smartwatches. The raw data were preprocessed with an overlapping sliding window segmentation (10-second windows) to provide fixed-length input to the FCN classifier.

The FCN classifier was trained using labeled inertial data collected during supervised physiotherapy activity. The exercise-type data labels were mapped to simplified label consisting of the principal motion involved in that exercise. This mapping is detailed in Multimedia Appendix 1. The FCN model architecture is detailed in Multimedia Appendix 2.

Temporal data splitting was used to validate algorithm performance, using the last physiotherapy session for each patient in the test set, and all prior physiotherapy sessions for the training set. The training data set was augmented with data collected from 16 healthy volunteers as they performed routine activities of daily living including rest for 3 hours each. The test set was augmented with similar activities of daily living data from 4 healthy volunteers.

The FCN classifier performance was evaluated on the test set for (1) differentiating all physiotherapy activity from activities of daily living, and (2) differentiating between different physiotherapy activities.

Physiotherapy Participation Tracking

Physiotherapy participation was assessed by processing a patient's recorded inertial data using the trained FCN classifier for differentiating physiotherapy activity from activities of daily living. Patients, treating clinicians, and all research personnel were blinded to the physiotherapy participation rate measured by the system.

For the purposes of this study, daily physiotherapy participation was defined as the ratio of physiotherapy exercise measured for a patient to an expectation of 20 minutes per day (up to a daily maximum of 100%).

Patient Experience

The patients were asked questions (Table 1) about their experience with smartwatch-based physiotherapy tracking.

Table 1. Survey questions.

Questions	Response options
How often did you use your smartwatch when you performed home physiotherapy?	Every time, most of the time, some of the time, rarely, never
What challenges did you have that prevented you from using the smartwatch when you performed your home physiotherapy?	None, battery, inconvenient, uncomfortable, other (specify):
How did having a smartwatch affect your participation in your home physiotherapy program?	I exercised a lot less; I exercised a little less; no effect; I exercised a little more; I exercised a lot more

Data Analysis

Univariable Analyses

The relationship between outcomes (dependent variable) and cumulative participation was examined with least squares linear regression analysis after 4 weeks, 8 weeks, and 12 weeks of physiotherapy treatment.

The relationship between cumulative physiotherapy participation at 4 weeks (dependent variable) and individual baseline adherence predictor variables was explored with univariable statistical analyses. Parametric and nonparametric correlation analyses were conducted for continuous and ordinal predictor variables, respectively, and the 2-sample t test was used for binary predictors. Note, education was converted to a binary variable for analysis with a 2-sample t test.

Sample Size

This analysis reports on a cohort of 42 patients whose minimum treatment duration was 4 weeks, of whom, 42, 35, and 27 patients respectively received treatment for a duration of up to 4 weeks, 8 weeks, and 12 weeks, respectively.

We hypothesized the existence of moderate correlations (from 0.40 to 0.59) between improvement in outcomes and participation which requires a minimum of 19 to 45 patients to achieve a power of 0.8 to detect the relationship.

This interim analysis is not sufficiently powered to conduct robust multivariable analyses of adherence predictor variables.

Results

Patient Characteristics

Patient flow through the study is shown in Figure 1, and a summary of patient characteristics is provided in Table 2.

Figure 1. Patient flow through clinical study as of April 28, 2020. Physiotherapy treatment and data collection was suspended for 16 patients enrolled in the study due to physical-distancing measures imposed during the COVID-19 pandemic. PT: physiotherapy.

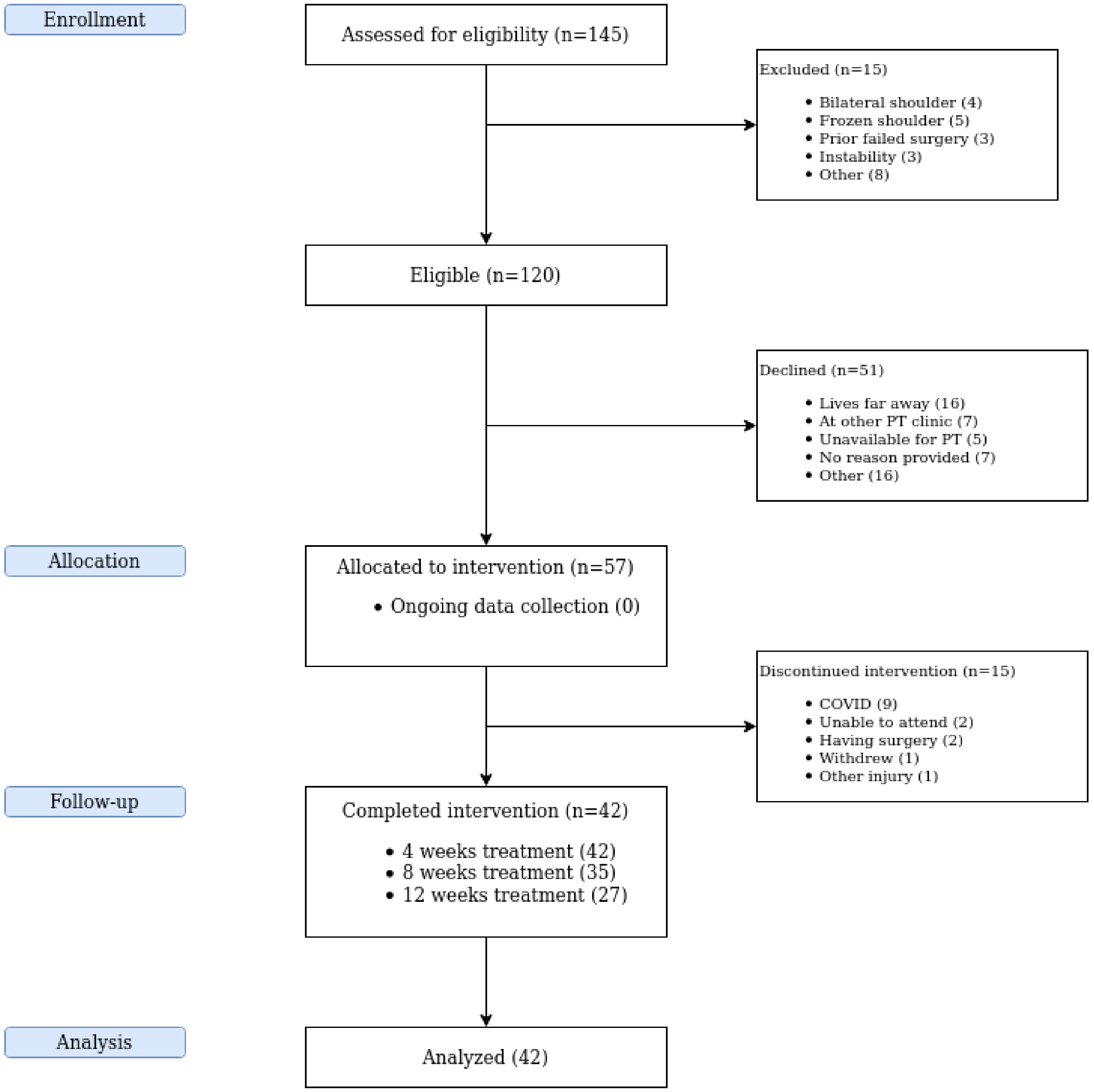


Table 2. Patient characteristics.

Variable	Value (n=42)
Age (years), mean (SD)	45 (13)
Gender, n (%)	
Male	15(36)
Female	27 (64)
BMI (kg/m^2), mean (SD)	26 (4)
Baseline physical activity (hours/week), mean (SD)	3.6 (4.4)
Currently working status, n (%)	
Currently working	19 (45)
Not currently working	23 (55)
Active worker's compensation claim, n (%)	
Yes	9 (21)
No	33 (79)
Rotator cuff tear, n (%)	
Full thickness	13 (31)
Partial thickness	12 (29)
No tear	17 (40)
Smoking, n (%)	
Currently smokes	1 (2)
Previously smoked	6 (14)
Never smoked	35 (83)
Income, median (CAD)	40,000-60,000
Education, n (%)	
Professional or university degree	21 (50)
College or no degree	21 (50)
Diagnostic imaging, n (%)	
Magnetic resonance imaging	23 (55)
Ultrasound	26 (62)
None	2 (5)
Physiotherapy treatment adjuncts, n (%)	
Manual therapy	23 (55)
Heat therapy	18 (43)
Ultrasound	17 (40)
Electrotherapy	3 (7)
Perceived social support (ENRICHD Social Support Inventory), mean (SD)	26 (5)
Pain self-efficacy (Pain Self-Efficacy Questionnaire), mean (SD)	8.0 (3.2)
Patient Expectation Questionnaire, mean (SD)	18 (4)
Anxiety (Hospital Anxiety and Depression Scale), mean (SD)	7.0 (5.5)
Depression (Hospital Anxiety and Depression Scale), mean (SD)	5.5 (3.5)

Inertial Data Collection

Inertial sensor data were collected using a Huawei 2 smartwatch from each study participant during in-clinic supervised physiotherapy and in the home setting. In total, 1275 hours of inertial data were collected. Of this, 290 hours were collected during supervised physiotherapy. Technical issues impacting inertial data collection occurred with an incidence of 4%

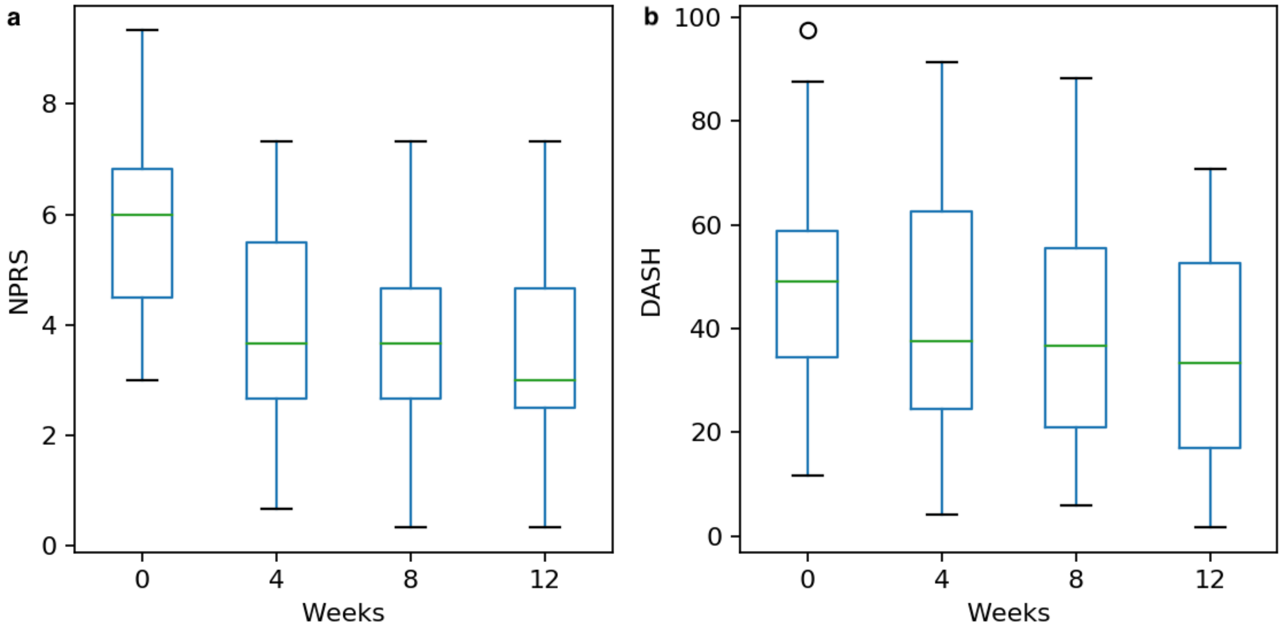
(101/2376 attempted recordings). The majority of these errors occurred due to Wi-Fi connectivity problems with the hospital network.

Primary Outcomes

Pain

The pain outcome was modeled as the mean of the 3 NPRS survey items. There was a reduction in NPRS scores from a mean of 5.2 (SD 1.9) at baseline to a mean of 3.4 (SD 1.7) at 12 weeks (*t*=6.8, *P*<.001), with 93% of patients (39/42) experiencing at least some improvement. Improvement in pain score exceeded the minimal clinically important difference (MCID) for the NPRS (1-2.2) [45-47] in 48% to 78% of patients (Figure 2).

Figure 2. Clinical improvement in (a) pain and (b) disability. NPRS: numeric pain rating scale. DASH: Disability of the Arm, Shoulder, and Hand.



Disability

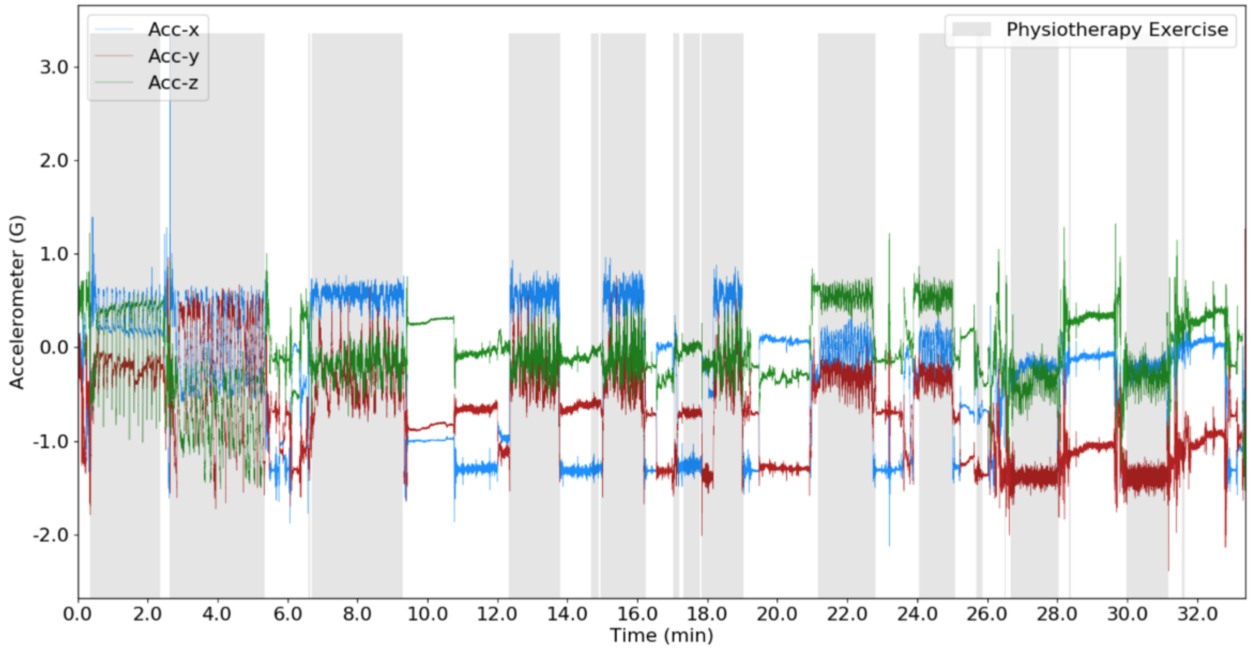
There was a reduction in DASH score from a mean of 44 (SD 21) at baseline to a mean of 35 (SD 20) at 12 weeks (*t*=6.8, *P*<.001), with 81% of patients (34/42) experiencing at least some improvement. Improvement in DASH scores exceeded the MCID (10.83 [48]) in 48% of patients (20/42) (Figure 2).

Machine Learning Validation

For the binary classification task of differentiating physiotherapy activities from rest and activities of daily living, the FCN model achieved high levels of performance (accuracy 0.95; sensitivity 0.94; specificity 0.97; area under the receiver operating characteristic curve 0.99). An example demonstrating the physiotherapy classifier correctly predicting exercise and rest intervals during a physiotherapy session is shown in Figure 3.

For the multiclass problem of differentiating individual physiotherapy exercises types, the FCN classifier achieved an accuracy of 0.90 and an F1 score of 0.82.

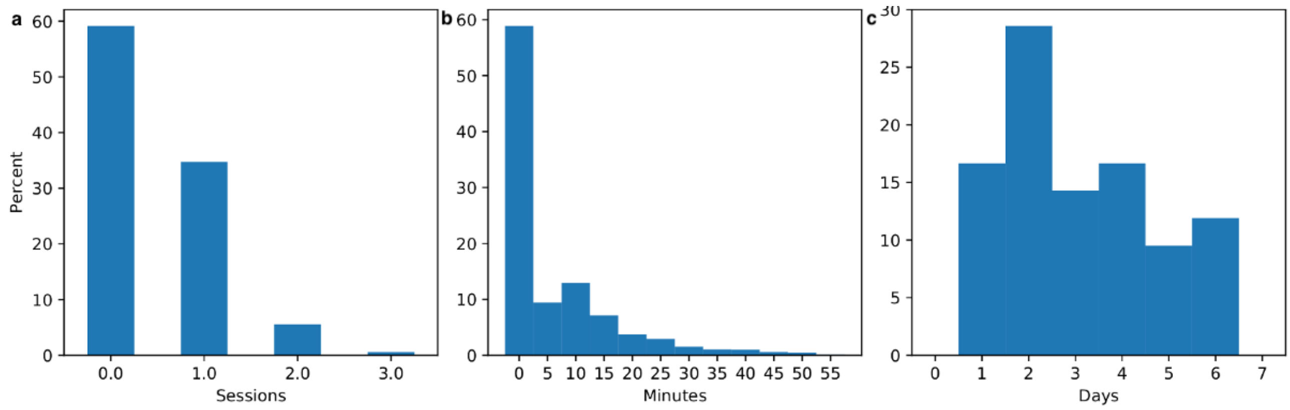
Figure 3. Predicted binary classification of physiotherapy exercise activity and interexercise rest periods overlaid on triaxial accelerometer data. The repetitive oscillatory patterns of exercise are correctly identified by the model.



Physiotherapy Participation

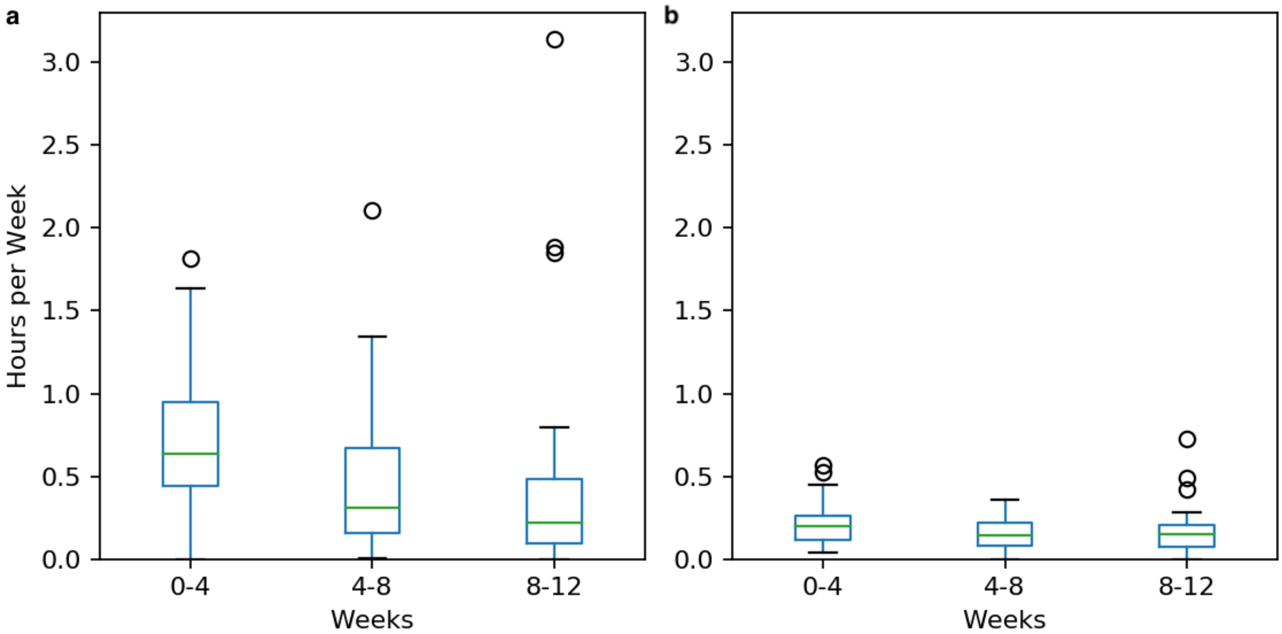
Patients participated in physiotherapy on 41% of the days on which they were assigned treatment (1388/3386 patient-days), usually for a single physiotherapy session with exercises lasting between 5 to 15 minutes. Figure 4 depicts the distribution of total physiotherapy participation rates in terms of sessions per day, minutes per day, and days per week.

Figure 4. Total physiotherapy participation by (a) sessions per day, (b) minutes per day, and (c) days per week.



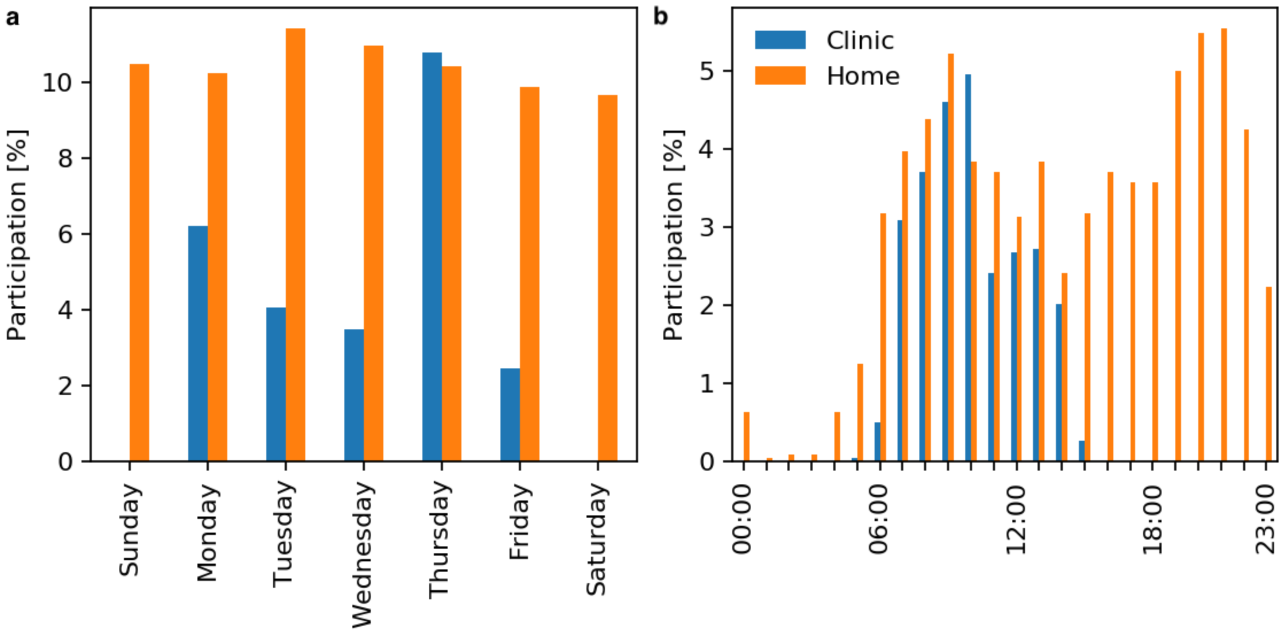
Home physiotherapy participation decreased over time (see Figure 5), from a median 38 minutes per week in the first 4 weeks of treatment to a median of 13 minutes per week in weeks 8 to 12 (t=2.3, P=.03). There was no statistically significant decrease in physiotherapy participation in clinic, which remained at approximately 10 minutes throughout the 12 weeks of therapy (t=1.7, P=.09).

Figure 5. Changes in physiotherapy participation for (a) home and (b) clinic settings.



Daily patterns of physiotherapy participation are shown in Figure 6. Home physiotherapy participation is spread equally across days of the week. There was a bimodal distribution of home physiotherapy participation, peaking in the morning (10 AM) and evening (9 PM). Differences in patterns of home physiotherapy participation based on sex, work status, and age are provided in Multimedia Appendix 3 (Figures S1-S3).

Figure 6. Patterns of physiotherapy participation for (a) days of the week and (b) time of the day (from midnight to midnight the next day).

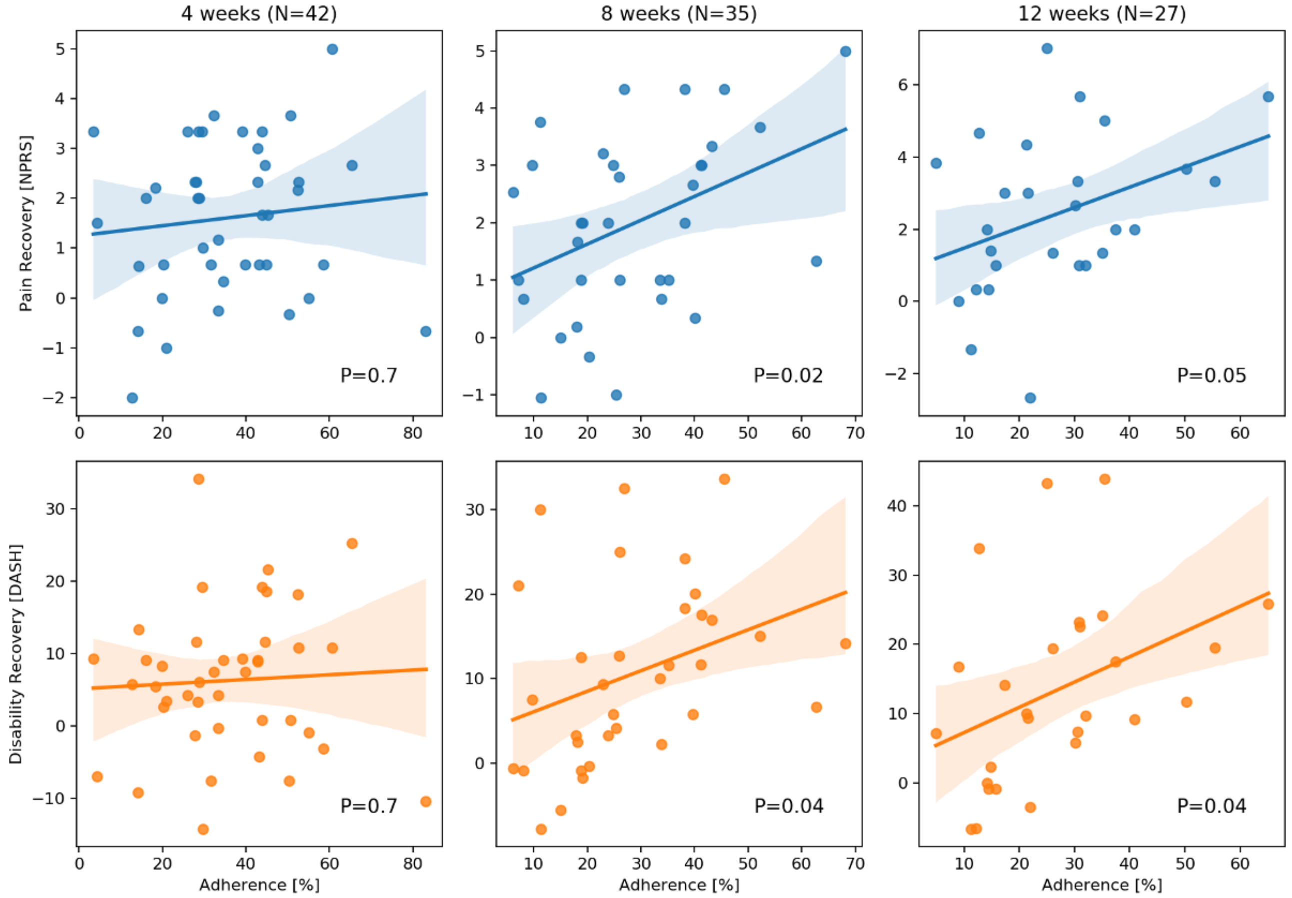


Participation and Recovery

The relationship between total physiotherapy participation and recovery in pain and disability scores is shown in Figure 7.

There was a relationship between participation and improvement in DASH score at 8 weeks (*R*=0.35, *P*=.04) and 12 weeks (*R*=0.39, *P*=.04) but not at 4 weeks (*R*=0.06, *P*=.70). The magnitude of this effect at 12 weeks (slope 0.37) was such that improvement in participation by 29% or more was correlated with clinically important differences in recovery (MCID 10.83 [48]).

Figure 7. Physiotherapy dose response. Participation was defined as the ratio of physiotherapy exercise measured for a patient to an expectation of 20 minutes per day (100%).



There was a relationship between participation and improvement in pain score at 8 weeks (*R*=0.40, *P*=.02) and 12 weeks (*R*=0.37, *P*=.05) but not at 4 weeks (*R*=0.11, *P*=.48). The magnitude of this effect at 12 weeks from the regression slope (0.056), was such that improvement in participation of 18% to 39% or more was correlated with clinically important differences in recovery (MCID 1-2.2 [45-47]).

Predictors of Adherence

Descriptive statistics and univariable analyses for the potential adherence predictors collected for exploratory analysis are detailed in Table 3. The following predictors were found to be positively correlated with physiotherapy participation: patient expectations for recovery (*P*=.007), self-efficacy (*P*=.04), lower anxiety scores (*P*=.03), and greater income (*P*=.03).There was also a nonsignificant trend for greater physiotherapy participation in older patients (*P*=.06).

Table 3. Univariable analysis of patient variables with cumulative physiotherapy participation over 4 weeks of treatment.

Patient variables	Value	*P* value
Continuous, Pearson correlation		
Age (years)	0.33	0.06
BMI (kg/m^2)	0.01	0.95
Baseline pain (numeric pain rating scale)	–0.01	0.94
Baseline physical activity (hours/week)	0.21	0.21
Ordinal, Spearman correlation		
Social support (ENRICHD Social Support Inventory)	0.19	0.24
Pain self-efficacy (Pain Self-Efficacy Questionnaire)	0.32	0.04
Patient Expectation Questionnaire	0.42	0.007
Anxiety (Hospital Anxiety and Depression Scale)	–0.34	0.03
Depression (Hospital Anxiety and Depression Scale)	–0.21	0.19
Income	0.35	0.03
Categorical, adherence mean (SD)		
Sex		0.41
Male	39 (12)	
Female	34 (19)	
Work status		0.62
Working	37 (19)	
Not working	35 (13)	
Worker's compensation		0.51
Active claim	32 (18)	
No claim	36 (16)	
Education		0.44
Professional or university degree	38 (17)	
College or no degree	34 (17)	

Patient Experience With Physiotherapy Tracking

There were 26 respondents to the patient experience survey. Patients reported using the smartwatch during home physiotherapy every time (11/26), most of the time (12/26), or some of the time (3/26). Challenges encountered with the technology were related to battery life (8/26), remembering to use the smartwatch (1/26), and the recording function (1/26). Most patients reported exercising at home as result of wearing the smartwatch in this study either a lot more (5/26) or a little more (14/26). The other respondents reported that smartwatch use did not affect their home physiotherapy participation (7/26).

Discussion

Our study's findings echo previous findings in the literature based on patient self-report, indicating that there is high rate of poor participation in home physiotherapy [9,11]. We also found that there was a significant decline in physiotherapy participation over the course of treatment. The low level of participation that we observed was particularly notable given that many patients (19/26, 73%) indicated they were participating more than they would otherwise without tracking, despite blinding of both patients and health care providers to the tracking results.

The most important finding of this analysis is the dose response observed for cumulative physiotherapy participation at 8 and 12 weeks of treatment. It is generally assumed that if a treatment program is efficacious, adherence to treatment yields improved results. There are existing data to support this notion in the context of physiotherapy. Holmgren et al [49] demonstrated that a specific exercise protocol supervised by physiotherapists was superior to self-directed range of motion exercises performed at home. Østerås et al [50] demonstrated a dose response to rotator cuff rehabilitation, with high-dose (greater frequency and intensity) exercise training producing greater benefits than low-dose training under the direct supervision of a physiotherapist. To our knowledge, our study is the first to directly and objectively measure the dose response to shoulder physiotherapy exercises performed by patients independently at home. We found that there was a correlation between relatively modest increases in home physiotherapy participation and clinically meaningful improvements in pain and disability outcomes.

The common paradigm for physiotherapy treatment delivery is the same as that of this study. Patients are typically trained in the required exercises by their treating physiotherapist and periodically reassessed; however, they are responsible for performing the majority of their exercise-based therapy independently. The physical-distancing measures imposed by the current COVID-19 pandemic have even further restricted patient access to supervised in-person exercise physiotherapy. The major limitation of the current approach to treatment delivery is highlighted by the mounting evidence that the independent exercise required of patients often does not occur and that many patients are thus not receiving the full benefit of this important and effective treatment. Finding a feasible solution to this issue remains an open problem.

To improve independent physiotherapy exercise participation in the home setting first requires an understanding of patient motivations and barriers to adherence. There is a growing body of literature that has carefully considered these issues, using patient self-reported home exercise adherence or clinic attendance as the principal instruments for data collection [12,51-55]. The 2010 systematic review by Jack et al [12] reported low baseline levels of physical activity, low adherence to exercise under supervision, low self-efficacy, depression, anxiety, helplessness, poor social support, greater perceived number of barriers to exercise, and increased pain during exercise as factors related to physiotherapy adherence.

Our study found that patients with greater expectations for recovery and greater self-efficacy had better participation in physiotherapy. While our patients, on average, had reasonable expectations for recovery with their physiotherapy treatment (survey score out of 23: mean 18, SD 4), patients who were not confident in the benefit of the assigned program were less likely to participate in it independently. This insight could motivate better assessment and communication of treatment expectations in our program. The conceptual importance of patient expectations in relation to placebo and nocebo effects is also worth considering, as patients with higher expectancies are likely to have higher treatment outcome scores independent of other factors [56].

Various strategies for improving self-efficacy [57] that may be worthwhile to explore in the context of exercise-based physiotherapy also exist. We also found higher physiotherapy participation in patients with lower anxiety scores and higher personal income. While these 2 factors are not necessarily easily modifiable, this insight may assist clinicians in identifying patients at risk of poor adherence.

There was also a trend (statistically not significant) of greater physiotherapy participation in patients who were older. We found no relationship between physiotherapy participation with sex, BMI, baseline physical activity, baseline pain, perceived social supports, depression, work status, worker's compensation status, or education level. With a sample size of 42, this study does not rule out these variables as potentially important predictors of physiotherapy participation. However, our data suggest that a moderate or weak effect size would be expected for these predictors if they are indeed found to be statistically significant in a larger population sample.

Further work is required to better understand patient motivations, barriers to adherence, and the efficacy of different methods for improving engagement in order to develop a coherent strategy for tackling this problem. We feel that objective and quantitative measurement of participation is important in all these arenas, both as a research tool and as part of a suite of derived strategies to motivate and drive further engagement. The relationship between modifiable predictors and physiotherapy participation shown in this exploratory analysis suggests that interventional strategies designed to target these areas (expectation and self-efficacy) may be promising avenues to pursue to increase participation and recovery.

Our deep learning approach was successfully validated for accurately tracking shoulder physiotherapy participation using inertial data collected on a smartwatch. The smartwatch proved to be an accessible method for data capture, with patients reporting smartwatch use during all or most home physiotherapy sessions and minimal challenges. An advantage of using wearable devices for activity tracking is that they are unobtrusive and easy to use anywhere, unlike some solutions based on video capture. A limitation of wearable devices is that they are only suitable for tracking physiotherapy exercises involving the limb or anatomic region on which the device is worn. This interim analysis has focused on total physiotherapy participation which represents one element in the broader notion of treatment adherence. We intend to also consider assessment of effort and adherence to specific exercise techniques, however, this future work depends on capturing inertial data from a larger sample of patients.

This study has a number of limitations. Our sample size of 42 patients limited our ability to detect weak relationships in the data or perform a meaningful multivariable analysis. The sample size was further reduced in the analysis of the 8- and 12-week data, due to the suspension of the study as COVID-19 pandemic protocols took effect. The COVID-19 pandemic interrupted our ability to provide ongoing in-clinic physiotherapy treatments to a number of our study participants, who therefore received shorter duration treatment than they otherwise would have. However, we felt it important to share the data that we have gathered thus far given its relevance to current COVID-19 physical-distancing restrictions, which impose a greater need for patients to engage in independent physiotherapy exercise. In addition, due to the small sample size, responses to multiple questions in the patient expectations survey that addressed different concepts were summed and analyzed as one single variable. This is based on an assumption of approximation to an interval scale (for all questions), which allows the latent variable of the overall expectation to be represented with a single summed value.

There are limitations with respect to the smartwatch and machine learning approach that we used for digital measurement of physiotherapy participation. The accuracy of our digital measurement depended on the correct use of the technology by patients. Patients were asked to wear their smartwatch during every physiotherapy session and to not wear it otherwise. Instances in which patients either neglected to wear their smartwatch or charge its batteries, as well as errors in the recording app introduced discrepancies between the digital participation measure and actual participation that could bias results. However, the impact of these effects is likely modest since 88% of patients (37/42) indicated that they used their smartwatch during all or most physiotherapy sessions, and we encountered few errors with the technology.

Instances in which patients wore their smartwatch outside of performing physiotherapy activities is another potential source of measurement error. Our FCN machine learning model was validated to accurately discriminate physiotherapy activity from activities of daily living, including resting, working at a computer, walking, jogging, etc. A limitation of our approach is that we could not validate the model to discriminate physiotherapy activities from all possible activities and did not specifically assess model performance against other fitness activities (eg, swimming, yoga, weight training) that might have similar inertial signals to physiotherapy. The discriminative performance of the FCN model would likely be degraded on activities outside of the training set, which could impact results for patients who chose, against instruction, to wear their smartwatch during such activities.

A further limitation the study design is that correlations were found between home physiotherapy participation and recovery support but do not prove a causal relationship. Any patient baseline variables related to both outcome and adherence, as well as uncontrolled treatment differences could bias the results. A multivariate analysis would be required to determine if physiotherapy participation is an independent correlate of clinical outcome, which would lend support to the causal notion. Unfortunately, our small sample size precluded such analysis. Ultimately, a prospective interventional study design would be the best approach to evaluate this question.

A final limitation of our study, and one that could impact future interventional study designs, is that tracking in itself could be considered an intervention with a measurable impact on adherence and recovery. A 3-arm randomized controlled trial with an untracked control, a passive (noninterventional) tracked control, and a tracking-enabled engagement platform would be the most rigorous path forward to study an adherence intervention.

In-home shoulder physiotherapy exercise participation was poor, and this was correlated with inferior pain and disability treatment outcomes for patients with rotator cuff pathology. While participation is correlated with higher expectations for recovery, better self-efficacy, lower anxiety, and higher income, further work is required to better understand the reasons for poor participation and develop methods to optimize home physiotherapy adherence.

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Conflicts of Interest

DB and CW hold equity in Halterix Corporation, a digital physiotherapy company founded by David Burns.

Multimedia Appendix 1
Exercise motion mapping.
[DOCX File , 16 KB - rehab_v8i1e21374_app1.docx]

Multimedia Appendix 2
Machine learning model.
[DOCX File , 56 KB - rehab_v8i1e21374_app2.docx]

Multimedia Appendix 3
Patterns of home physiotherapy participation.
[DOCX File , 900 KB - rehab_v8i1e21374_app3.docx]

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Abbreviations

COVID-19: coronavirus disease 2019
DASH: Disabilities of the Arm, Shoulder and Hand
FCN: fully convolutional neural network
MCID: minimal clinically important difference
NPRS: numeric pain rating scale

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Original Paper

Satisfaction and Acceptability of Telemonitored Home-Based Exercise in Patients With Intermittent Claudication: Pragmatic Observational Pilot Study

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Abstract

Background: Current guidelines recommend supervised exercise training (SET) as a first-line treatment in patients with intermittent claudication (IC). SET has been shown to be more effective than home-based exercise therapy (HBET). However, the lack of available SET programs hampers broad SET implementation in clinical practice.

Objective: The aim of this study is to assess patient satisfaction and acceptability of a structured HBET program using wearable technology and elastic band resistance exercises.

Methods: A total of 20 patients with IC (Rutherford 1-3) with internet access and currently not engaged in structured exercise training were recruited in a pragmatic observational pilot study. Participants were instructed to complete 3 walking sessions and 2 elastic band resistance exercise sessions per week in their home environment during a 4-week period. Patient satisfaction and acceptability were assessed using a 5-point Likert scale questionnaire (1-2=very unsatisfied, 3=neutral, and 4-5=very satisfied) evaluating the materials and intervention content. Secondary outcomes were evaluated at baseline and at completion of the 4-week intervention and included maximal walking distance (MWD) and pain-free walking distance (PFWD), physical fitness, and patient-reported outcomes on quality of life, walking capacity, levels of kinesiophobia, and self-efficacy. Statistically significant changes were tested using paired *t* tests or Wilcoxon signed-rank tests.

Results: All patients (15 men, 5 women; mean age 64.6, SD 10.6 years; range 41-81 years) completed the 4-week intervention and were highly satisfied with the program (mean overall score 4.5, SD 0.5). Patients' questionnaire responses documented willingness to recommend the exercise program to other patients (mean 4.5, SD 0.5; median 4.5) and preference for continuing the intervention (mean 4.3, SD 0.5; median 4). Furthermore, participants endorsed the use of the sports watches to track walking sessions (mean 4.25, SD 0.6; median 4), felt safe (mean 4.4, SD 0.6; median 4), and appreciated personal feedback (mean 4.55, SD 0.5; median 5) and flexibility of training (mean 4.1, SD 0.7; median 4). Resistance training was not preferred over walking training (mean 2.65, SD 0.8; median 3). In addition, PFWD (+89 m; P=.001), MWD (+58 m; P=.03), Walking Impairment Questionnaire distance score (+0.18; P=.01), activity-related scores (+0.54; P<.001), and total quality of life (+0.36; P=.009) improved following the intervention. Other patient-related outcomes, physical fitness, and physical activity remained to be statistically unaltered.

Conclusions: Patients with IC were satisfied and accepted technology to monitor and guide HBET, with observed short-term effectiveness regarding walking capacity and quality of life. However, elastic band resistance exercises as a part of HBET were not preferred over progressive walking.

Trial Registration: ClinicalTrials.gov NCT04043546; https://clinicaltrials.gov/ct2/show/NCT04043546

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KEYWORDS

eHealth; telerehabilitation; intermittent claudication; pilot

Introduction

Background

Lower extremity artery disease (LEAD) is a chronic disease characterized by progressive atherosclerotic narrowing of the lower limb arteries. As such, insufficient blood flow to active muscles during exercise may result in complaints of intermittent claudication (IC), which often presents as cramping or burning-like pain during physical activities. Although not immediately life-threatening, LEAD and IC have a great impact on patients' functional status and quality of life [1] through long-term pathophysiological changes (eg, atrophy, muscle weakness, reduced cardiorespiratory fitness) [2-4]. Furthermore, IC limits the ability to be physically active, enhancing the risk of serious cerebral and cardiovascular events [5].

Recent guidelines emphasize the importance of a first-line lifestyle-oriented approach when consulting with IC [6]. In this context, supervised exercise and walking in particular are cornerstone therapies that result in clinically significant improvements in pain-free walking distance (PFWD) and maximal walking distance (MWD) [7]. Meta-analytic research has shown that direct supervision of exercise training (SET) is a major contributor to progression in walking capacity [8]. However, SET is not readily available in most European countries, with only 30% of vascular surgeons having direct access [9,10]. Furthermore, even when SET is available, patients' participation is low, mainly because of a lack of transportation and time [11,12]. In addition, reimbursement issues and lack of uptake in health policy plans further hamper the widespread use of SET [13]. As a result, next to optimal pharmacological treatment, first-line IC management is often limited to a less-effective Go-Home-And-Walk advice. Structured home-based exercise therapy (HBET) seems promising to bridge the gap between Go-Home-And-Walk advice and the underuse of SET programs [9,10]. Although recommended as the best available therapy when SET is unavailable [6], evidence supporting HBET programs is considerably scarce [7,14]. However, it is noteworthy that the first HBET studies included only general advice to exercise, relied on patient recall, and did not incorporate behavioral change techniques [15,16]. A more recent meta-analysis by Golledge et al [17] showed that when HBET was more structured (and monitored), the effectiveness of HBET in improving walking performance and physical activity was increased. Furthermore, the importance of regular contacts empowering behavioral change and a therapeutic relationship is crucial for success [16,18,19].

At present, eHealth technologies offer valuable tools to elicit the full potential of HBET [20]. Currently, eHealth, referred to as *telerehabilitation* in cardiac rehabilitation, includes exercise supervision (*telemonitoring*), guidance of exercise (*telecoaching*), and promotion of a healthy lifestyle [21]. Telerehabilitation interventions, such as telephone or internet-based coaching, designed to increase physical activity behavior and compliance to exercise therapy, have already proven to be feasible and effective in cardiac patients [22,23]. Moreover, recent advancements in commercial wearables offer a unique opportunity to monitor physical activity and exercise and support behavioral changes toward an active lifestyle [24]. As such, wearable technology might help to bridge the gap by preserving the patient-provider relationship and offering home-based structured exercise therapy of adequate intensity in a health care system under pressure [14].

However, one needs to address the needs and interests of all stakeholders, including patients [21]. In this line, a previous cohort study from our group showed that 81% of patients owning a computer and telephone were interested in telecoaching [25]. In addition, most patients preferred home-based exercise [26], and physiotherapists showed utmost interest (89%) in GPS tracking to monitor these sessions [27]. With regard to the mode of exercise, most guidelines highlight the use of walking intervals until experiencing moderate-to-severe IC pain to improve walking distance [16]. However, resistance training is also considered to be an effective exercise mode and offers the potential to induce a pain-free exercise stimulus [28]. Furthermore, in addition to offering general health-related benefits, the addition of resistance exercises seems promising in terms of disease-specific measures [29] in patients with IC. However, the most recent review did not include any home-based resistance training alternatives, although elastic band exercises might be an effective home-based solution [28].

Objectives

In this exploratory, pragmatic observational pilot study, we primarily aimed to evaluate patient satisfaction and acceptability of a structured model of HBET using wearable technology during walking, in combination with home-based resistance exercises. In addition, we aimed to report on the adherence and potential effectiveness of this combined intervention on walking capacity, physical fitness, physical activity levels, and quality of life in the development of an HBET program for patients with IC.

Methods

Study Design

We conducted a 4-week exploratory observational cohort study to assess patient satisfaction and acceptability of an experimental HBET program combining walking therapy with elastic band exercises. The study was approved by the Ethical Committee of UZ (ethics approval number: S59686; Belgian registration:

B322201630074) Leuven/KU Leuven (Leuven, Belgium) and registered on ClinicalTrials.gov (NCT04043546).

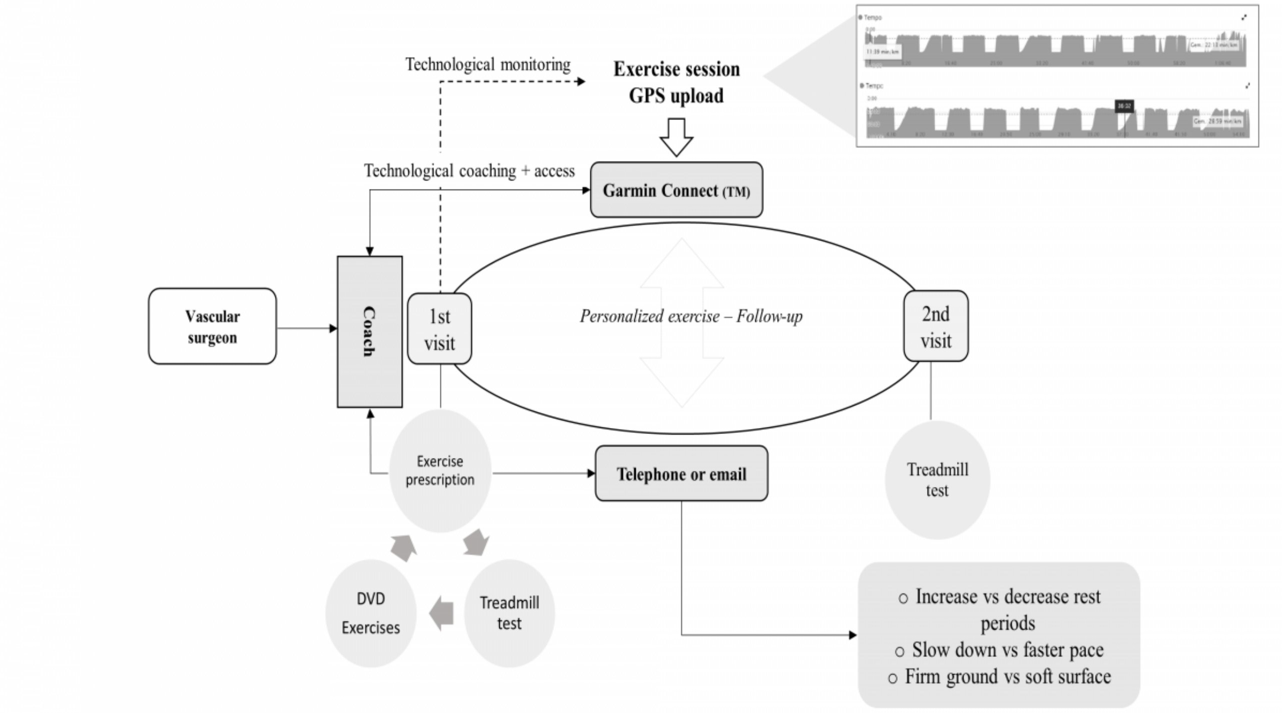
Participants

Patients consulting the ambulatory vascular center of the University Hospitals Leuven (Leuven) between October 2017 and July 2018 were recruited by vascular surgeons. Using convenience sampling, we aimed to recruit 20 patients. Eligibility criteria included patients presenting with LEAD (Ankle-Brachial Index [ABI] ≤0.9 and/or a 15% decrease in ABI after a maximal treadmill test) and new-onset or conservatively treated IC (Rutherford I-III). Patients were excluded if they (1) had already participated in a structured, regular exercise program (eg, weekly physiotherapy); (2) showed exercise-induced signs of myocardial ischemia or complex ventricular arrhythmias during maximal treadmill exercise; (3) did not receive medical clearance for exercise; or (4) did not have access to a computer or the internet.

Intervention

The flow of this study is schematically depicted in Figure 1. To guide the 4-week home-based exercise program, participants were offered an informative booklet, a self-developed DVD with demonstration of the resistance band exercises (Multimedia Appendix 1), and a Garmin Forerunner 210. The booklet provided background information about the symptoms of IC, a person-tailored walking prescription with a logbook, and images to illustrate the resistance exercises.

Figure 1. Pilot 4-week exercise intervention flow: baseline testing was done to provide a personal exercise program. The exercise program was monitored through GPS-derived data, uploaded by the participant. Telecoaching was provided through telephone or email.



Walking and Resistance Program

The exercise intervention consisted of 3 walking days and 2 resistance training days each week. Walking was prescribed according to the Dutch activity guidelines for IC [30] and person tailored (eg, adjustment of walking speed, hilly terrain, duration of rest period, unsteady surface) to elicit only moderate claudication pain during 2- to 10-minute intervals. Interval breaks were generally 1.5 to 2 minutes depending on pain recovery. Walking sessions were monitored and evaluated using GPS-derived data from the web-based Garmin Connect platform. Resistance training consisted of 4 elastic band exercises: plantar flexion, hip flexion, hip extension, and hip abduction. The appropriate resistance was selected during a single familiarization session at baseline to successfully complete the prescribed 2 sets of 12 repetitions for each leg. According to their individual preferences, participants received feedback twice weekly to only once during the 4-week intervention period via telephone or email. Exercise therapy was monitored and guided by a physiotherapist (NC) who progressively adjusted the volume and intensity over the 4-week period. This was personalized during contact moments using subjective reflection from the patients, baseline treadmill tests, and GPS-derived data. As such, participants had the possibility to self-monitor their walking sessions, received timely feedback on their performance, and were provided with information on how to adapt their walking program [31].

Outcome Measures

After a consultation at the vascular center, participants were invited for baseline and 4-week follow-up measurements at our research laboratory (University Hospitals Leuven), as shown in Figure 1. Doppler measurements from the latest clinical evaluation at the ambulatory vascular center were used to report the ABI of the most affected leg. Similarly, sociodemographic and clinical characteristics (eg, Rutherford classification) were derived from the electronic patient records of the last clinical consultation. In addition, the feasibility of physical activity assessment was evaluated at baseline and after 3 months.

Primary Outcome Measures: Patient Satisfaction and Acceptability

Patient satisfaction and acceptability of HBET were evaluated using a feedback survey adapted from Learmonth et al [32]. Patients were asked to rate the HBET, offered materials, coaching, and exercise prescription on a 5-point Likert scale (ie, *very unsatisfied*, *unsatisfied*, *neutral*, *satisfied*, *and very satisfied*). In addition, the participants were asked to provide written feedback on the received intervention and to provide suggestions for improvement.

Furthermore, all communication logs (telephone calls and emails) were registered and adherence to exercise was assessed using walking uploads and self-reported walking or resistance logs provided by the participant. Adherence was defined as the ratio of the number of exercise sessions to the number of prescribed exercise sessions.

Secondary Outcomes

Walking Capacity

Participants performed a progressive treadmill test using the Gardner protocol [33]. The walking speed was set at 3.2 km/h and adjusted (SD ±1 km/h) if needed. Every 2 minutes, we increased the inclination by 2% to a maximum of 10%. Participants were asked to report the onset and maximally tolerated claudication pain. Patients without IC symptoms who limited their walking capacity on the treadmill were excluded from this analysis. In addition, we used the Walking Impairment Questionnaire (WIQ) [34] to evaluate the walking distance, walking speed, and stair climbing capacity, with lower scores indicating greater impairment.

Quality of Life, Exercise Self-Efficacy, and Kinesiophobia

Patients were asked to fill in VascuQoL, a disease-specific questionnaire to assess quality of life. VascuQoL contains 25 seven-point Likert statements to measure the activity, symptom burden, pain, emotions, and social consequences related to LEAD [35]. Total scores and subscores for the VascuQoL questionnaire ranged from 1 to 7, with higher scores indicating a better quality of life. In addition, the Exercise Self-Efficacy Scale (ESES) was used to evaluate participants' confidence in overcoming personal and environmental barriers to be physically active [36]. The ESES has a total score of 40 (highest level of exercise self-efficacy), combining 10 statements scored with a 4-point ordinal outcome. Finally, kinesiophobia, or movement-related fear of pain, was evaluated using the Tampa Scale of Kinesiophobia (TSK) [37], which assists in identifying participants avoiding physical activity because of unjustified pain beliefs. The TSK is scored on a 17-item questionnaire, with higher scores (4-point Likert scale) indicating elevated levels of kinesiophobia. A cut-off score of ≥37 was used to diagnose kinesiophobia [37].

Physical Fitness

Physical performance was assessed using the Short Physical Performance Battery (SPPB) and the Timed-Up-and-Go (TUG) test, with patients wearing their shoes. The SPPB evaluates the standing balance, 4-m gait speed, and lower extremity strength [38]. Each category of SPPB is scored from 0 to 4, resulting in a maximum score of 12 points, with higher scores indicating better performance. The TUG test is a functional test that evaluates functional chair stand and walking flexibility [39]. Participants were instructed to stand up from a chair, walk fluently around a 3-m separated cone, and sit down again. We used the fastest time for the 2 attempts in the analysis.

Physical Activity

Participants were instructed to wear a Sensewear (R) Mini device (Bodymedia) on the right upper arm for 7 days to measure the daily physical activity levels. An assessment was considered valid if the patient had worn it for at least 3 weeks and 2 weekend days with 90% daily (24-hour measurement) wear time [40]. Physical activity intensity was categorized as light (1.5-2.9 metabolic equivalents [METs]), moderate (3.0-5.9 METs), and (very) vigorous (≥6 METs). Sedentary behavior included all activities below a threshold of 1.5 METs. In addition, steps were registered to assess walking activities in daily life.

Statistics

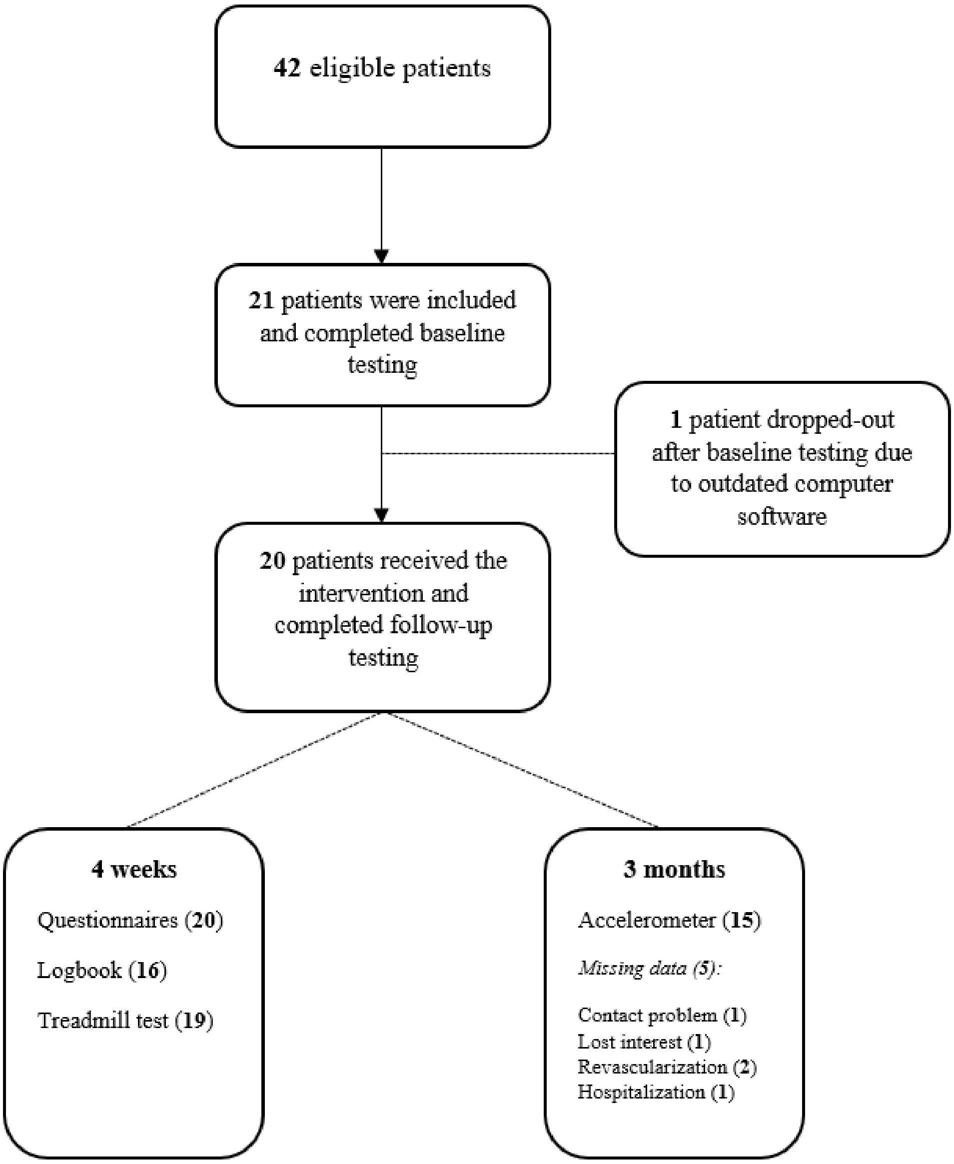
All data were presented as median and IQR or mean and SD. Normality of data was evaluated using the Shapiro-Wilk test. Statistical analyses were performed using JASP 0.11.1 (University of Amsterdam), with pre-post parametric (paired two-tailed *t* test) and nonparametric equivalent (Wilcoxon signed-rank) tests. An alpha level of 5% (two-sided) was used for statistical significance. No power calculations were performed on the study outcomes.

Results

Participants and Data Collection

Out of 41 eligible patients, 21 (50% recruitment success) volunteered to participate (15 men and 6 women). A total of 3 patients were referred for additional cardiologic screening after baseline measurements because of presumed cardiac ischemia, complaints, or arrhythmias. Consequently, for 1 participant (P1), the intervention start was postponed, resulting in a 75-day interval period between measurements. One patient was excluded after recruitment. Our participants' average age was 64.6 years (SD 10.6; range 41-81 years) and heterogeneous with regard to comorbidities, walking capacity, claudication location, duration of symptoms, and severity of disease (ABI; mean 0.65, SD 0.20; Rutherford classification [3 in 50%]). Moreover, all participants had dyslipidemia, 70% were hypertensive, 25% had diabetes, and 85% were ex-smokers or were still smoking. Individual demographic characteristics are detailed in Multimedia Appendix 2, and the study flow is presented in Figure 2. Baseline and follow-up measurements were completed within a median time period of 36 days (IQR 6), which corresponds to a median intervention time of 32 days (IQR 5).

Figure 2. Flowchart with study inclusion and final analysis.

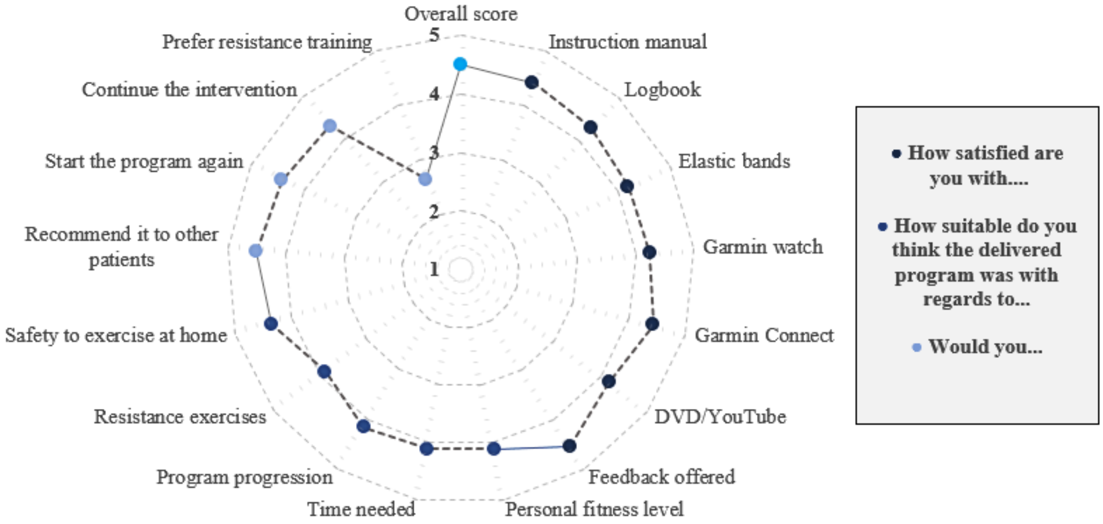


Primary Outcomes

All users were very satisfied (mean overall score 4.5, SD 0.5; median 4.5, range 4-5) with the HBET program. These results were reflected in high adherence to the prescribed walking sessions (GPS and logbook combined=mean 89%, SD 25; GPS only=mean 86%, SD 28), with 75% (15/20) of the patients completing all prescribed walking sessions. In contrast, patients were less compliant with resistance training (mean 85%, SD 22; 56% (9/16) completed all prescribed sessions and 20% (4/20) of patients did not return their logbook) and did not prefer this exercise alternative over conventional walking therapy (mean 2.65, SD 0.8; median 3, range: 1-5). Intervention satisfaction scores regarding materials, feedback, personalization, and content of the intervention are depicted in Figure 3. Furthermore, it is important to note that participants perceived the home-based program as safe (mean 4.4, SD 0.6; median 4, range 3-5). Most participants also stated that they would re-enroll in the exercise program (mean 4.4, SD 0.5; median 4, range 4-5) and would recommend it to their peers (mean 4.5, SD 0.5; median 4.5, range 4-5). Qualitative reporting revealed that participants were positive about the option to visualize progression using the recorded training logs (n=2) or trigger to improve (n=2), personal guidance (n=2), and flexibility (n=2). However, resistance training (n=7) and pain during sessions (n=2) were perceived as less enjoyable.

In addition, we registered the number of telephone and/or email contacts. A median of 5 contacts during the 4-week intervention was provided for each patient: 3 follow-up contacts, 1 contact moment to provide technical assistance, and 1 contact combining the aforementioned. In addition, most contacts were provided through email (median 3) as compared with telephone calls (median 2).

Figure 3. Feasibility of the intervention as scored by a 5-point Likert scale (mean scores). Range of scores: 1 (very dissatisfied or unsuitable), 2 (dissatisfied or unsuitable), 3 (neutral), 4 (satisfied or suitable), and 5 (very satisfied or suitable). Missing values: instruction manual (1), logbook (3), Garmin Connect (1), DVD or YouTube-link (3), personal fitness level (2), time needed (1), program progression (1), resistance exercises (1), safety to exercise at home (1), starting the program again (1), and continuing the intervention (1).



Secondary Outcomes

Walking Capacity

At baseline, MWD ranged between 141 and 828 m (median 414 m, IQR 253 m), with 2 patients being stopped by the investigator as claudication symptoms were not limiting the exercise test. In addition, 1 patient (*P2*) experienced claudication symptoms but stopped both tests because of gastric problems. Patients (n=3) were excluded from MWD analysis. Participants improved their PFWD and MWD compared with baseline, with a mean progression of +89 (SD 95) and +58 m (SD 97), respectively (*P*<.001 and *P*=.03; Multimedia Appendix 2). Similarly, the WIQ distance score (+0.18; *P*=.01) was significantly higher after the intervention. As no statistically significant change was established in WIQ speed (+0.03; *P*=.53) and WIQ stair climbing score (+0.02; *P*=.55), the overall WIQ score remained to be statistically unaltered (+0.08; *P*=.06; Multimedia Appendix 2).

Quality of Life, Exercise Self-Efficacy, and Kinesiophobia

Quality of life was better after the intervention (+0.36 on total VascuQoL; *P*=.009). The main areas of improvement were pain (+0.41; *P*=.04), physical activity (+0.54; *P*<.001), and emotions (+0.33; *P*=.06). No changes were noted in the social (+0.08; *P*=.56) and symptom (+0.15; *P*=.30) subscores. Kinesiophobia was elevated at baseline, with a median score of 38 (IQR 8.50). Self-efficacy (ESES) and kinesiophobia did not change (*P*=.18 and *P*=.17, respectively; Multimedia Appendix 2).

Physical Activity and Physical Fitness

At baseline, physical activity values for valid days were averaged for each participant, resulting in a median of 59 minutes of moderate to vigorous physical activity (IQR 63 minutes) per day. Moderate physical activity was the main contributor to daily physical activity in our sample, as 80% (16/20) of our sample did not reach 5 minutes of vigorous physical activity (median 2 minutes, IQR 4.3 minutes). In addition, our participants completed a median of 5297 (IQR 3118) steps per day. Follow-up data did not show any significant changes after 3 months. With regard to physical activity data acquisition, 95% (19/20) of participants fulfilled the targeted 90% daily Sensewear on-body time for at least 3 weeks and 2 weekend days at baseline. In contrast, 25% (5/20) of the patients did not complete the physical activity assessment after 3 months. Furthermore, the 4 follow-up measurements did not fulfill our strict validity criteria. Consequently, only 55% (11/20) of the participants had follow-up physical activity data. More information is provided in Multimedia Appendix 2, with elaboration on the encountered methodological issues. Physical performance (SPPB total score) was not significantly different (*P*=.06) after the intervention (Multimedia Appendix 2).

Discussion

Principal Findings

This study evaluated the satisfaction, acceptability, adherence, and potential effectiveness of a novel home-based exercise intervention that combines resistance training and walking therapy using wearables to monitor and guide patients with IC. Although our sample of 20 conservatively treated patients was heterogeneous in nature, participants generally perceived the exercise program with personalized feedback and monitoring as (very) positive. However, contrary to our hypothesis, elastic band exercises were not preferred over traditional walking sessions. Furthermore, we also found beneficial effects on quality of life (VascuQoL), subjective walking distance (WIQ), and objective walking distances (PFWD and MWD). Despite the short intervention duration, a clinically relevant improvement was found in the WIQ distance score [41]. As this study was designed to primarily evaluate patients' satisfaction and acceptance, our results complement contemporary pilot studies in the field of eHealth solutions in patients with IC [20,42-45].

We used commercially available wearables supported by GPS tracking to guide and monitor walking training. The exercise uploads showed additional value to evaluate adherence and guide personalized exercise prescription in our study. Researchers have already explored the advantages of GPS-derived walking information to evaluate community-based walking in patients with IC [46,47]. They found an acceptable 0.81 correlation comparing free-living PFWD and results from a standardized treadmill test documenting its usefulness for the evaluation of walking distances [46]. As such, wearables offer possibilities to assess physical activity levels and monitor [48], guide, and evaluate progress in future structured home-based exercise programs [46] (Figure 1). Recently, Dusha et al [44] reported on their 12-week pilot study in 10 patients in which they used commercial step counters with adapted coaching that resulted in improved walking capacity in patients with IC. Conversely, the largest trial to date—Home-Based Monitored Exercise for the PAD (HONOR) study [43]—did not provide feedback based on the uploaded exercise information. Patients only received monthly feedback for the last 4.5 months during the 9-month HONOR intervention, which might explain the unchanged walking frequency compared with usual care after 9 months. Our participants asked for and received weekly feedback. Therefore, incongruity between the use of activity trackers to increase the overall physical activity (eg, daily steps) and specific exercise recommendations with appropriate, direct feedback might explain the lack of improvement [43]. In summary, the appropriate use of technology seems mandatory to provide a symbiosis between the wearable (*tool*) and the intervention (*goal*), which is generally acceptable to patients with IC.

The novelty of this study was the incorporation of home-based resistance training. Although more than 80% stated that they were interested in using elastic bands as an alternative to walking therapy [25], patients now rated the addition of elastic band exercises as neutral or negative compared with walking. This was somewhat surprising, as pain is the most cited barrier to exercise [25], and resistance exercises were anticipated to result in less pain in terms of oxygen demand in the lower legs [28]. However, similar results were noted in geriatric inpatients, where objective measures of elastic band use contrasted with positive attitudes of staff and patients regarding the benefits [49]. Although no specific reasons were provided, we hypothesize that highly prevalent musculoskeletal comorbidities in patients with IC (eg, lumbar spine disease in 75.7% [50]) and lack of direct supervision might have hampered the correct execution of the elastic band exercises. Quality of execution has been proposed as an important driver of improved adaptation after supervised resistance programs compared with nonsupervised programs in older adults [51]. Therefore, direct supervision appears to be essential when prescribing technically challenging exercises.

Moreover, it is interesting to note that 60% (12/20) of our sample experienced some degree of kinesiophobia (ie, TSK≥37) at baseline. Compared with the significant changes observed in terms of walking outcomes, no change occurred at the level of fear avoidance. This discrepancy might be evoked by the short intervention period or the lack of patient education to *explain the pain* and induce behavioral change. These findings once again emphasize the importance of addressing these beliefs when designing an exercise intervention, as they might interfere with exercise therapy perception and adoption [52,53]. In addition, the importance of the patient-provider alliance using in-person visits may not be overlooked when designing telemonitored exercise programs [18,43]. Therefore, the development of so-called hybrid interventions [44] might bridge this gap, which has been shown in an earlier successful trial using step monitors [54]. Therefore, future studies should investigate the add-on effect of direct supervision in home-based interventions to (1) evaluate patient perception and methods to implement resistance exercises and (2) reduce activity-related fear using behavioral change or educational interventions.

Furthermore, this study also included a feasibility evaluation of the different assessments. Our findings were in line with earlier publications, that is, 2 recent studies also reported difficulties (55% and 50% baseline and follow-up data, respectively [43,45]) in collecting physical activity data using a triaxial pedometer or accelerometer on the hip. A possible explanation for these missing values might be the instruction to wear the monitor during waking hours compared with a more compliant 24-hour protocol [55]. In addition, one has to consider the trade-off between the study power and validity of the collected physical activity data [55]. However, missing follow-up data were mainly because of early revascularization or hospitalization (3 participants) and lack of valid combinations of at least three weekdays, Saturday, and Sunday (4 participants). Thus, missing follow-up data in our pilot study were considered to be the result of the selected analysis protocol [40] and patient hospitalization at follow-up.

Limitations

Further limitations include the generalizability of this pilot intervention, which was part of developing a larger trial and should be interpreted as such. Only one researcher provided feedback and evaluated all outcomes. With regard to monitoring and feedback, calls or emails were structured to discuss walking training, elastic band training, and progression toward the new week. Although we incorporated some behavioral change techniques through the addition of sports watch technology (eg, self-monitoring), we did not assess and evaluate the underlying psychosocial constructs or the distinct effect of each behavioral change technique on effectiveness [31]. However, our evaluation of satisfaction and acceptance of technology could drive future research to evaluate and design technology to support long-term behavioral changes in a home-based environment. We did not assess the similarity between the uploaded exercise sessions and the actual walking prescription, which limits the interpretation of quantity and quality of exercise prescription [19]. One barrier to this approach was the presence of uninterpretable GPS signals (eg, because of a lack of satellite connections or an obstructed environment [high buildings or trees]) [46]. Similarly, although technology was well accepted, patients often reported the need for technical assistance during setup and interpretation [56]. In addition, it is well known that self-reported adherence rates from walking sessions and resistance training might result in overreporting [19]. However, our pilot did show good adherence to the walking sessions in comparison with other physiotherapy-led home-based exercise programs (67%) [19]. Moreover, our sample was generally fit in terms of activities of daily life measured by the SPPB and TUG total scores, which resulted in a ceiling effect [57]. Although both SPPB and TUG possess prognostic (eg, mortality [58]) information in patients with IC, high baseline scores impose an important risk for type II errors in clinical trials [57]. Therefore, physical fitness levels can be overestimated, as can be seen from the comparison of our measured time data with normative values [57]. As such, future studies are encouraged to report the measured time for both chair-stand and 4-m gait speed tests [57].

Conclusions

This observational pilot study has shown that patients with IC are satisfied and accept technology to monitor and guide a home-based combined exercise program through remote feedback. Participants did not prefer resistance training over walking exercise; however, a general positivity toward the combined intervention was reflected in clinically relevant improvements in subjectively reported walking distances and quality of life.

Acknowledgments

The authors would like to thank the participants for their dedication and willingness to volunteer in this pilot project. In addition, they are grateful for the efforts of the UZ Leuven hospital staff involved in the recruitment of patients.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Elastic band resistance exercises: instructional video.

[AVI File , 180691 KB - rehab_v8i1e18739_app1.avi]

Multimedia Appendix 2

Tables and figures with results on primary and secondary outcomes.

[DOCX File , 672 KB - rehab_v8i1e18739_app2.docx]

Multimedia Appendix 3

CONSORT-eHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 7973 KB - rehab_v8i1e18739_app3.pdf]

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Abbreviations

ABI: Ankle-Brachial Index
ESES: Exercise Self-Efficacy Scale
HBET: home-based exercise therapy
HONOR: Home-Based Monitored Exercise for the PAD
IC: intermittent claudication
LEAD: lower extremity artery disease
MET: metabolic equivalent
MWD: maximal walking distance
PFWD: pain-free walking distance
SET: supervised exercise training
SPPB: Short Physical Performance Battery
TSK: Tampa Scale of Kinesiophobia
TUG: Timed Up and Go
WIQ: Walking Impairment Questionnaire

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Original Paper

Electromyography-Driven Exergaming in Wheelchairs on a Mobile Platform: Bench and Pilot Testing of the WOW-Mobile Fitness System

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Abstract

Background: Implementing exercises in the form of video games, otherwise known as exergaming, has gained recent attention as a way to combat health issues resulting from sedentary lifestyles. However, these exergaming apps have not been developed for exercises that can be performed in wheelchairs, and they tend to rely on whole-body movements.

Objective: This study aims to develop a mobile phone app that implements electromyography (EMG)-driven exergaming, to test the feasibility of using this app to enable people in wheelchairs to perform exergames independently and flexibly in their own home, and to assess the perceived usefulness and usability of this mobile health system.

Methods: We developed an Android mobile phone app (Workout on Wheels, WOW-Mobile) that senses upper limb muscle activity (EMG) from wireless body-worn sensors to drive 3 different video games that implement upper limb exercises designed for people in wheelchairs. Cloud server recordings of EMG enabled long-term monitoring and feedback as well as multiplayer gaming. Bench testing of data transmission and power consumption were tested. Pilot testing was conducted on 4 individuals with spinal cord injury. Each had a WOW-Mobile system at home for 8 weeks. We measured the minutes for which the app was used and the exergames were played, and we integrated EMG as a measure of energy expended. We also conducted a perceived usefulness and usability questionnaire.

Results: Bench test results revealed that the app meets performance specifications to enable real-time gaming, cloud storage of data, and live cloud server transmission for multiplayer gaming. The EMG sampling rate of 64 samples per second, in combination with zero-loss data communication with the cloud server within a 10-m range, provided seamless control over the app exergames and allowed for offline data analysis. Each participant successfully used the WOW-Mobile system at home for 8 weeks, using the app for an average of 146 (range 89-267) minutes per week with the system, actively exergaming for an average of 53% of that time (39%-59%). Energy expenditure, as measured by integrated EMG, was found to be directly proportional to the time spent on the app (Pearson correlation coefficient, r=0.57-0.86, depending on the game). Of the 4 participants, 2 did not exercise regularly before the study; these 2 participants increased from reportedly exercising close to 0 minutes per week to exergaming 58 and 158 minutes on average using the WOW-Mobile fitness system. The perceived usefulness of WOW-Mobile in motivating participants to exercise averaged 4.5 on a 5-point Likert scale and averaged 5 for the 3 participants with thoracic level injuries. The mean overall ease of use score was 4.25 out of 5.

Conclusions: Mobile app exergames driven by EMG have promising potential for encouraging and facilitating fitness for individuals in wheelchairs who have maintained arm and hand mobility.

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KEYWORDS

exergaming; gamercising; mobile health; wheelchair exercises; wireless electromyography; mobile phone

Introduction

Individuals with paraplegia are at a greater risk for many secondary health problems associated with sedentary behavior [1-3]. The benefits of physical exercise on the health and quality of life of people with disabilities have been reported [4-6]. Dishearteningly, individuals with impaired mobility face substantial barriers to exercise, such as difficulty in accessing exercise programs and facilities, which contribute to an overall reduction in participation in physical activity [7-9]. With the known benefits that physical exercise has on health, digital sensor-driven technology is being considered as an approach to make exercise more accessible and entertaining [10-14]. Exercising in the process of achieving the objectives of a digital video game is termed exergaming [15,16]. Reportedly, 61% of internet-based exercise interventions lead to significant gains in physical activity [17]. Some researchers have gamified exercises to encourage more active lifestyles [16,18,19]. A recent review paper examined studies showing the beneficial health effect of exergaming and pointed to the ripe opportunity to apply exergaming to the health issues that individuals with neurological disabilities face [14]. At its inception, *exergaming* was popularized as arcade games or console games and has more recently been implemented as desktop and web apps [20-25]. Now, exergaming is beginning to appear on mobile platforms (namely, smartphones and tablets) [16,26,27], which could help in overcoming transportation challenges and inaccessible gym environments for people using wheelchairs. However, among those that have been implemented, there are none to the authors' knowledge that are tailored to exergaming in wheelchairs.

We have developed a mobile app that communicates with body-worn sensors that monitor physical activity and feed electromyography (EMG) input into a mobile app game engine that gamifies exercises designed to be carried out independently by individuals in wheelchairs. The current recommendations for exercise regimens for individuals in wheelchairs holistically combine cardiovascular conditioning and strength training [28]. Evidence of the need for building muscle strength to prevent overuse injury and pain and to enable individuals in wheelchairs to sustain sufficient exercise on a weekly routine basis has led to the development of exercise interventions, such as circuit resistance training (CRT), which include muscle strengthening [28,29]. CRT entails interspersing arm resistance strength exercises (such as weight lifting) with high-speed cardiovascular exercise (such as arm cranking) and incomplete recovery periods during which the heart rate was still sustained well above the resting heart rate. Our app implements these exercises in the form of 3 different games that allow the user to engage in a combination of resistance and aerobic conditioning activities developed to be used in a wheelchair.

Many of the existing fitness apps rely on heart rate and accelerometers. The well-known exergames (eg, Dance Dance Revolution and balance board–centered Wii Fit) rely on step detection or lower limb mobility for an effective workout [12,21-23,30,31]. These systems use pressure sensors to detect body weight or accelerometers to detect ballistic or discrete movements. Accelerometers have sufficient resolution to detect steps and therefore have been relatively effective in fitness apps to date when the physical activity being tracked involves moving the whole body mass. In contrast, detecting muscle activity provides a real-time measurement of continuous changes in physical exertion, that is, by sensing muscle activity via EMG, we would be able to detect the continuous intensity of each muscle contraction rather than only binary detection of a movement. This is especially important in the case of individuals with paraplegia, where the movements involve only the upper body and not their whole body and where strength training entails isometric contractions rather than binary actions (eg, steps, cycles). Commercial wireless EMG sensors are beginning to be used with mobile apps for applications such as monitoring driving and monitoring cadence while biking [32,33]. Our app senses EMG to measure the amount of muscle activity continuously used. Therefore, our app can sense the strength of isometric contractions during muscle strengthening exercises as well as how hard a wheelchair push was during spinning exercises.

The limitation of the existing technology to facilitate and encourage exercise for individuals with lower limb mobility impairment is the lack of a combination of providing exergaming on a mobile platform and tailoring games toward exercises that can be performed in wheelchairs; of particular need for such exergames is the ability to track isometric contractions through EMG sensing. Our objective was to design, implement, and test the feasibility of an EMG-based mobile exergaming app for individuals in wheelchairs. Our mobile app is distinct from other fitness apps in a few key ways. First, the app gamifies exercises that can be performed in a wheelchair on a mobile platform while monitoring effort and providing feedback, thereby making exercises entertaining and accessible. Second, the selection of the exercises was informed by research on the fitness needs of individuals who use wheelchairs as a primary mode of transportation. In particular, the exercises were specifically selected so that individuals in wheelchairs could exercise independently without relying on access to adapted equipment or specialists or physical therapists for their daily physical exercise. Third, the games were driven by EMG, which enables higher resolution and continuous readings of physical exertion from upper limb movements.

The purpose of this study, therefore, is to describe the development and feasibility of a mobile phone app that implements EMG-driven exergaming to encourage and enhance exercise for individuals who use wheelchairs. In this work, we assess the perceived usefulness and usability of this mobile health system by asking the following research questions:

1. Does this mobile fitness app enable individuals who use wheelchairs to increase their level of physical activity?
2. Does use of this mobile fitness app allow individuals who use wheelchairs to reach their self-reported peak fitness levels?
3. Does this mobile fitness app improve self-reported motivation to exercise?
4. Does this mobile fitness app enhance the effectiveness of a workout session for individuals who use wheelchairs?
5. Does this mobile fitness app allow the user to track their progress?
6. How do users perceive the ease of use of this app?

These questions pertain not to a generic mobile fitness app but to one specifically designed to enable people in wheelchairs to perform exergames, used in CRT, independently and flexibly in their own home. As such, the Methods section describes the implementation of our Workout on Wheels (WOW) mobile fitness app.

Methods

Mobile Fitness App Concepts

We designed a mobile fitness app, called Workout on Wheels—Mobile (or WOW-Mobile), to encourage and facilitate exercises at home for individuals who have lower mobility impairment and use wheelchairs for ambulation. Table 1 provides an overview of the features or enabling technology that we incorporated into our app design to achieve specific objectives. Ultimately, the goal of the overall design of the app is to help app users achieve greater fitness levels than without the app.

The hardware system and architecture are described elsewhere [34]. Here, we describe the implementation of our design and show the feasibility of achieving these design objectives through the integration of EMG sensing with our mobile fitness app. All code was written in Java using the Android Studio IDE, and the mobile app was installed and tested on the Samsung Galaxy J3.

Table 1. Features implemented in the Workout on Wheels-Mobile app and the corresponding enabling design.

Objective	Enabling design or technology
Goal-oriented exercise	Exergaming
Holistic exercise workout in wheelchairs	Spinning, boxing, and arm resistance games
Increase in fitness levels	Electromyography-driven game engines (game performance correlates with effort level)
Fitness tracking	Calories metric, trends page
Encouragement	Audio feedback, text pop-ups
Independence, flexibility	Wireless sensing, mobile platform
Competition	Multiplayer gaming
Socialization	Leaderboard

Sensor Validation and App Bench Testing

Wireless EMG sensors (Flexdot, Dynofit Inc) were used to drive the exergames and provide feedback on estimated energy expenditure (Multimedia Appendix 1). In addition to the 3 exergames described in the following sections, users also had access to a monitoring activity, which simply displays the signals obtained from the wearable sensors. To validate the EMG acquisition and sensing, we collected surface EMG readings from the bicep bracii muscle from 2 brands of sensors: the Flexdot and the Trigno (Delsys, Inc), a popular high-end commercial wireless EMG sensor and data acquisition system. The mobile fitness system was tested in our research laboratory for power consumption and data transmission performance using Android Studio Profiler. The results from this testing are presented in a later section (*WOW-Mobile Validation and Bench Testing*).

EMG-Driven Exergame and Monitoring Concepts

We created 3 video games within our mobile phone app (Multimedia Appendices 2-4) to implement corresponding exercises that were developed by coauthors from the School of Kinesiology as part of a circuit training regimen [35]. de Leon established a mobility center on our campus that provides individuals in our community with mobility impairment because of spinal cord injury (SCI) and other causes with very low-cost physical therapy. Other coauthors served as trainers in the clinic and led the development of the exercise protocol on which the exergames were based. The training circuit was designed to help people with SCI achieve recommended cardiorespiratory intensity levels and provide strengthening and endurance to help prevent repetitive use injuries [28,36]. A brief description of the gamified exercises is provided in Table 2. Each game provided an entertaining objective that users could focus on and help them exercise at appropriate intensity levels without focusing on the exercise themselves. It also provided feedback to the user to encourage gains in strength, endurance, and cardiorespiratory fitness in the form of game performance metrics. Audio-visual feedback was incorporated to encourage users to meet the game objectives.

Table 2. Conceptual design of Workout on Wheels-Mobile exergames.

Game	Analogous exercise	Exercise objective	Game objective	Feedback provided
Racing	Spinning	High cadence, low resistance	Complete designated number of laps within target time	Time to complete given number of laps. HR[a], EMG[b] level, and METs[c]. Audio of car engine; visual of car speed based on EMG level.
High striker	Resistance armbands	Isoinertial resistance (via shoulder press, chest fly, bicep curls)	Raise bar level to upper target with EMG	Number of flexions detected; number of hits of upper target. Audio (bell) when upper target reached. Visual of bar height based on the EMG level. Max EMG reached, HR, and METs.
Boxing	Ball exchange	Maintain HR with a high-cadence, low-resistance exercise + adds variety.	Complete 3 rounds of punches	Audio (punch sound) and visual (stars) with each detected punch.

[a]HR: heart rate.

[b]EMG: electromyography.

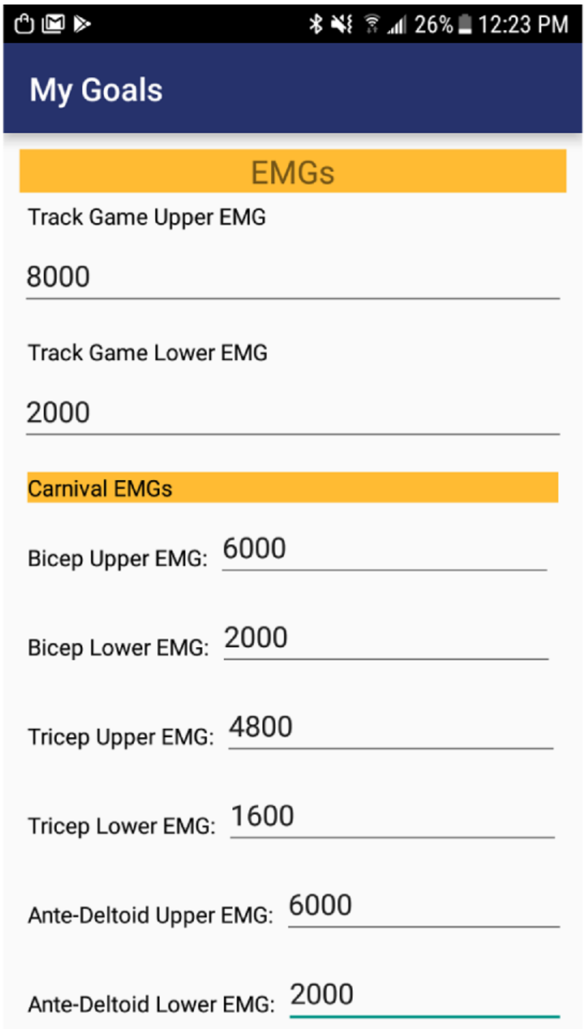
[c]MET: metabolic equivalent.

Calibration and Goals

Thresholds must be set before playing an exergame to appropriately calibrate each game performance with the user's effort level. A calibration activity was developed, which guides the user through 3 maximum voluntary contractions (MVCs) of the selected muscle (tested separately for the bicep, tricep, anterior deltoid, and posterior deltoid). The average EMG level over a 3-second period during the MVC was used as the 100% effort level. We measured the MVC during orientation in a laboratory setting. EMG thresholds were required for the detection of each muscle contraction in the boxing and high striker game and to calibrate the car's speed in the racing game.

A *MyGoals* activity (Figure 1) was also created to allow the user to save their thresholds so that it does not need to be reentered for each session; rather, the thresholds are fetched for the appropriate game at the start of each session. MVC was measured at baseline testing using the *Calibration* activity. For the high striker game, the upper and lower thresholds were set to 90% and 20%, respectively, of the baseline MVC; for the boxing game, the upper and lower thresholds were set to 80% and 30%, respectively, of MVC. For the racing game, the upper threshold was set to 100% of the MVC, and the lower threshold was set to the empirically determined noise floor.

Figure 1. Screenshot of the My Goals page, which stores user-defined electromyography thresholds for each game. EMG: electromyography.



High Striker: Arm Resistance Band Game Design and Implementation

The high striker game replicated the game typically found at carnivals (Multimedia Appendix 2). The player hits one end of a lever to launch a puck up a graduated column. The greater the force the player uses, the higher the puck climbs up the height of the column. The player wins if the puck reaches the top of the column and strikes a bell. We implemented resistance arm band exercises as a game based on the high striker (Figure 2). The column is represented by a bar whose height is proportional to the integrated EMG level over a given contraction (Figure 3). The user selects which muscle's EMG should drive the bar's height according to the exercise they plan to perform and on which they are currently focusing (eg, biceps for the bicep curls or anterior deltoids for the shoulder press and chest fly). As the user performs each contraction, the number of contractions (or *hits*) detected is incremented, and the number of times the maximum target (or *bell*) was hit is incremented. The user interface also includes encouraging text pop-ups, upbeat background music, and the bell audio clip each time the bar reaches the maximum.

Figure 2. User carrying out chest press exercise to play the high striker exergame.

Figure 3. Screenshots showing the app interface for the high striker arm resistance band exergame. User selects which muscle to monitor. The ratio of the yellow bar height to the scaled background bar is equal to the iEMG: MVC level. (a) Interface during the middle of the game. Feedback also includes encouraging text, number of reps, and number of bells hit. (b) Interface at the end of the game, providing summary statistics and a prize based on the number of bells. iEMG: integrated electromyography; MVC: maximum voluntary contraction.

Boxing: Exchange Game Design and Implementation

The workout developed for this research project included a second high cadence, low-resistance exercise to add variety to the cardiorespiratory exercise, maintain heart rate between the other exercises, and reduce the risk of overuse injury. This exercise was implemented as a boxing game (Figure 4, Multimedia Appendix 4). Players need to complete 30 punches to advance to the next round; there are 3 rounds (Figure 5). To progressively increase the workout intensity, the threshold that defined what constituted a punch increased with each round.

Figure 4. Participant plays the boxing exergame. The EMG sensor can be seen on the right bicep; phone is suspended by phone holder so that the user can monitor progress while playing. EMG: electromyography.

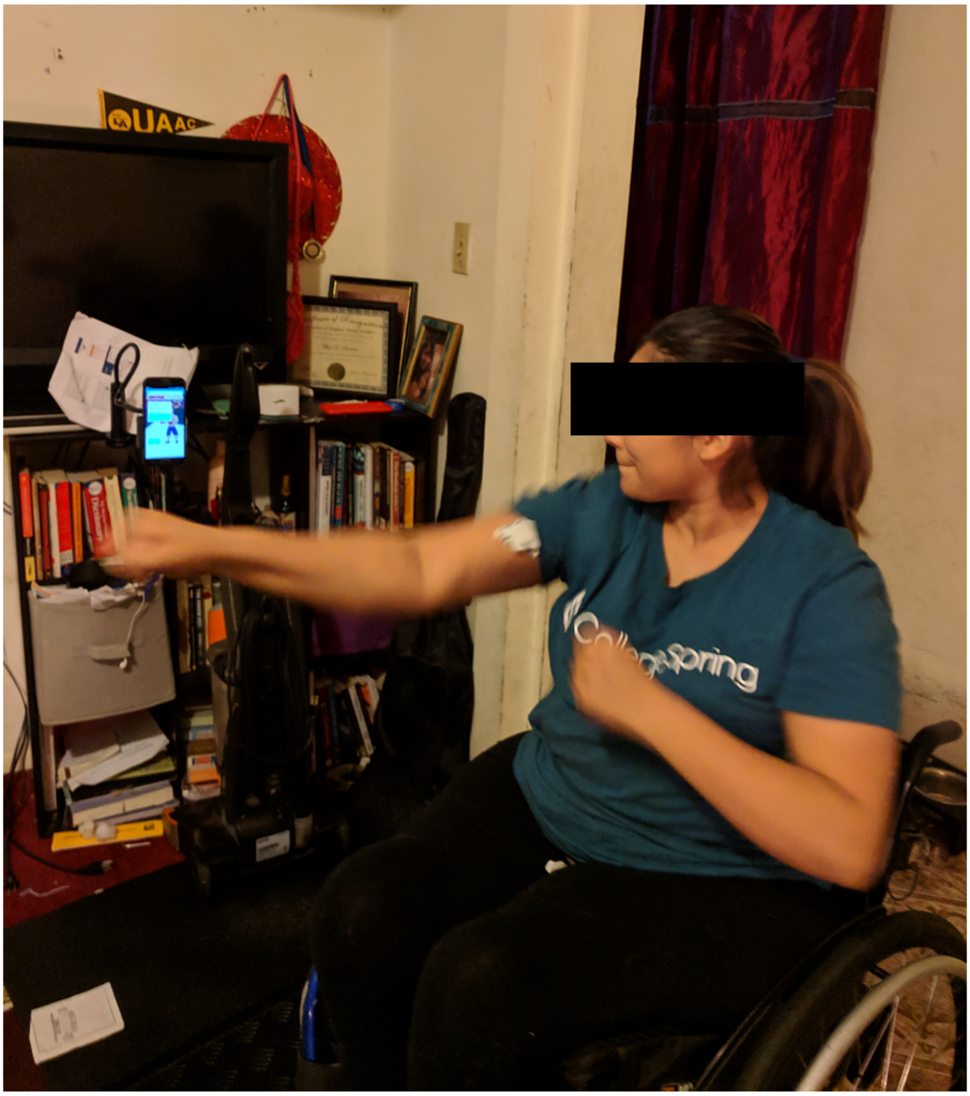
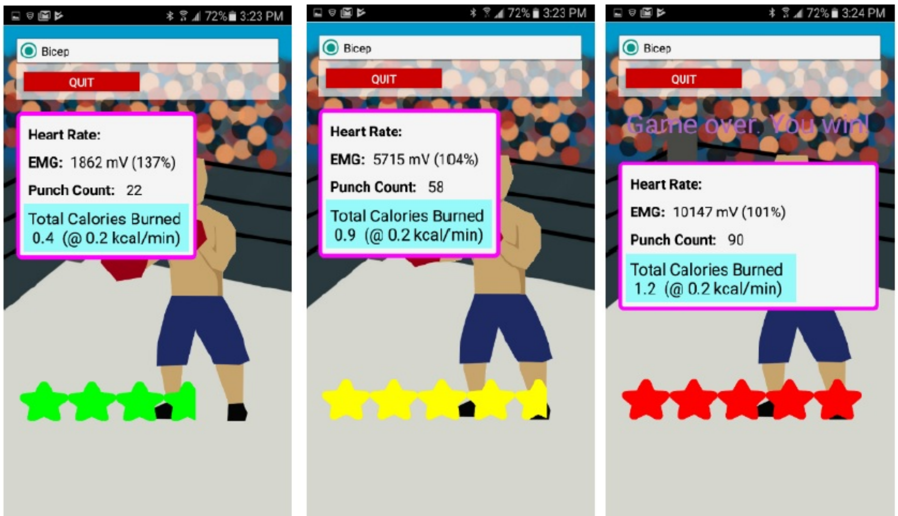


Figure 5. Sequence of screenshots during the boxing game. Each round gets progressively more difficult (the threshold for a punch being detected increases).



Car Racing: Cardio-Spinning Game Design and Implementation

The spinning exercise was implemented as a car racing game (Figure 6, Multimedia Appendix 3). The angle of the elliptical path around the track increased in proportion with the effort level, whereas the user spun on a stationary roller (Invictus Active Trainer). The effort level was computed as the ratio of the EMG amplitude to the MVC for the given muscle. The metrics displayed to the user during the game included the elapsed time, number of laps to complete, total calories burned, and the current METs. The sound of an engine running would play as background audio throughout the game, whereas an audio clip of *One final lap!* would play as the lap counter decreased to 1 to encourage the user.

We also implemented a multiplayer gaming feature that allows users to select a previous session to be played back as a ghost player against which to race. This feature is outside the scope of this paper and is described in a separate paper.

Figure 6. Single-player track game: Angular speed of the car is proportional to the EMG (level for a punch being detected increases). EMG: electromyography.

Pilot and Feasibility Testing

In total, 4 individuals with incomplete SCI took home and used our WOW-Mobile system for 8 weeks. The California State University, Los Angeles institutional review board approved all study procedures (#18–273). Participant demographics are listed in Table 3. Of 4 participants, 1 (25%) already had an adapted gym at their home and exercised regularly before participating in the study, another had access to adapted exercise equipment in the apartment building, and the other 2 did not have access to a gym and did not exercise regularly before participating in the study. None of the participants had prior experience with exergaming.

Table 3. Demographics of study participants.

Subject ID	Age	Gender	Ethnicity	Injury level	Years since injury	Regular exercise at baseline?	Exercise in home?
S1	28	Female	Hispanic	T12	6	No	No
S2	40	Male	Hispanic	T12	13	Yes	Yes
S3	52	Male	Hispanic	T6	10	No	No
S4	38	Male	African American	C7	17	Yes	No

Before beginning the 8 weeks, each participant came to our campus for orientation to the mobile fitness system in a controlled laboratory setting. Physical trainers from the Kinesiology department gave instructions on how to carry out the exercises at home, and they, along with engineering research students who developed the app, guided the participants through a practice session of placing sensors, positioning the armbands, and carrying out the exergames on the mobile app. These physical trainers and engineering students then went to the participants' homes to set up a stationary spinning device and provided a mobile phone with WOW-Mobile installed, sensors, electrodes, spare batteries, and resistance armbands (TheraBand) and guided the participant one more time through the mobile fitness workout. A workout frequency of 3 times a week for 45 minutes each time was recommended to the participants. The messaging mobile app WhatsApp (Facebook, Inc) was installed on the participants' phones; a chat room including the participants, engineers, and trainers was created. Participants were instructed to provide feedback regarding the WOW-Mobile app and were encouraged to message the group any time they had issues or questions regarding the app. The participants were visited once at 4 weeks to replenish supplies and check if there were any problems they faced using the app that could better be addressed in person. Participants were paid a weekly US $25 participation stipend for logging into the app at least twice a week, but participants were free to use the app as they chose. This was the same compensation provided for a separate study on gym-based exercise.

Data written to the cloud from each game session were analyzed for number of log-ins, time spent on the app, and actual time spent playing the games. In addition, by analyzing the acquired EMG signals, we also measured the number of detected muscle contractions, the integrated EMG levels (iEMG), and peak EMG levels during each game session using custom-written MATLAB code (Mathworks, Inc). A Likert-scale survey, based on a widely used questionnaire for the *perceived usefulness*, *perceived usability*, and *user acceptance of information technology*, was administered on the web after the 8-week training period.

Before any pilot testing on these 4 participants, 2 other participants were enrolled to conduct feasibility testing. Feasibility testing was conducted to ensure that individuals with moderate and very limited upper mobility would be able to set up and carry out the exergames on their own. These participants helped provide feedback on the app, and several features were modified and some functionality was corrected as a result of their input. Examples include changing the background in the racing game, making threshold adjustments more user-friendly with the calibration feature and saving the user's default thresholds, and enlarging the control buttons on the screen to make navigating the app more user-friendly.

Usability of the System

The usability of the system was addressed via a web survey administered through Qualtrics. Participants who had used the WOW-Mobile app were asked 21 questions regarding the usability and usefulness of the app. Of the 21 questions, 18 (86%) were ranked on a Likert scale and 3 were open ended. All 4 WOW-Mobile pilot participants responded to the survey. The mean and SDs were calculated using SPSS Statistics 24 for the quantitative questions, and the qualitative questions are described below. Given that the sample size was 4 and the qualitative responses were very brief, these responses were not analyzed using a qualitative coding method and are presented below.

Results

WOW-Mobile Validation and Bench Testing

The performance specifications of the wireless sensors are provided in Table 4. The sampling rate is sufficiently fast to provide what appears to the user to be continuous monitoring of muscle activity, heart rate, and acceleration. All use Bluetooth Low Energy, which provides reliable wireless transmission of the physiological data while optimizing for energy consumption. They are all battery operated, and batteries can either be very easily replaced or have a rechargeable battery.

Table 4. Workout on Wheels-Mobile sensor performance specifications.

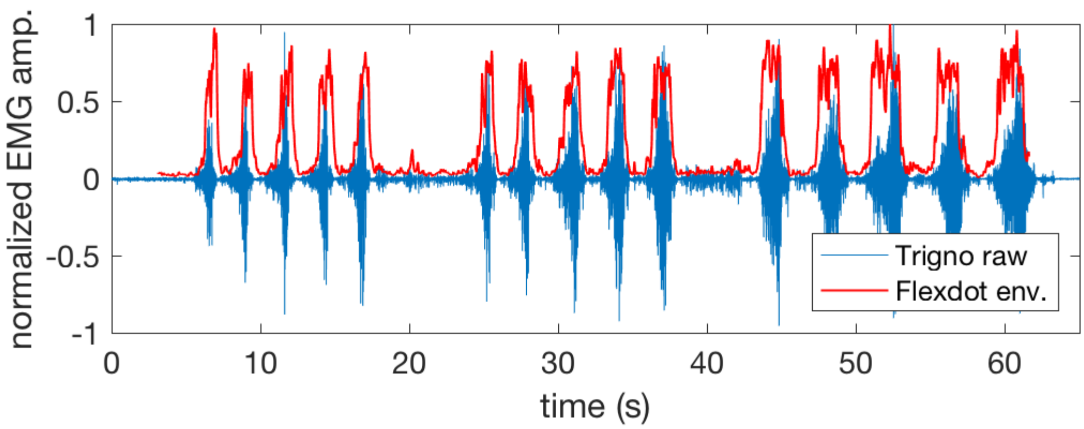
Characteristics	Electromyography sensor	Alpha 2 heart rate monitor (Mio Global)	Custom accelerometry module
Sampling rate	64 Hz	Continuously	4 Hz
ADC[a] resolution	15 bits	Unknown (1 BPM[b])	10 bit
Dynamic range	0-60 V	30-220 BPM	±8G
Dimensions	3.5 cm×3.5 cm×1.2 cm	4.5 cm×3.2 cm×1.5 cm+wrist strap	3.8 cm×5 cm×1.27 cm+wrist strap
Wireless protocol	Bluetooth Low Energy	Bluetooth Low Energy	Bluetooth Low Energy
Battery	3 V 210 mAh Li coin cell	3.7 V 170 mAh Li-Po	Rechargeable 3.7 V 500 mAh Li-Po
Battery life	8 hours of transmission	5 years	5 years

[a]ADC: analog to digital converter.

[b]BPM: beats per minute.

The raw EMG from the Trigno during 3 sets of 5 bicep curls is shown in blue in Figure 7. The Flexdot performs on-board signal processing and transmits a 2-pole low-pass filtered EMG envelope, shown in red in Figure 7. The Flexdot envelope can be seen to accurately track the gold standard activity acquired by Trigno. Some differences are expected because of the differences in the position of the sensors. The Flexdot and Trigno were placed adjacent to each other on the same muscle belly. The completely stand-alone wireless nature of the Flexdot and the Bluetooth transmission enable the user to use our app virtually anywhere at any time. Other commercial wireless EMG systems require a base station connected via a USB cable to a computer or otherwise require tethering to a computer.

Figure 7. EMG acquired by the Flexdot sensors (red) accurately captured the envelope of the raw EMG activity that was measured by high-end commercial EMG sensors (blue). EMG: electromyography.



All data collected from the connected sensors were written to the server at the end of each game session. Data transmission was monitored on Android Studio Profiler, whereas the user wearing the sensors walked gradually away from the phone. The range of transmission for the Bluetooth connection was 10 m inside the building and as far as 100 m in an unobstructed environment. Within the 10-m range, there was zero packet loss. Server upload and download speed were monitored on Speedtest by Ookla and was measured to be 54.8 Mbps and 55.3 Mbps, respectively. Data from a 10-second game with 1 Flexdot connected, for example, require 5 milliseconds on average to write.

Pilot Study Results

A total of 4 participants with varying levels of SCI, whose primary mode of ambulation is by wheelchair, exergamed on a weekly basis for 8 weeks using our WOW-Mobile app. The mean time spent on the app ranged from 89 to 267 minutes per week (Figure 8). The 2 participants who reportedly did not exercise at the start of the study (T12 and T6 injuries) averaged 58 (SD 24) and 157 (SD 61) minutes of exercise per week during the study. The participant with a C7 injury, who had not previously exercised in his home, averaged 48 (SD 14) minutes per week, and the participant who already had an adapted gym in his home averaged 52 (SD 18) minutes per week. From the EMG collected on the cloud server, we measured the total integrated EMG, which is linearly related to energy expenditure [37]. iEMG and inferred energy expenditure increased in proportion to the time spent on the app (Figure 9; r=0.86); that is, the more they used the app, the more energy they expended. In contrast, the maximum EMG level during the sessions, or peak EMG, did not correlate with the time spent on the app (r=0.040), as would be expected, because the peak value is fairly arbitrary—the goals of the games did not encourage them to try to hit their true MVC. Similar results were found for the racing game (r=0.86 for iEMG vs total session time) and boxing (r=0.57).

Figure 8. The average number of minutes spent per week using the app and exergaming by each participant.

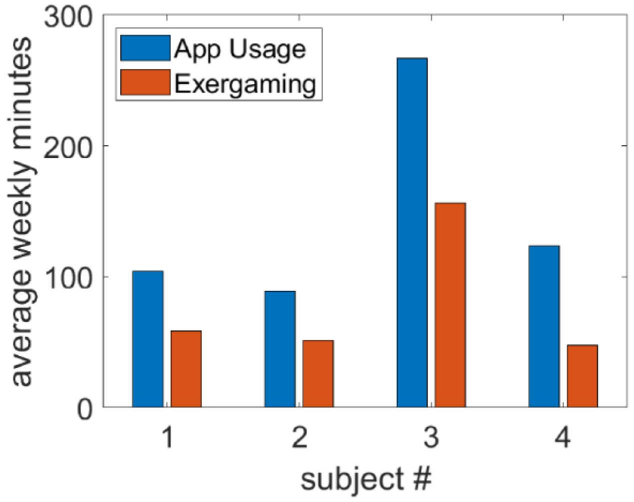


Figure 9. Scatterplots indicating the correlation between time spent on app and energy expenditure, as measured by iEMG. iEMG: integrated electromyography.

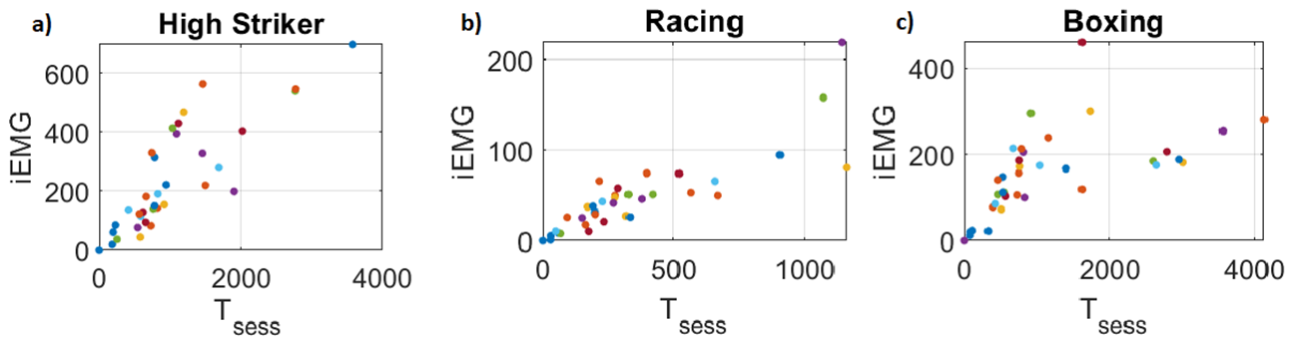
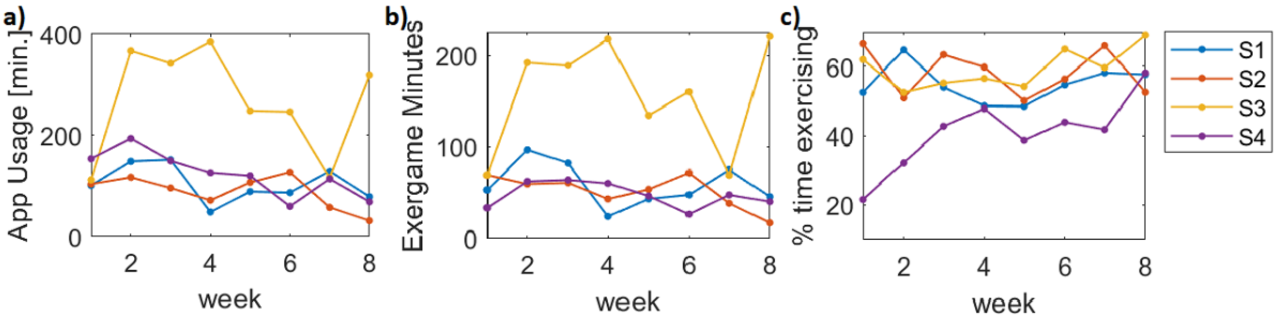


Figure 10 shows that the minutes spent exergaming each week varied from week to week. From the group chat, participants indicated certain weeks that were busier and did not feel able to make more time for exercising. Participant S3 far exceeded other participants in minutes spent exergaming. This participant indicated through the group chat the most interest in the leaderboard and how to improve his rank in the leaderboard. He also expressed hesitation with allowing others to see him while exercising.

The percentage of time logged onto the app that was spent in the exergaming sessions ranged from 48% to 69% for S1, S2, and S3. S4 was the only participant who had hand mobility impairment and had to use his knuckles to tap the screen and had a home care helper to help with snapping electrodes to the sensors. By week 3, his efficiency reached 43%, and by week 8, his efficiency reached 58%.

Over the course of 8 weeks, 234 messages, comprising 20 conversations or *threads*, were sent over the WhatsApp group chat. The 4 participants reported a total of 18 issues and concerns about the WhatsApp group chat, 9 (50%) of which were related to the mobile app itself. These included issues regarding difficulty assigning sensors, games not working because the threshold was not set appropriately, and app crashing when Wi-Fi connectivity was lost, and once because of a billing issue with the cloud service that disabled app use for a day until service was restored. Most of these issues were resolved by week 2. Other nonapp-related issues included running out of the disposable EMG electrodes or batteries or not feeling physically well enough to exercise. There were a couple of conversations consisting of dozens of messages to welcome the participants to the group chat and encourage the participants to write to the group about any issues they had using the app. It was clear that in a few of the issues reported, the instructions simply needed to be made clearer at orientation (eg, the fact that multiplayer functionality was only enabled at that stage for the racing game); most of the other app-related issues were resolved by having a video chat to adjust the EMG thresholds during the first week of the study.

Figure 10. WOW-Mobile app usage over the 8-week period. (a) Total number of minutes spent on the app. (b) Number of minutes spent in exergaming sessions on the app. (c) Percent time on app spent exergaming.



User Perceptions—Quantitative Responses

The results from the questionnaire on the perceived usefulness of the WOW-Mobile app are presented in Table 5. Participants largely found the app to be useful. Participants reported that the app made it easy to track progress, increased motivation to exercise, and enabled participants to increase their level of physical activity. This information is presented in Table 5. Participants were also asked about the perceived ease of use of the WOW-Mobile app. Participants reported that the app was clear and easy to use. These data are presented in Table 6.

Finally, participants were asked about the usefulness of the various features of the app (Table 7). The highest rated game features were the single-player racing or spinning game and the boxing game. The lowest rated game was the resistance band game. The highest rated exercise features were the ability to monitor the heart rate and the ability to adjust EMG thresholds. The ability to monitor muscle activity was the lowest rated feature for all participants.

Table 5. Perceived usefulness of the app on a Likert scale ranging from 1 to 5 (higher scores indicate stronger agreement).

Perceived usefulness	Mean score (SD)
Using the mobile fitness app enabled me to increase my level of physical activity	4.25 (0.96)
Using the mobile fitness app enabled me to reach my peak fitness levels	3.75 (0.5)
Using the app improved my motivation to exercise	4.5 (1.0)
Using the app enhanced the effectiveness of a workout session	4.0 (0)
Using the app made it easier to track my progress	4.7 (0.77)
I found the app useful for improving, and then maintaining, fitness level	3.3 (0.5)

Table 6. Perceived usability of the app on a Likert scale ranging from 1 to 5 (higher scores indicate stronger agreement).

Perceived usability	Mean score (SD)
How to operate the app is clear	4.5 (5.8)
I found it easy to get the app to do what I want it to what I wanted it to do	4.0 (1.7)
It would be easy for me to become skillful at using the app	4.3 (1.2)
Overall, I found the app easy to use	4.3 (1.2)

Table 7. Usefulness of various app features (both games and exercise monitoring features; ranked on a Likert scale from 1 to 5, with higher scores indicating more usefulness).

Usefulness of app features	Mean score (SD)
Single-player racing or spinning game	4.0 (1.2)
Boxing game	4.0 (1.2)
Resistance band game (*Break-It-Like-Junior*)	3.5 (1.0)
Multiplayer racing game	4.5 (1.0)
Leaderboard (seeing your ranking and score among the other app users)	4.5 (1.0)
Ability to monitor muscle activity	3.0 (0)
Ability to monitor heart rate	4.0 (1.2)
Flexibility to adjust EMG[a] (muscle activity) thresholds for each game and muscle	4.0 (1.2)

[a]EMG: electromyography.

User Perceptions—Qualitative Responses

The questionnaire also included open-ended responses. The participants reported that the most positive aspects of the app included monitoring their progress and that it keeps track of how much time was spent in each session, helped them to "exercise in an animated and engaging way," and motivated them to work out. The most negative aspects of the app were reported to be glitches, app crashing, and that *some of the games can be interpreted as being created for children not adults*. There was one response to the free-response question: "Overall, I believe like anything, the app could use improvement, maybe look more modern, and include more features or different exercises but the fact that someone is creating an exercising app for people who are wheelchair bound is simply amazing."

Discussion

Although mobile technology is being leveraged for fitness monitoring [38,39], and now includes exergaming [16,18], these apps are not tailored for individuals in wheelchairs. The exergaming apps that are available do not focus on upper limb exercises and are not equipped to track isometric contractions, as used in resistance exercises recommended for individuals in wheelchairs [38,39]. An exergaming PC app was very recently developed [40], but our app was distinct in its design to enable exergaming for individuals in wheelchairs in at least 2 ways: (1) exergames by Garcia-Hernandez et al [40] are on a PC platform, whereas WOW-Mobile was designed to maximize the flexibility of where and when this system could be used to help overcome barriers to exercise; and (2) the games developed in the study by Garcia-Hernandez et al [40] do not require sustained isometric strengthening contractions, such as resistance arm band exercises that are recommended for CRT; rather, their games require short bursts of muscle contraction. The WOW-Mobile system achieved its design objectives of increasing the likelihood of improving fitness levels and providing individuals in wheelchairs with the independence and flexibility to work out in the convenience of their own home by using body-worn sensors that communicate wirelessly with the WOW-Mobile phone app. The exergaming enabled the 3 of the 4 participants who had lower mobility impairment and had not previously exercised in the convenience of their own home to do so regularly (Figure 7 and Figure 9—S1, S3, and S4). Analysis of the participants' EMG indicated that when users increased their time on the app, they burned more calories. SDs in minutes of exercising per week ranged from 14 to 61 minutes, which, based on participant feedback, was because of variability in busyness from week to week. Even after drops in exercise, participants still tended to resume more typical levels of exercise (Figure 9), indicating that they were incorporating exercise into their lifestyle, not just letting it be a one-time spurt of commitment. The participants with paraplegia who had good hand mobility had more consistent percent time exercising, whereas the one participant with tetraplegia showed a logarithmic rise in time efficiency on the app (Figure 9). This learning curve pattern indicates that it took time to settle into a routine and become accustomed to using the WOW-Mobile system, but by week 3, he already reached similar levels of efficiency as the rest of the cohort. According to feedback from the perceived usability and usefulness questionnaire as well as on the mobile messaging app, the app was usable and exercised more motivating.

On the basis of the problems that were expressed on the group chat, the most problematic issues using the app were due to lost internet connectivity, assigning sensors incorrectly, or difficulty setting appropriate EMG thresholds for each game to ensure that the users were challenged to reach an appropriate effort level. We are currently working on developing an offline version of the app that does not require continuous cloud server communication and devising algorithms to automate the threshold setting process. We have also been improving the user interface to make the assignment of sensors more user-friendly.

The mobile app, while allowing participants to perform holistic upper limb exercises, did not explicitly facilitate the circuit training prescribed by our team and others. When playing the exergames, the users were motivated to reach high scores and did not necessarily pace themselves as would be done in a circuit training program guided by knowledgeable physical trainers. One way to overcome this limitation is to design the games such that compliance with the desired workout is measured and users gain higher scores for closer compliance with the workout. For example, for the racing game, the physical trainers could create their own sessions exercising for the prescribed duration and intensity levels. The participants could select these sessions as the ghost player in a multiplayer game, and the objective of the game would be to remain within a certain distance from the ghost player. The WOW-Mobile fitness app already has the basic functionality built in to carry out such a protocol. Future versions of the app will include an option to play the games in a preset sequence rather than the user choosing games and number of repetitions.

The multiplayer gaming and leaderboard features were designed to make exercise and mobile fitness feel like an activity that could be done in a community with friends. One limitation of the study is that the participants did not have much opportunity to build community with each other before beginning to use the app, nor were they given opportunities to get to know each other outside of using the app together, and therefore, the potential of these features to help motivate users to play the games, and therefore exercise more, could not be evaluated in this study. Despite the participants not knowing each other before the study, the participants with thoracic level injuries strongly agreed that the app motivated them to exercise. We observed that for one participant who had impaired hand mobility, using the app would take substantially more effort and tedium to use, for example, to tap the screen to navigate the app. Although we can only speculate from our pilot study over differences in perception by age, gender, level of injury, and access to exercise facilities at baseline, the results provide us more basis for hypotheses to test in the future. For example, given that the one participant with a cervical level injury consistently rated the app's usefulness lowest out of all the participants, we would hypothesize for future studies that WOW-Mobile is effective for individuals whose lower mobility is impaired but not their hand mobility. In addition, the participants who only rated the app's usefulness with 4s and 5s did not exercise regularly before the study. This is consistent with our hypothesis that WOW-Mobile helps individuals with lower mobility impairment to overcome barriers to exercise.

On average, participants rated the usefulness of all the features between agree and strongly agree (4.0-4.5), with the exception of the monitoring EMG, for which the average was 3.75/5. They expressed valuing the ability to monitor their heart rate on the app, but less so on muscle activity. This could be due to target heart rates being more common knowledge and people, in general, being more accustomed to seeing heart rate. Therefore, we plan to design a more relatable metric based on EMG, such as calories burned, in future versions of WOW-Mobile.

The participants reported agreeing or strongly agreeing that it was clear how to use the app and that the app was easy to use but were more neutral on getting the app to do when they wanted it to do. The latter is consistent with the issues that were reported on WhatsApp, which were either already resolved or related to app functionality that is tied to network connectivity and the requirement to be connected to their user account on the cloud. We plan to develop an offline mode in which users can still enjoy, albeit limited, functionality even when the connection to the cloud drops.

The barriers to exercising that the participants were able to overcome by using the WOW-Mobile system included lack of access to adapted gyms, transportation to physical therapy clinics or gyms, and cost of physical therapy or gym memberships. Furthermore, anecdotal evidence indicates that being able to exercise in the comfort and privacy of one's own home helped the participants overcome self-consciousness with their disability [41]. For example, one participant wanted help with a problem setting threshold but was reluctant to do a video chat; this same participant was the only one who declined a photo or media release form. Other participants expressed wanting to know what they looked like while exercising and expressed discomfort with having to be transferred while others besides the regular personal assistant were around. The fact that all these participants spent between 89 and 267 minutes per week carrying out their workout in wheelchairs for 8 weeks indicates that mobile app–based EMG-driven exergaming is a promising approach to facilitate and encourage regular exercise for individuals in wheelchairs.

Conclusions

We have developed a mobile app–based fitness system that provides individuals in wheelchairs with a flexible way to carry out a goal-oriented, holistic workout with motivating feedback. We have bench tested the WOW-Mobile system and found the system to meet design specifications to support a circuit training workout that has been recommended for people with SCI and which supports individuals in wheelchairs to overcome existing barriers to regular exercise, including transportation and financial means to access gyms with adapted equipment and frequent and regular in-person visits with physical trainers. We also tested and verified the feasibility of individuals in wheelchairs using the WOW-Mobile system in their own homes. The participants who had thoracic level injuries and maintained hand mobility benefited most from WOW-Mobile and reported strong agreement with the overall ease of use of the app as well as the usefulness of the app in motivating them to exercise and enabling them to exercise more. As noted by one of the participants, mobile fitness tailored for individuals in wheelchairs is an unmet need and “the fact that someone is creating an exercising app for people who are wheelchair bound is simply amazing.”

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Demonstration of connecting the wireless sensors.
[MP4 File (MP4 Video), 16672 KB - rehab_v8i1e16054_app1.mp4]

Multimedia Appendix 2
Demonstration of the high striker or resistance arm band exergame.
[MP4 File (MP4 Video), 35731 KB - rehab_v8i1e16054_app2.mp4]

Multimedia Appendix 3
Demonstration of the multiplayer racing or spinning exergame.
[MP4 File (MP4 Video), 29891 KB - rehab_v8i1e16054_app3.mp4]

Multimedia Appendix 4
Demonstration of the boxing exergame.
[MP4 File (MP4 Video), 60407 KB - rehab_v8i1e16054_app4.mp4]

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Abbreviations

CRT: circuit resistance training
EMG: electromyography
iEMG: integrated electromyography
MVC: maximum voluntary contraction
SCI: spinal cord injury
WOW: Workout on Wheels

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Original Paper

One-to-One and Group-Based Teleconferencing for Falls Rehabilitation: Usability, Acceptability, and Feasibility Study

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Abstract

Background: Falls have implications for the health of older adults. Strength and balance interventions significantly reduce the risk of falls; however, patients seldom perform the dose of exercise that is required based on evidence. Health professionals play an important role in supporting older adults as they perform and progress in their exercises. Teleconferencing could enable health professionals to support patients more frequently, which is important in exercise behavior.

Objective: This study aims to examine the overall concept and acceptability of teleconferencing for the delivery of falls rehabilitation with health care professionals and older adults and to examine the usability, acceptability, and feasibility of teleconferencing delivery with health care professionals and patients.

Methods: There were 2 stages to the research: patient and public involvement workshops and usability and feasibility testing. A total of 2 workshops were conducted, one with 5 health care professionals and the other with 8 older adults from a community strength and balance exercise group. For usability and feasibility testing, we tested teleconferencing both one-to-one and in small groups on a smartphone with one falls service and their patients for 3 weeks. Semistructured interviews and focus groups were used to explore acceptability, usability, and feasibility. Focus groups were conducted with the service that used teleconferencing with patients and 2 other services that received only a demonstration of how teleconferencing works. Qualitative data were analyzed using the framework approach.

Results: In the workshops, the health care professionals thought that teleconferencing provided an opportunity to save travel time. Older adults thought that it could enable increased support. Safety is of key importance, and delivery needs to be carefully considered. Both older adults and health care professionals felt that it was important that technology did not eliminate face-to-face contact. There were concerns from older adults about the intrusiveness of technology. For the usability and feasibility testing, 7 patients and 3 health care professionals participated, with interviews conducted with 6 patients and a focus group with the health care team. Two additional teams (8 health professionals) took part in a demonstration and focus group. Barriers and facilitators were identified, with 5 barriers around reliability due to poor connectivity, cost of connectivity, safety concerns linked to positioning of equipment and connectivity, intrusiveness of technology, and resistance to group teleconferencing. Two facilitators focused on the positive benefits of increased support and monitoring and positive solutions for future improvements.

Conclusions: Teleconferencing as a way of delivering fall prevention interventions can be acceptable to older adults, patients, and health care professionals if it works effectively. Connectivity, where there is no Wi-Fi provision, is one of the largest issues. Therefore, local infrastructure needs to be improved. A larger usability study is required to establish whether better equipment for delivery improves usability.

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KEYWORDS

aged; postural balance; telerehabilitation; patient compliance; accidental falls; mobile phone

Introduction

Background

There are approximately 55,000 falls-related emergency hospital admissions in England among patients aged 65 years and older, and around a third of people aged 65 years and above fall each year [1], costing the National Health Service (NHS) £4.6 million (US $6.2 million) per day [1]. Strength and balance exercises have been proven to be effective in reducing the risk and rate of falls [2-4]. However, for these exercises to be effective, a minimum effective dose (3 times a week) must be reached and then maintained in the long term for sustained effects [3]. We know that the role of health care professionals is important in both motivating older adults and progressing their exercise to ensure that the exercises are challenging [5,6]. Currently, strength and balance programs delivered by NHS falls rehabilitation services are inadequate in dose [7], and most services see patients only once per week [7].

Teleconferencing could be an effective way of delivering evidence-based strength and balance exercises by providing increased contact with health care professionals. It has been demonstrated that introducing video consultations is complex and disrupts established processes and routines [8,9]. Concerns have been raised about technical and clinical quality, privacy, safety, and accountability [8,9]. The evidence base on remote consultations by video technology is increasing [10-12], and studies have reported positive benefits and similar satisfaction levels. However, studies that focus on the role of teleconferencing for fall prevention are sparse. Some studies have focused on the delivery of Tai Chi [13,14], and others have focused on other types of rehabilitation [15-17]. The systematic review by Kairy et al [15] examines the clinical outcomes, clinical process, health care utilization, and costs associated with telerehabilitation (therapy delivered through teleconferencing). Clinical outcomes of telerehabilitation programs were found to be as good if not better when compared with those of standard programs. In addition, adherence to telerehabilitation was found to be good. Other reviews have provided some potential but are still not conclusive [18]. Social networks and friendship have also been identified as important aspects of group telerehabilitation programs [19].

As health professionals do not need to travel (cost and time) to patients' houses, teleconferencing could allow them to see patients more regularly than once a week, increasing exercise dose and motivation. We know that health professionals are an important source of motivation [5,6,20]. Strength and balance exercises could be delivered both one-to-one in patients' homes or in groups. Some patients do not have the confidence or ability to attend face-to-face group exercise sessions [21]. It may be that being part of a small virtual group either increases confidence and ability to attend a face-to-face group session or enables adherence through long-term exercise and peer support available in the home [22].

Objectives

The aim of our study is to examine whether smartphone-based teleconferencing (linked to a television [TV] or screen) is usable, acceptable, and feasible for health professionals and older adults as a means of delivering evidence-based fall prevention strength and balance home exercise programs. Acceptability is a multifaceted construct that considers the extent to which people that deliver or receive a health care intervention consider it to be appropriate [23]. When referring to feasibility, we particularly focus on practicality (to what extent teleconferencing could be conducted with the intended participants using existing means, resources, and circumstances) and implementation (to what extent teleconferencing could be used to successfully deliver rehabilitation to intended participants) [24]. Usability focuses on whether a person can use it for its intended purpose [25]. Models such as the technology acceptance model (TAM), which focuses on whether a technology is perceived as useful and whether it is easy to use [26], are important when developing technological interventions and are considered within our study. We took a two-step approach to explore acceptability, usability, and feasibility.

Methods

Patient and Public Involvement Workshops

We held 2 patient and public involvement (PPI) workshops to gain initial feedback on teleconferencing:

1. Group of health professionals from a Manchester Falls Service
2. Group of community-dwelling older adults aged 60 and over years from an Age UK strength and balance falls exercise group

The teleconferencing involved using Skype on the smartphones of health professionals and patients and connecting the phones to either a screen or TV. We know that older adults feel more comfortable using technology they are familiar with [27], and therefore, we thought this would be more acceptable than specific teleconferencing equipment.

The health professional workshop was run by a researcher who was also an occupational therapist (OT) in a different falls team. The older adult workshop was run by the OT and the lead researcher for the project. In the workshops, we discussed the initial concept of the technology with an explanation of why we thought it was important (perceived usefulness), what we were trying to achieve, and how teleconferencing could work for rehabilitation. We then connected the phone to a large screen (as would have been done for delivery) and demonstrated to the whole group what patients and health professionals would need to do and what they could see. We asked for feedback on the concept and whether participants (health professionals and older adults) thought health professionals and patients would be able to use it (perceived ease of use). Discussions on stands for smartphones and equipment used (whether to use Chromecast or a high-definition multimedia interface [HDMI] cable to connect the phone to a TV or screen) were included. Notes were taken on the feedback provided.

Contact with older adults and health professionals was classed as PPI rather than formal research. Therefore, we only collected aggregate details on gender, ethnicity, and previous experience of technology for participants and gender and clinical background for health care professionals.

Usability and Feasibility Testing

The research proposed in this stage was predominantly qualitative. This enables us to establish whether the technology is acceptable to patients and health professionals (qualitative methods) and assess its usability and feasibility in practice (technology testing) and to make improvements if required. The study was granted ethical approval by the North West Greater Manchester Central NHS Ethics Committee (integrated research application system: 205980, June 2016).

Sampling Principles and Procedures

Older adults at risk of falls (aged 50 years and above), identified through the current community falls rehabilitation services from one service in Manchester, were recruited, with the aim to recruit 20 participants. Participants were those who would usually be offered a home exercise program by the service and could be at any stage in their rehabilitation (eg, we wanted patients both at the start of their program and also further on in their program so that we could assess the feasibility of the delivery of most of the evidence-based program through teleconferencing). Older adults who were unable to follow instructions and those with severe visual or hearing impairment were excluded. At this point, there were no other exclusion criteria. The lead researcher provided technical support to patients and health professionals during the study period.

The Intervention

The Technology

For testing, we used Samsung Galaxy S4 phones and *pay as you go* sim cards and 4G networks, and where possible, we connected them to the patients' Wi-Fi networks. Both the health professional and patient had a phone provided by us that they connected to either their own TV or a provided screen either using a HDMI cable or through Google Chromecast. When the device was used for teleconferencing, it could be placed in a docking station, which then connected to the television.

The technology was tested using either 4G-enabled phones or by providing broadband at patients' homes. The broadband (where not already in place) was paid for and set up by the research team with no cost to the patient. The smartphones and docking station were provided by the research team, and compatible screens were also made available. They were also given a wireless headset to ensure they could hear each other during the videocall. We used Skype for both individual and group-based virtual home exercise in the patients' own homes, with health professionals delivering the exercise program from their offices.

The Exercise

Patients were offered standard service for 2 weeks (to ensure safety) before usability testing. They were then offered the same evidence-based home exercise program that is delivered through standard service, but it was delivered through the technology virtually. Patients received additional contact (twice a week rather than once a week) during the testing period. The health professional delivered the evidence-based Otago exercises [28], with additional exercises from the evidence-based falls management exercise (FaME) program where appropriate [29].

The technology was used to deliver the following:

1. One-to-one home-based exercise twice over a period of 2 weeks for an hour through the smartphone system.
2. A group-based strength and balance program (2-3 patients) once over a period of 1 week for an hour through the smartphone system. The health professional was able to see all the patients, and the patients were able to see each other.

The researcher was present with the patients at the time of the exercise session and supported the patient to use the technology where required.

Measurements

Usability

This included recording issues the health professional and the older adults faced with regard to the technology throughout the testing period (issue-log or field notes).

We explored usability issues such as setting up and connecting the technology and accessing Skype, requirement for internet access or testing of 4G through mobile phone and whether teleconferencing would connect, and whether it was reliable through the use of 4G technology rather than Wi-Fi. The positioning of the technology for delivery of exercise both in the patients' homes and at the offices of health professionals.

Feasibility

The size of the groups receiving the intervention (ie, the ideal number of patients) and the types of exercise that could be delivered through the smartphone system were considered.

Interviews and Focus Groups

Health professionals from 3 falls services in Manchester were recruited to participate in 3 focus groups following the testing period. We chose focus groups, as each group of health professionals was a team delivering a service together. The focus groups allowed them to discuss their experiences and "bounce off" each other, eliciting more experiences and rich data. All members of the staff (n=17) in each team were given study information by their team leader and asked if they were available for a focus group at their place of work.

The service involved in the testing gave direct feedback on their experiences of using the technology. The other two services received a demonstration of the technology and were asked to give their feedback based on a similar interview schedule (Table 1).

Older adults who participated took part in a one-to-one interview from their own homes. The questions in the interview and focus group schedules were based on FAll Repository for the design of Smart and sElf-adaptive Environments prolonging Independent livinG (FARSEEING) [30] consortium guidelines (a European-funded project that examined the design and implementation of technologies around falls) and the TAM [26]. The following key areas were explored in relation to the hardware (phone and setup) and teleconferencing (Skype): ease of use, adaption of use, reliability, choice, and control. We explored whether it was acceptable and feasible for patients to receive their program in this way and whether health professionals were willing to deliver this way, and preference for group or individual virtual exercise was also explored. Open-ended questions were designed to elicit a wide-ranging response.

Table 1. Interview and focus group schedule.

Questions	Acceptability	FARSEEING[a] guideline	TAM[b]	Feasibility
Older adults' interview schedule				
What did you like or dislike about using a smartphone to exercise with the health professional?	✓[c]	• Ease of use • Adaption of use • Reliability	• Perceived ease of use	✓
Were there any issues with using a smartphone to participate in your exercise sessions?	—[d]	• Ease of use • Adaption of use	• Perceived ease of use	✓
Were there any issues with space to do the exercises?	—	—	—	✓
Did you feel safe?	—	• Choice and control • Reliability	—	✓
How did it compare to the normal program delivered in person by the health professional?	✓	—	• Perceived usefulness	—
What did you think about exercising in a small group?	✓	—	• Perceived usefulness	✓
Were there any issues?	—	• Ease of use • Reliability	• Perceived ease of use	✓
Did you enjoy it?	✓	—	• Perceived usefulness	—
What did you enjoy or dislike?	✓	—	• Perceived usefulness	—
Would you exercise in a group without a health professional?	✓	—	• Perceived usefulness	✓
Did you prefer exercising one-to-one or in a group?	✓	—	• Perceived usefulness	—
How did you feel about being provided with broadband? (where applicable)	—	—	—	✓
Health professionals' focus group schedule				
Teleconferencing and taking part in the exercises using a smartphone				
ALL[e]: What do you think about delivering exercise virtually?	✓	• Reliability • Choice and control	• Perceived usefulness • Perceived ease of use	✓
What do you think the barriers or issues are?	—	• Reliability • Choice and control • Ease of use • Adaption of use	• Perceived ease of use	✓
What do you think the advantages are?	—	—	• Perceived usefulness	—
CFS[f]: How was your experience of delivering exercises virtually?	—	• Reliability • Choice and control • Ease of use • Adaption of use	• Perceived ease of use • Perceived usefulness	✓
CFS: Were there any exercises that you could not deliver?	—	—	• Perceived usefulness	✓
CFS: Were you able to adapt the exercises?	—	—	• Perceived usefulness	✓
CFS: Did you feel that there were safety issues?	—	• Reliability • Choice and control	• Perceived usefulness • Perceived ease of use	✓

Questions	Acceptability	FARSEEING[a] guideline	TAM[b]	Feasibility
CFS: Did you feel that patients were confident in carrying out exercises in this way?	—	—	• Perceived usefulness	✓
CFS: For which patient group do you feel that this intervention would be appropriate?	—	—	• Perceived usefulness	✓
CFS: Were there any issues with connecting the technology?	—	• Ease of use	• Perceived ease of use	✓
CFS: Did you feel that you had enough technical support?	—	• Ease of use	• Perceived ease of use	✓
CFS: Were there any issues with Wi-Fi access or reliability?	—	• Reliability	—	✓
CFS: Were there any issues with having enough space or room to deliver the exercises from your office?	—	—	—	✓
CFS: Did you feel that patients were safe?	—	• Reliability	• Perceived usefulness	✓
CFS: How did it compare to delivering your normal home exercise service?	✓	—	• Perceived usefulness	✓
ALL: What do you think about using technology to deliver exercise virtually to a small group?	✓	—	• Perceived usefulness	✓
CFS: Were there any issues with using a smartphone to deliver to small groups?	—	• Ease of use • Reliability	• Perceived ease of use	✓
CFS: Did you feel that it was beneficial to patients. If so, how?	✓	—	• Perceived usefulness	—
CFS: Were there any issues with delivering in this way?	—	• Ease of use • Reliability	• Perceived ease of use	✓
CFS: What did the patients think of it?	✓	—	• Perceived usefulness	—
Overall				
Would you use a smartphone again or continue to use it if you could?	✓	—	• Perceived usefulness	✓
If not, why not and which parts of using a smartphone did you not like?	—	• Ease of use	• Perceived usefulness • Perceived ease of use	✓
What needs to be improved for using this system in your routine practice?	—	• Ease of use	• Perceived ease of use	✓

[a]FARSEEING: FAll Repository for the design of Smart and sElf-adaptive Environments prolonging Independent livinG

[b]TAM: technology acceptance model.

[c]✓: the question relates to that concept.

[d]—: the concept does not apply to the question.

[e]ALL: all teams were asked, including the ones given a demonstration.

[f]CFS: the identifier for the team who did the actual testing.

Analysis

Follow-up interviews with patients, focus group data with health professionals, and field notes were analyzed together using framework analysis [31]. This is a method of research that provides a clear structure for the coding. NVivo 11 qualitative data analysis software (QSR International) was used to manage the data. The validity of the analysis was checked by returning to the data once themes were identified and also through independent coding conducted by a second researcher on a sample of transcripts. Two researchers conducted discussions around the codes that emerged. This approach ensures rigor [32] by checking the coding of the data. Data from the issue-logs were collated, summarized, and coded within the qualitative data and used to provide triangulation for the focus group or interview data.

Results

Initial Consultation

Initial informal consultation with 3 services indicated that teleconferencing could aid delivery of rehabilitation, reduce the commute time of health care professionals and their chance of being caught up in traffic, and provide extra support to patients. Health professionals suggested that any intervention had to be carefully planned due to safety issues.

PPI Workshops

Demographics of the older adults and health professionals in the workshops are reported in more depth in a previous study [33]. We recruited 5 health professionals, including 2 physiotherapists, 1 OT, 1 rehabilitation assistant, and 1 assistant practitioner. A total of 8 older adults were recruited, 6 of whom were female and all were White British. Two of the older adults participating in the workshop had previously used technology such as smartphones, tablets, or computers.

Health Professional Workshop

The workshop with health professionals found delivering exercise safely was the priority. Health professionals felt that a risk assessment of patients' home environment would be required to ensure that it was safe to exercise and that the equipment was positioned correctly, for example, to ensure that the equipment was positioned where patients could access support during their exercises. They also felt that there were some challenges in delivering exercises through teleconferencing and that they may need to be adapted to be completed remotely.

Practitioners did not want to replace face-to-face consultations with only remote monitoring, as they felt that it is important to have personal contact with the patients. Health professionals felt that face-to-face contact enabled other issues to be identified (non-exercise related) and was also important to ensure that patients conduct exercises safely. They had no preference for the different types of stands or headsets for delivery.

Older Adults' Workshop

Older people did not want to lose their face-to-face contact with health professionals completely and expressed the fear that use of technology could mean that patients would no longer get visits from a health professional. Some older adults stated that the health care professional is the only person they see all week. They thought that extra virtual sessions with health professionals could provide opportunities to reduce loneliness and isolation.

Some older adults stated that they would not like any technology within their homes; they felt that with the presence of technology, their homes would not feel like a home, and they also found the technology intimidating.

Older adults in the workshop had no preference for the different types of stands or headsets, and they were quite happy to wear the headsets; in fact, they quite liked the idea of doing so, as it brought back memories from working.

Usability and Feasibility Study

A total of 7 patients (4 men) with a mean age of 77 years (range: 64-92) participated, and of these patients, 6 agreed to be interviewed; for one interview, the participant's son was also present. Only 2 of the participants who took part already owned a smartphone. Only 2 of the patients already had Wi-Fi, and 1 agreed to let us install Wi-Fi to enable them to use teleconferencing. A total of 11 health professionals took part in the focus groups; 8 were women, 9 were physiotherapists, 1 was a nurse, and 1 was an OT (see the study by Hawley-Hague et al [33] for further demographics).

Data were summarized under barriers and facilitators, with 7 further subthemes. We have also linked themes to the theoretical framework (Table 2). Two overarching themes related to smartphone were established and are discussed in a separate paper where patients used a smartphone app (see the study by Hawley-Hague et al [33]). Some themes only occur for either patients or health professionals.

Table 2. Themes and subthemes from the interviews and focus groups.

Theme and subtheme	Theoretical framework	Quotes	
		Patients	Health care professionals
Barriers			
Poor connectivity	• Reliability • Perceived usefulness • Feasibility	• "If you're not here to rectify it, I wouldn't know what to do, would I?" [Male, aged 92 years] • "So last time we got at least ten minutes, that's the most we ever got, wasn't it?" [Female, aged 69 years]	• "When it worked it was good, but I must say after that session where it overheated so many times, following that I thought what is it, are we going to have that again. So I was very relieved to get through a session where it went all the way through" [Female, physiotherapist, S1] • "They drained when we were actually using it. So battery life wasn't good enough to do the actual full exercise programme" [Female, occupational therapist, S1] • "It was just unfortunate that it was that patient where the phone froze on numerous occasions…then it was the secondary kind of safety issue of it freezes in the middle of the session" [Female, physiotherapist, S1] • "It didn't work as well, connectivity...I don't think you could do it with 4G really" [Female, physiotherapist, S1]
Cost of connectivity	• Feasibility • Acceptability	• "It's the expense of getting the landline as well as getting the broadband...you've got to have broadband and we're going to charge you bom-bom-bom, whatever it is, I didn't like so I got rid of it" [Male, aged 82] • "we'd still have to pay the rental..." [Female, aged 69]	—[a]
Safety concerns	• Feasibility • Perceived usefulness • Perceived ease of use	—	• "I had some concerns also about safety...I'd have thought if we're doing a longer term study you wouldn't be there, and some of the positioning that the equipment would be in wasn't necessarily as safe for the patients..." [Female, physiotherapist, S1] • "Because things like when we went to feet, we couldn't see feet...Yeah. It was those things that I hadn't anticipated until we actually tried it...things like you couldn't see if they had matching black socks then." [Female, physiotherapist, S1] • "...and I was trying to move so that I could actually see what was important, but then to get two people doing that was quite tricky. I couldn't move them around" [Female, physiotherapist, S1] • "...it was very difficult to hear. Because at some points there were almost four people talking...the participants were talking and you were kind of explaining to them" [Female, physiotherapist, S1]
Intrusiveness of the technology	• Adaption of use • Feasibility • Acceptability	• "To leave something permanent it's got to have its place like the television" [Male, aged 82]	• "I think the other thing that frightened the patients was the amount of equipment that came in, like the screens and the cables and that sort of thing. It is kind of intrusive into a person's property" [Female, physiotherapist, S1]

Theme and subtheme	Theoretical framework	Quotes: Patients	Quotes: Health care professionals
Group teleconferencing	• Feasibility • Acceptability	• "I think you've got to be a certain type of person to do a group thing and I'm not that type of person actually, I just prefer to do it my way, my time, when I want, because if you're doing it with a group you're tied to however many number's in the group" [Male, aged 82] • "Probably on my own to be honest but I was willing to give it a go testing that technology" [Male, aged 64]	—
Facilitators			
Increased support or monitoring	• Perceived usefulness • Acceptability	• "Oh yeah, it's nice...yeah, it's like being at a group" [Male, aged 74]	• "If you deliver a one-to-one on the screen, that's a fantastic idea. And I think it would relieve our time, the patient's time. I think you're kind of creating space...when we go and do a one to one at someone's house you've got travelling time, you've got time in the house" [Male, physiotherapist, S2] • "More reinforcement, isn't it? So that's good...monitor their adherence to the programme. Potentially less clinician time." [Female, physiotherapist, S3] • "you could phone them in or teleconference in if you like in between times and check, because you've already shown them, but you could check and do some basic correction and stuff in between and then go for your visits back to increase the programme...Ideally you would go back a few more times to really make sure their technique's perfect, but if I feel they're managing okay, they understand, they've got instructions and papers and all that type of stuff then I will let them go for a few weeks and then go back and see them." [Female, physiotherapist, S2] • "We often find on discharge that we've had voluntary drivers to bring them to groups and things, but then that's not available on discharge; so people that would happily come out can no longer come out. So they would love to carry on exercising in a group, so they would fit into that criteria" [Female, physiotherapist, S3] • "I think one of my chaps did. Because when his son was there in the house, oh, I don't know anyone with Skype, well, I do, Dad, here we go…" [Female, physiotherapist, S1]
Positive solutions	• Feasibility • Ease of use	—	• "Like a CCTV camera, rotation...At least 180 degrees, and up and down" [Female, physiotherapist, S1] • "You have to make sure that technique's right, don't you? That's the thing" [Male, physiotherapist, S3] • "I think if they're screened properly and you're checking them, and also if you've given them a certain exercise you're confident with and then you go back to give them the next ones then I suppose they're just as safe as if...because they'd be doing them by themselves anyway" [Male, physiotherapist, S3]

[a]—: the theme did not occur.

Barriers

Poor Connectivity

The reliability of teleconferencing was a very important issue, and reliability was threatened by a number of issues related to the connectivity of the phone during teleconferencing. One of the issues that occurred was overheating of the device during teleconferencing, which occurred mostly when testing the phone over 3/4G networks. This issue caused anxiety in health professionals. The patients were not as concerned as the health professionals, as a member of the research team was with them; however, they discussed the implications of what they would do if they were alone.

The battery life also seemed to be poor, and we think this was related to overheating due to poor connectivity. When the phones did not overheat, they froze during the teleconferencing, and this also caused concern, particularly for patient safety.

The lack of connectivity did not only cause the phone to overheat or freeze but also caused Skype sessions to suddenly switch off. We tested other forms of teleconferencing, such as Google Hangouts and WhatsApp video calling, but these performed more poorly in places with poor connectivity. In one female patient's house, the reception was very poor, and we never managed to get to the end of a full rehabilitation session without the phone being frozen or the Skype session being disconnected.

Cost of Connectivity

As part of the study, we offered to fund broadband connections if needed. When exploring broadband as a solution to connectivity issues, we learned that a large number of patients do not have landlines; therefore, we could not provide broadband connections for these patients without disruption. In some cases, there was resistance to broadband even when we offered to provide it because of the cost that would need to be sustained once the study had finished. One patient previously had broadband but stopped it because of the cost. Some patients had their landlines taken out due to extra cost because they had mobile phones (even if not smartphones).

Safety Concerns

We have already outlined how poor connectivity caused issues with teleconferencing and concerns over safety. However, there were other practical safety issues around delivering teleconferencing through the phone.

There were concerns over the positioning of the equipment. The majority of patients conducted their exercises in their kitchen (using the kitchen worktop for support), and sometimes, they faced issues with finding enough space and room. We could not use their TVs as originally planned and had to use a separate screen. We used the built-in cameras of the smartphones and found that placing the phone on top of the refrigerator often gave the best view. However, placing the phone on the refrigerator caused other safety issues and would have required patients with balance issues to reach up in the absence of the researcher.

There were issues not only with positioning but also with view and contrast. If patients wore black trousers and black shoes, it was difficult to see their feet, and the room's source of light also affected the view and what the health professional could see. This became a significant issue with group teleconferencing, as the picture of each person became smaller with more people on the screen. Issues with sound were also observed when we tested group teleconferencing (2 patients and the health professional). This was exacerbated by the time lag in Skype and led to patients talking over each other. These were the issues that were predominantly highlighted by health professionals and did not seem to concern patients.

Intrusiveness of the Technology

In addition to positioning and safety, there were issues with the intrusiveness of the technology. Originally, we wanted to use the patients' own TVs for teleconferencing, but as most patients conducted their exercises in the kitchen, this was not feasible; therefore, screens were provided. The intrusiveness of the equipment was raised as an issue by the health professionals. One patient also discussed the worry that the equipment could be seen from his front window and that it could cause a risk of a break-in. He felt that participants had to feel that the equipment had a specific place for it not to be intrusive. However, most patients did not mind having the equipment in their house. Health professionals stated that this could become an issue if we tested it with more patients for a longer period.

Group Teleconferencing

Only 2 patients were able to take part in group teleconferencing, as we needed 2 patients with broadband to be recruited at the same time for it to be reliable. We tried group teleconferencing using 3/4G, which would not connect and thus was not feasible. However, we did discuss group teleconferencing with all patients who participated. Some of the patients felt that they were not "group people," whether the group met face-to-face or virtually, although all participants agreed to test it for us. There were increased safety issues related to group teleconferencing in terms of view and sound. The service we worked with did offer group sessions, and only 2 of the patients recruited for the testing chose to attend a face-to-face group as well as perform their exercises at home.

Facilitators

Increased Support or Monitoring

Health professionals saw the idea of teleconferencing as a time-saving intervention with the potential to save travel time, which enabled them to invest that time back into patients. They also saw it as another tool to enable them to monitor patients' adherence to their program and give them more support. During the follow-up phase of rehabilitation (where the health professional did not see the patient every week), they felt that the technology would enable them to give more input than a telephone call, allowing them to check technique. It would also enable the health professional to check up on the patients remotely and then see them face-to-face if required.

Group teleconferencing also provided an opportunity for group support that patients would not normally get when based at home. From the 2 patients who took part in the group teleconferencing, we received positive feedback, despite one being uncertain about groups. Despite their initial anxiety, this patient enjoyed the group sessions and went on to actually attend a face-to-face group exercise class. Health professionals could see the potential benefits of group teleconferencing for tackling social isolation and building confidence to attend a face-to-face group session. They also discussed how group teleconferencing could provide support through follow-on opportunities where transport was prohibitive to attending face-to-face follow-on groups. Teleconferencing provided an opportunity for other support as several patients went on to explore options for skyping family and friends.

Positive Solutions

Health professionals came up with active solutions for issues with teleconferencing, such as positioning of the equipment and the view of patients. They suggested getting cameras that could rotate so that the patient would not have to reposition them.

They discussed the types of patients it would work with, and that it would be important to ensure that technique was right face-to-face first before delivering virtual support and checking technique. If patients were given the right combination of support (a mix of face-to-face and virtual), they would not perceive a safety issue.

Discussion

Principal Findings

Using teleconferencing for the delivery of rehabilitation exercises for falls prevention seemed to offer more barriers than facilitators. However, the barriers are not insurmountable if we have better connectivity and equipment. The original aim was to make teleconferencing accessible and easy to use by using existing equipment (eg, smartphones' cameras). Although the current technology system is acceptable (perceived usefulness) to health professionals and patients and adequate for follow-up support calls, it is not adequate for the delivery of exercises (not easy to use, feasible, or reliable) [26]. Phones overheated, there was poor connectivity where there was no Wi-Fi, and the view was not adequate for the delivery of new exercises. Issues highlighted around ease of use were predominantly related to the smartphone camera and positioning. The only issue raised with the software (Skype) was the view and sound during group teleconferencing, and the reliability of the teleconferencing was affected by connectivity regardless of the platform. Further equipment is required to enable the safe delivery of exercises to patients.

Overall, participants and health professionals in the workshops and usability testing could see some benefits of teleconferencing in terms of additional support that could be provided and better utility of resources, for example, travel time (perceived usefulness and acceptability). Increased contact and support was identified as the main facilitator for teleconferencing in both the workshops and usability testing and has been identified as important in previous studies [19], and it has also previously been found to lead to higher levels of adherence [15]. We know from other exercise studies and behavioral theory, such as the Theory of Planned Behavior, that social support or social norms (perception that the health professional thinks it is a good thing to do) from health professionals is important to exercise behavior [5,34].

Some of the older adults in the workshop and patients in the usability testing did have some concerns about bringing the technology in to their homes and the technology being intrusive (feasibility), which is something often found in the literature [27]. This was one of the reasons that we tried to focus on technology that patients would already have, for example, connecting phones to existing TVs. However, the location of the TV was not always the best place for the patient to exercise; therefore, separate screens were provided.

Patients who took part in the usability and feasibility testing at no point suggested that they would prefer face-to-face delivery or showed fear that technology would replace human interaction (acceptability and perceived usefulness), which is something often cited in the literature [27,35] and raised by older adults in the PPI workshop. Battery life was one of the other issues raised in the usability testing, and this was especially an issue when the phone was under high use (reliability). Battery life is a recurring issue in usability studies using smartphones [36,37]. The phones used have been upgraded for subsequent studies using smartphones.

In the usability and feasibility study, the main issue within the UK context was the lack of good 4G connectivity. This was particularly an issue in some of the more deprived areas of Manchester, where the connectivity was very poor (reliability and feasibility). It seems that due to socioeconomic reasons, patients had decided to have landlines removed and only used mobile phones (often not smartphones). This raises issues related to digital exclusion, an issue already associated with older adults and those who are on lower incomes [38]. In the current climate where rehabilitation is being delivered remotely because of the COVID 19 pandemic, there are concerns that patients will be excluded because they cannot afford Wi-Fi or a suitable device. They may be excluded because they do not have the skills to use the device even if they are provided with one (digital literacy), as our patients were provided with a large amount of support from the research team. They may have physical, cognitive, and sensory impairments or language barriers that make using technology challenging, particularly if they live alone [39].

Recruitment of health professionals covered 3 different teams in the workshops and usability and feasibility testing, but only 1 team used the technology in practice. We found that the teams that only had the technology demonstrated to them (service 2 and 3) but did not actually use it in practice were more positive about its use (perceived usefulness and acceptability) and generated further ideas around other functionality. In contrast, those who had used the technology (service one) identified more barriers, particularly because the technology was not reliable, but rather than being negative or resistive to technology, they also proposed potential solutions and implementation suggestions (adding another rotating camera).

Limitations

There were limitations to the study during both the workshops and usability and feasibility study. During the workshop, we only illustrated how teleconferencing and the equipment would work, showing the patients and health professionals and older adults what would be seen. However, we did not demonstrate a full session. We did not ask health professionals to deliver an exercise session or ask the older adults to take part in one. This led to some issues not being identified until the usability testing that could have been preempted, such as the challenges related to the view from the phone camera.

At this point, the workshop was conducted with community-dwelling older adults and not patients; therefore, the participants were less frail and complex. It could be argued that they were two different populations, which may have influenced the feedback given. However, we would argue that it was a strength to represent a wide variety of older adults' views. In both the workshops and the usability study, we had a good representation of gender across the older adults, patients, and health professionals.

For the usability and feasibility study, recruitment took longer than anticipated; therefore, a much smaller number of patients were recruited than initially planned. We were also unable to test group teleconferencing effectively, as only one set of patients had Wi-Fi at the same time. However, recruited participants represented a good mix of patients in terms of comorbidities, age, gender, and previous technology experience (some with experience of smartphones and some with no experience). None of the participants had previously used Skype or teleconferencing before the study.

The time period for testing the technology was short and may not have identified all the usability issues. If we had established a longer testing period, then we may have asked the patients to exercise alone using the technology without the presence of someone from the research team. However, during the testing period, we established that with the current technological setup, using the equipment alone would not have been safe.

Conclusions

Overall, we established that teleconferencing as a way of delivering falls rehabilitation can be acceptable to this group of patients and health professionals if it works effectively. There is a lack of research on smartphone-based teleconferencing interventions for the delivery of falls prevention exercise programs.

A larger usability and feasibility testing study is required to establish whether better equipment for delivery improves usability and makes delivery more feasible. The intervention can only be effectively delivered in patients' homes where there is Wi-Fi. The options for delivery still need further investigation, as it is clear from testing that in normal circumstances, teleconferencing cannot be used as a full alternative to face-to-face delivery and can only be used to reduce face-to-face visits and to enhance current care. This study provides important information to health professionals now having to deliver care remotely because of the COVID-19 pandemic. In its current form, although it could possibly be a suitable delivery method for some older adults (those who are able to conduct their exercises without the requirement of physical correction by the health professional) because of connectivity issues, it can only be a suitable option for some patients, not all. The intervention may work more effectively in other countries, such as in the Nordic countries where Wi-Fi is more widely available.

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Authors' Contributions

HH led the research project and its design, has managed the study overall, and has led the writing of the manuscript. C Tacconi and SM provided technical support and advised on the setup and the manuscript. JH, LC, C Todd, and SM provided scientific advice around the design of the study and commented on the manuscript. EM led the PPI work and gave advice on the operationalization of the study and commented on the manuscript.

Conflicts of Interest

C Tacconi owns a share in the spin-off company of the University of Bologna, mHealth Technologies srl. SM owns a share in the spin-off company of the University of Bologna, mHealth Technologies srl. LC owns a share in the spin-off company of the University of Bologna, mHealth Technologies srl.

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Abbreviations

FaME: falls management exercise
FARSEEING: FAll Repository for the design of Smart and sElf-adaptive Environments prolonging Independent livinG
HDMI: high-definition multimedia interface
NHS: National Health Service
OT: occupational therapist
PPI: patient and public involvement
TAM: technology acceptance model
TV: television

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Original Paper

Tablet-Based Telerehabilitation Versus Conventional Face-to-Face Rehabilitation After Cochlear Implantation: Prospective Intervention Pilot Study

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Abstract

Background: Technologies allowing home-based rehabilitation may be a key means of saving financial resources while also facilitating people’s access to treatment. After cochlear implantation, auditory training is necessary for the brain to adapt to new auditory signals transmitted by the cochlear implant (CI). To date, auditory training is conducted in a face-to-face setting at a specialized center. However, because of the COVID-19 pandemic’s impact on health care, the need for new therapeutic settings has intensified.

Objective: The aims of this study are to assess the feasibility of a novel teletherapeutic auditory rehabilitation platform in adult CI recipients and compare the clinical outcomes and economic benefits of this platform with those derived from conventional face-to-face rehabilitation settings in a clinic.

Methods: In total, 20 experienced adult CI users with a mean age of 59.4 (SD 16.3) years participated in the study. They completed 3 weeks of standard (face-to-face) therapy, followed by 3 weeks of computer-based auditory training (CBAT) at home. Participants were assessed at three intervals: before face-to-face therapy, after face-to-face therapy, and after CBAT. The primary outcomes were speech understanding in quiet and noisy conditions. The secondary outcomes were the usability of the CBAT system, the participants’ subjective rating of their own listening abilities, and the time required for completing face-to-face and CBAT sessions for CI users and therapists.

Results: Greater benefits were observed after CBAT than after standard therapy in nearly all speech outcome measures. Significant improvements were found in sentence comprehension in noise (*P*=.004), speech tracking (*P*=.004) and phoneme differentiation (vowels: *P*=.001; consonants: *P*=.02) after CBAT. Only speech tracking improved significantly after conventional therapy (*P*=.007). The program’s usability was judged to be high: only 2 of 20 participants could not imagine using the program without support. The different features of the training platform were rated as high. Cost analysis showed a cost difference in favor of CBAT: therapists spent 120 minutes per week face-to-face and 30 minutes per week on computer-based sessions. For CI users, attending standard therapy required an average of approximately 78 (SD 58.6) minutes of travel time per appointment.

Conclusions: The proposed teletherapeutic approach for hearing rehabilitation enables good clinical outcomes while saving time for CI users and clinicians. The promising speech understanding results might be due to the high satisfaction of users with the CBAT program. Teletherapy might offer a cost-effective solution to address the lack of human resources in health care as well as the global challenge of current or future pandemics.

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KEYWORDS

computer-based auditory training; correction of hearing impairment; cochlear implant; effectivity; intervention study; telerehabilitation; pandemic

Introduction

Background

In recent years, information technology solutions have been developed that allow professionals to treat patients via teletherapy. With regard to rapidly increasing health care expenses owing to the aging of society and even faster medical and technical advances, cost-effective rehabilitation is both a priority and a challenge for users and therapists [1]. This phenomenon has been stressed by the current COVID-19 pandemic crisis, which is transforming our society and has implications for health care [2-4]. Telemedicine has been shown to be an option in previous outbreaks, such as severe acute respiratory syndrome–associated coronavirus or Middle East respiratory syndrome coronavirus [4,5]. An additional benefit is that these digital solutions have the potential to reduce health care costs associated with supervision and high-frequency training [6-8].

So far a teletherapeutic approach is often used in psychotherapeutic sessions with a high level of satisfaction and compliance [9-11]. A positive outcome after home-based therapy has also been reported in patients with chronic pain [12] and those who received knee or hip replacements [13].

Rehabilitation After Cochlear Implantation

Auditory training is an important part of rehabilitation after cochlear implantation. Several consensus papers have reported that it is necessary for the brain to adapt to the new auditory stimulus transmitted by the implant [14-16]. However, rehabilitation after cochlear implantation differs among countries. In some countries, postoperative rehabilitation programs are not routinely offered because of a lack of reimbursement by health insurance companies and a shortage of specialized therapists [17], whereas in others, cochlear implant (CI) recipients follow an intensive rehabilitation regime that is regularly covered by the general health insurance for at least 2 years after surgery [16]. Auditory training usually takes place in a face-to-face setting in specialized centers; computer-based applications are used only as an additive to standard (face-to-face) therapy. In a previous study, we developed Train2hear, which is a highly individualized digital training platform that combines different components of adaptivity, feedback, and motivation to allow CI users to receive computer-based auditory training (CBAT) that is tailored to their specific therapeutic needs. The first evaluation, within the setting of an applicant's workshop, clearly demonstrated that CI users enjoyed using Train2hear [18]. A challenge faced by teletherapy is to achieve the same efficiency as standard face-to-face therapy.

Computer-Based Auditory Training

Few studies have assessed the effectiveness of digital auditory rehabilitation in adult CI users, and these studies also have only analyzed some aspects in a small number of participants (ie, less than 20) [19-21]. In Schumann et al [22] 15 CI users received 3 weeks of training on phoneme discrimination. A control group and follow-up assessments were not included. Fu et al [23] used a similar approach and studied phoneme discrimination in 10 participants over 4 weeks. In addition to improved performance in trained skills, a transfer effect on sentence comprehension was observed. This observation contrasts with that of Stacey et al [24] who found a significant improvement in consonant discrimination but not in sentence comprehension. Self-perceived improvement was reported in only 2 of the 11 participants. The only publication so far that has compared standard face-to-face therapy with a computer-based approach was by Bernstein et al [6] who analyzed speech tracking ability in 9 patients after a 4-week period. In their study, the tracking rate was improved, but no difference was observed between the two methods.

Furthermore, only a few studies have investigated the ability to listen in noise after CBAT [19,21,25]. However, there were conflicting results, with small number of participants. In Ingvalson et al [21], 5 CI users with postlingual deafness and at least one year of hearing experience showed improved speech perception only in quiet conditions. In contrast, Oba et al [19] reported a significant improvement in babble and steady noise after a 4-week digit training in 10 participants with CI. Even Green et al [25] observed in 9 participants with postlingual deafness that the thresholds to understand 50% of the sentences presented in noise significantly improved after 4 weeks of training in noise, but transfer effects on phoneme discrimination and memorization could not be demonstrated. In short, a systematic evaluation of a complete teletherapeutic rehabilitation program is lacking.

Therefore, the aims of this study are (1) to assess the usability and feasibility of the CBAT platform Train2hear in adult CI users; (2) study the objective and subjective auditory development as well as the economic benefit after a 3-week tablet-based rehabilitation as compared with a 3-week conventional face-to-face setting; and (3) analyze the impact of sociodemographic variables on outcomes.

Methods

Participants

In total, 20 adult CI users were included in this study (Table 1). To be included in the study, potential participants had to be adults (≥18 years); CI users with postlingual bilateral hearing loss and a CI experience of at least 3 months; have no significant motor, visual, or cognitive impairment; be willing and able to complete the tasks inherent in the study; and to give their informed consent. All subjects attended weekly face-to-face therapy at the implant center before the study (range: 7-48 sessions; SD 10.3).

Table 1. Profile of the participants (n=20).

Characteristics	Value
Age (years)	
Mean (SD)	59.4 (16.3)
Range	26-82
Sex, n	
Female	14
Male	6
Years of education	
Mean (SD)	11.8 (1.7)
Range	8-17
Duration of hearing impairment (years)	
Mean (SD)	29.4 (19.9)
Range	1-74
Hearing loss in contralateral ear (dB)	
Mean (SD)	78.6 (27.3)
Range	22.5-120
Cochlear implant experience (months)	
Mean (SD)	10.3 (5.3)
Range	3-22
Etiologies of hearing loss, n	
Idiopathic sudden hearing loss	6
Viral infection	4
Meniere disease	3
Chemotherapy	2
Petrous bone fracture, cholesteatoma	2
Unknown cause	2
Acoustic trauma	1

Economic Evaluation

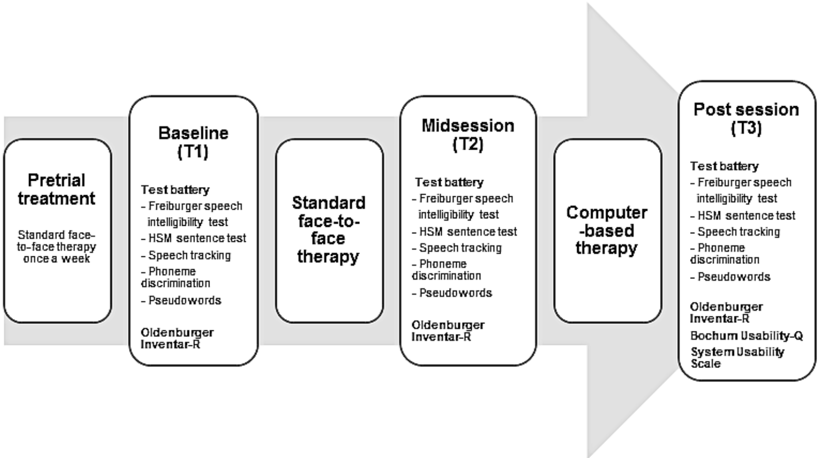
During the intervention period, costs were measured for both CBAT and face-to-face therapy according to the international guidelines for conduction cost analysis [26,27]. Cost-related data covering costs relevant to the health center and costs for the patients were assessed on a standardized cost sheet for each patient. Subsequently, the costs of the two treatment modalities were compared.

Study Design

All participants performed at least seven therapeutic face-to-face sessions in the rehabilitation center before the start of the study (mean 26.3, SD 10.3). Internet access and an audio loop were required to use the telerehabilitation system at home. The tablets were provided by the clinic.

Participants completed 3 weeks of conventional face-to-face rehabilitation followed by 3 weeks of self-training with the home-based digital auditory training program, Train2hear. All participants were assessed at baseline, after the 3-week face-to-face rehabilitation, and after the 3-week digital training program, as shown in Figure 1.

Figure 1. Timeline of the study.



Outcome Assessment

Freiburg Speech Intelligibility Test

Speech comprehension on word level in quiet was examined using the Freiburg Speech Intelligibility Test [28]. In total, 20 monosyllabic words and 10 two-digit numbers were presented to the participants in free field at 65 dB. For each test session, different but comparable lists were chosen to prevent false learning effects. Lists 1, 3, and 5 for the number test and lists 6, 7, and 5 for the monosyllabic test were chosen. For participants with residual hearing in the contralateral ear, masking was performed with an earplug and acoustic earmuffs.

Hochmair-Schulz-Moser Sentence Test

Speech perception of sentences in noise was measured by the Hochmair-Schulz-Moser (HSM) sentence test, which contains 3 exercise lists and 30 test lists with 20 sentences of everyday life [29]. Different comparable test lists (lists 5, 6, and 7) were presented at 65 dB with a signal-to-noise ratio (SNR) of +10 dB.

Speech Tracking

Speech tracking, as described by Filippo and Scott [30], was assessed using SpeechTrax, developed by MED-EL (Innsbruck). Over a period of 5 minutes, the short story *The lighter* by Hans Christian Anderson was presented via a live voice by an experienced speech and language pathologist with 70 words per minute. Participants were asked to repeat word by word and sentence by sentence. Afterwards, the tracking rate was calculated by dividing the total number of words the patient understood by the duration of the test. For participants with residual hearing in the contralateral ear, masking was performed using an earplug and acoustic earmuff.

Phoneme Discrimination

Phoneme discrimination was tested by presenting 7 vowels (a, e, i, o, u, ü, and ö) and 16 consonants (d, t, k, g, w, f, ch, sch, r, l, b, p, n, m, s, and z). Presentation was performed via an audio file and an audio loop. The consonants and vowels were presented in nonsense syllables (vowels:/m/-vowel-/m/; consonants:/a/-consonant-/a/), as described by Schumann et al [22]. The participants were asked to choose the target item from a selection of distractors. For vowels, all other target items were used as distractors (n=7). For consonants, the distractors were selected based on the similarity of the articulation´s location, type of articulation, and pitch. Items were presented in a random order to avoid the learning effect.

Pseudowords

To evaluate auditory perception independent of cognition and linguistic competence, pseudowords (30 nonwords with a length of 2-6 syllables) from the Mottier test were presented via an audio loop [31]. The participants were required to repeat the words as accurately as possible. In the first step, the ability to determine the number of syllables in the target word was analyzed. In the second step, the number of correctly repeated syllables was counted.

System Usability Scale

Train2hear’s usability was assessed using the System Usability Scale (SUS) questionnaire [31]. The SUS comprises 10 questions, each answerable on a 5-point Likert scale in which the end points are *I strongly disagree* and *I strongly agree*. For the 5 statements in which *I strongly agree* is a positive assessment of Train2hear, an answer of *I strongly agree* is worth 4 points and an answer of *I strongly disagree* is worth 0 points. This scoring method is reversed in the 5 statements in which *I strongly agree* would be a negative assessment of the Train2hear. Thus, the higher the score, the more positive is the assessment. A score of >68 indicates a high level of usability [32].

Bochum Usability Questionnaire

A specific questionnaire was developed with 34 closed questions covering 8 aspects of Train2hear’s training platform: (1) implementation of the program, (2) exercises, (3) feedback, (4) statistics, (5) handling regarding videoconferencing, (6) design, (7) motivational elements, and (8) overall assessment of the training program. Participants answered on a Likert scale from 0 to 4, with higher scores indicating better results. The total score for each subtest and each individual question was assessed.

The Oldenburger Inventory-R Score

Participants evaluated their own auditory skills based on the Oldenburger Inventory-R questionnaire [33], which assesses hearing in everyday situations. The 32 closed questions were divided into 7 categories: hearing in silent and in noisy conditions, localization, hearing effort, social interaction, and listening abilities. The subtest entitled *Other* includes questions about discrimination and perception of sounds, voices, and music. For all categories except *social interaction*, higher scores indicate a better subjective perception of hearing status. Multimedia Appendix 1 shows an English translation of the questions and categories.

Auditory Training

Face-to-Face Training

After baseline testing, all 20 participants received face-to-face therapy (120 minutes each, once a week for 3 weeks) according to the regular rehabilitation schedule by an experienced speech and language pathologist at the CI center. The content of the sessions was tailored to the participants' needs as assessed at the baseline assessment and according to a rehabilitation concept that is in accordance with (1) the guidelines of the German Society for Otorhinolaryngology, Head and Neck Surgery and (2) the current concepts of speech processing and auditory rehabilitation [34,35].

Therapists selected exercises on different auditory levels (detection, discrimination, identification, and understanding of syllables, words, sentences, and complex speech) and applied a synthetic and analytic approach. Tasks on word, sentence, and text comprehension were presented in closed or open sets with or without background noise (different SNRs) in live and computerized voices.

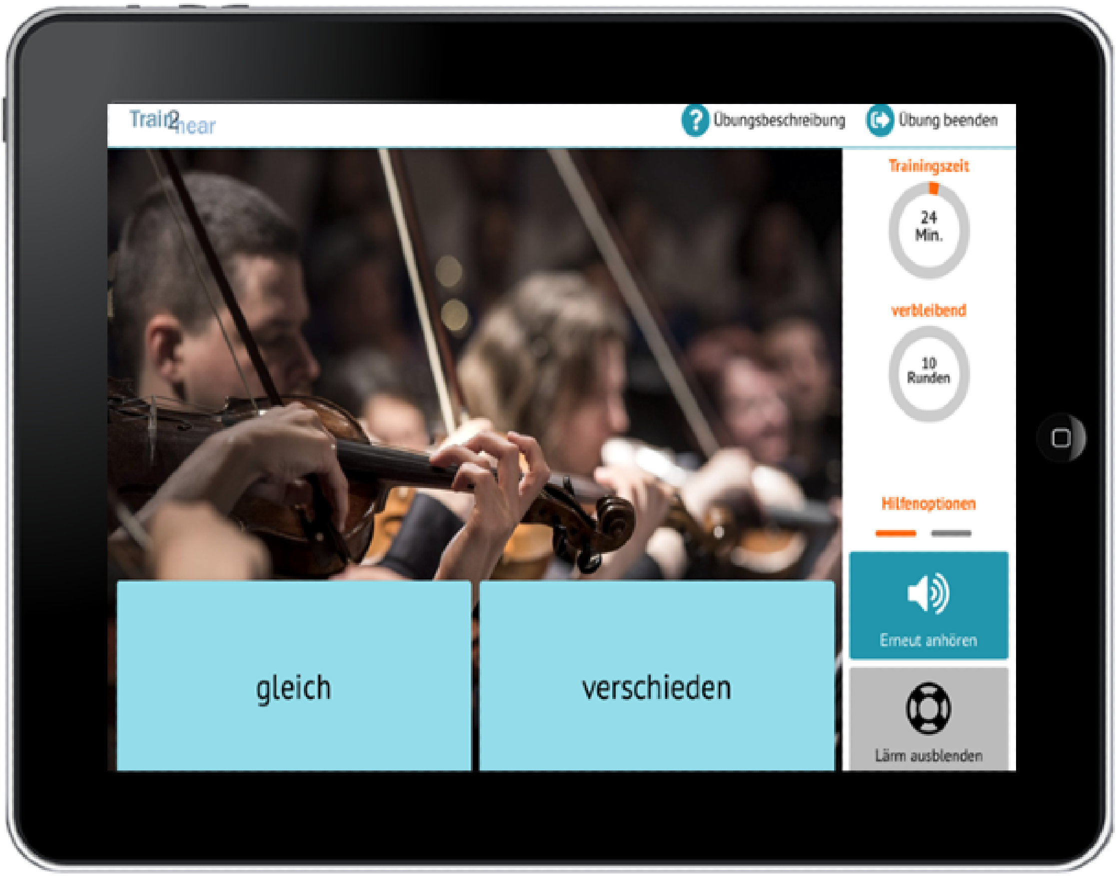
CBAT

Train2hear was based on a previously developed auditory training program for adult CI users [18]. The platform incorporates (1) an initial evaluation of the user´s body functions and structures, participation, and hearing status according to the International Classification of Functioning, Disability and Health and (2) an automatic adaptation of the exercises to the participant's performance.

Participants performed 27 exercises in total, which were arranged in a hierarchical order as supposed by the hearing model of Erber [34]. They started with the simplest exercises such as tasks on sound differentiation and identification to the most difficult ones, such as speech understanding in noise. Background noise varied between 15 dB and 5 dB SNR, depending on the patient's auditory abilities.

Screenshots illustrating different parts of the Train2hear intervention are presented in Figure 2 and Multimedia Appendices 2 and 3. For more detailed information, please see a recent publication by our group, where a specific description of the different exercises as well as the motivation and feedback mechanisms is included [18].

Figure 2. Example of an exercise (differentiation of different instruments, gleich in German means similar, verschieden in German means different).



Before starting the Train2hear training, all participants were shown by an experienced speech and language pathologist on how to use the system. The participants then independently performed CBAT 5 days per week for 25 minutes each. Subjects with residual hearing in the contralateral ear were trained only with the implanted ear using an audio loop. After 10 days, a videoconference chat between the participants and the language therapist took place to check the participants' adaptation, review the program, and assess adverse events.

Statistical Analysis

First, a descriptive analysis of the data using the mean value and SD was performed.

Thereafter, rank-analysis of variance (ANOVA; Friedman test) was performed to prove that there were significant changes between the three measurements (T1, T2, and T3). Afterward, the Wilcoxon signed-rank test for paired samples was applied to evaluate participants' results after the two types of therapy. For rank binding, a sign test was applied. The exact *U* test was used to determine the correlation between the results and sex.

Further correlations between outcome and continuous sociodemographic factors, such as age and years of education, were calculated. If there was no normal distribution, then the Kendall rank correlation in case of rank binding was applied. The significance level was set at *P*=.05. Statistical analyses were performed using Medas (Grund).

Ethics committee approval (19-6618-BR) was received from the Ethics Committee of the Medical Faculty of Ruhr University Bochum.

Results

Therapy Time

All participants completed face-to-face and CBAT training sessions. For each participant, therapists spent 360 minutes (3×120 minutes) on face-to-face procedures and 60 minutes (30 minutes of videoconferencing and 30 minutes of introducing the digital program) for CBAT. To participate in the 3-week face-to-face training, participants needed approximately 6 hours of travel time (range: 1.5-12 hours).

Previous experience of using digital media differed among the participants: 13 had regularly used a computer (daily or several times a week), whereas 4 had never worked with a computer. In total, 11 participants regularly used a tablet several times a week, whereas three did not. All other participants had previous experience of using digital devices (tablets, smartphones, and computers). Before the study, 16 participants had no experience with videoconferencing, whereas 4 had used videoconferencing to communicate with family members or friends.

Digital experience did not correlate with speech understanding assessed by the test battery at T2 or T3. In contrast, affinity to digital media had a significant impact on the assessment of the usability of the program. Participants who frequently used a computer stated significantly more often that the videoconference was easy to use (*P*=.03; Bochum Usability Questionnaire Q16). A significant positive correlation among questions 3, 5, 6, and 7 of the SUS and digital experience could be detected. Participants with more experience judged the program to be easier to use (*P*=.03; SUS Q3) and more often stated that the different functions were well integrated (*P*=.02; SUS Q5). Experienced users also stated, significantly more often, that the handling of the program could be learned quickly (*P*=.007; SUS Q7). Nevertheless, regular tablet users still found the program cumbersome to use (*P*=.02; SUS Q8).

Test Outcome

The results of the test battery at baseline (T1), after face-to-face therapy (T2), and after CBAT (T3) are shown in Multimedia Appendix 4. Tests that did not significantly differ in rank-ANOVA (Friedman test) between the three test times were not further investigated (Multimedia Appendices 4 and 5).

Freiburg Speech Intelligibility Test

Neither the Freiburg number test nor the Freiburg monosyllabic test showed significant changes during the study. However, the following correlations between test performance and sociodemographic data could be identified: regarding monosyllabic speech comprehension, older participants were less likely to benefit (*P*=.04) from the CBAT. At T3, the results depended on sex (*P*=.04): men's score was increased by 19.2%, whereas women's score was slightly decreased by 1.1%. In addition, participants with more hearing experience showed less improvement (*P*=.04) after the CBAT. At the end of the intervention (T3), prolonged hearing impairment was negatively related to performance in the Freiburg monosyllabic test (*P*=.04) and the Freiburg number test (*P*=.004).

HSM Sentence Test

The mean HSM scores improved significantly from T2 to T3 (*P*=.004). At the last assessment (T3), the duration of hearing loss and improvement were significantly correlated (*P*=.02). Age and sex did not affect the results either at T2 or T3 (age, *P*=.39; sex, *P*=.90), but the performance in the Freiburg monosyllabic test was significantly associated with the improvement in sentence comprehension at T3 (*P*=.04). Furthermore, participants with better results in the HSM rated their ability to understand speech in noise significantly better, as shown in the Oldenburger Inventar-R Questionnaire (*Listening in noise*) subscore (*P*=.03).

Speech Tracking

The speech tracking rate significantly increased. At T1, participants had a tracking rate of 31.3 words per minute (wpm; SD 16.38), which increased after face-to-face training by 4.92 wpm (SD 7.26; *P*=.009). After 3 weeks of CBAT, the subjects reached 41.3 wpm (SD 18.29; *P*=.003). Sex, age, hearing experience, and duration of hearing loss had no impact on performance. Monosyllabic word recognition (Freiburg) at baseline was significantly correlated with improvement in speech tracking at T2 (*P*=.02).

Phoneme Discrimination

Comparing T2 and T3, improvements in vowel discrimination (*P*=.001) and consonant discrimination (*P*=.02) were observed. A shorter duration of hearing loss was significantly correlated with an improvement in vowel discrimination between T2 and T3 (*P*=.02).

The ability to discriminate consonants was also significantly associated with age and the duration of hearing loss (T1-T2). Older participants (*P*=.02) and participants with hearing loss for a longer period showed less improvement (*P*=.03).

Pseudowords

Throughout the study, no significant changes were observed in the identification of syllables (*P*=.64) and the repetition of syllables (*P*=.51). These observations did not depend on the length of the items. The results indicated that participants with better monosyllabic comprehension at T1 were able to repeat the syllables more accurately (*P*=.009).

SUS

Participants evaluated the usability of the Train2hear program as excellent (mean score: 87.0; SD 12.1; Multimedia Appendix 6). Question 1 received one of the highest scores: 18 out of 20 participants stated that they could imagine using the program regularly. In total, 70% (14/20) of the participants indicated that the various functions were well integrated into the program (Q3), 100% (20/20) agreed that the program was easy to use (Q2), and 95% (19/20) felt confident using the program (Q5).

The only questions with lower scores (Q4, Q7, and Q10) referred to the handling of the technology and the support necessary at the beginning of the training. No additional support was necessary in 70% (14/20) of cases (Q7).

The structure of the program (Q6, Q8, and Q9) was judged to be good. Only one participant claimed the program to be too complex (Q6) and too cumbersome to use (Q9). Two patients judged the program to be inconsistent. A significant correlation was found between questions Q4 (need for support) and Q10 (need for guidance) and age, both of which were rated worse by older participants (Q4, *P*=.008; Q10, *P*=.007). The overall score was also age-related: older participants were more critical than younger participants (*P*=.006; Multimedia Appendix 6).

Bochum Usability Questionnaire

The overall design of the program was rated very good. In total, 100% (20/20) liked the design (Q19), and the font size (Q20) and buttons (Q21) were judged to be appropriately sized by all the participants.

More than 60% of the participants rated the training tips and introduction videos to be very helpful (Q1, Q2). The participants liked the concept of a journey through Europe (Q9, mean 97.5%, SD 0.45). In this context, 95% (19/20) of the participants considered the tasks to be relevant to everyday life (Q3). The level of the exercises was appropriate for 17 out of 20 participants. All the questions concerning the exercises reached 89% (71.4/80) of the maximum score. The program statistics were regularly used by 70% (14/20) at least once a week (Q13). Presentation of the statistical data was comprehensible for 85% (17/20) (Q15). However, 20% (4/20) of the subjects declared that statistics did not help them to better understand their results. In general, the statistical features were rated as the weakest of all categories. The score reached 75% (60/80) of the maximum score.

Most participants would recommend the program to others (Q30, mean 98.8%, SD 0.23). An obligatory training time of 25 minutes per day could be conducted by the majority (Q34, mean 98.8%, SD 0.23). Older participants stated more frequently that CBAT could be an addition to face-to-face training (Q29, *P*=.007) and that working with Train2hear was highly motivating (Q31, *P*=.001). In addition, they had fewer problems conducting dedicated training days per week (Q33, *P*=.04).

Female participants judged the feedback to be significantly better than male participants (Q11, *P*=.04). However, there was no sex-related difference in the enjoyment of training (Q22, *P*=.08). Participants with a higher educational level would recommend computer-based training to others more frequently (Q30, *P*=.01) and were more satisfied with the support provided (Q8, *P*=.04). Furthermore, they claimed that videoconferencing was as satisfying as personal contact (Q18, *P*=.04).

The most significant correlation was found between the years of education and questions related to technology. Participants with higher education reported more often that the technology worked without any problems (Q26, *P*<.001). Participants with less education judged the program's feedback to be significantly better (Q10, *P*=.01). Participants with a lower speech perception score at T2 (as assessed by the Freiburg Speech Intelligibility Test) were more likely to feel anxious while using the program (Q25, *P*=.01; Multimedia Appendix 7).

Oldenburger Inventory Score

The subjects' self-perception did not change significantly in this study. As shown in Multimedia Appendix 8 this refers to all subcategories except for listening in noise, which has been judged to be better after face-to-face therapy (*P*=.003). Sociodemographic variables affected localization abilities, social interaction, listening effort, and the development of auditory skills in general.

Localization abilities were related to sex. Comparing T2 and T3 women achieved significantly worse results than men (*P*=.03). A correlation with sex was also evident in the social interaction subscale (*P*=.04). Furthermore, there was an association between social interactions and age. Younger participants improved significantly more due to CBAT (T2-T3; *P*=.04). Furthermore, age was negatively related to the development of auditory skills at T3 (*P*=.008). With regard to the duration of hearing loss, a negative correlation with listening effort was detected at T2 (*P*=.001).

Economic Evaluation

To attend the face-to-face session, patients had to travel 237 km (SD 80.7), which entailed spending on an average of 234 minutes (SD 58.6) on the road. Therapists devoted 450 minutes for a standard face-to-face therapy and 90 minutes per patient for CBAT (including the time of preparation and documentation). Therefore, costs could be reduced from €262.50 (US $320.25) to €52.50 (US $64.05) for the study period (Multimedia Appendix 9).

If standard face-to-face therapy, which regularly included 20 sessions of speech therapy (each of which lasted 120 minutes) was completely replaced by CBAT, then the costs would decrease from €1750.00 (US $2134.00) to €350.00 (US $427.00) based on the data obtained in this pilot study.

Discussion

Principal Findings

This study is, to the best of our knowledge, one of the first to demonstrate that a digital auditory rehabilitation program might reduce adult CI users' dependence on human resources while ensuring that they receive a clinical outcome similar to that of standard therapy, that is, conventional face-to-face rehabilitation at a specialized rehabilitation center.

A comparison of the two auditory training methods (face-to-face and CBAT) revealed a greater benefit in sentence comprehension in background noise after CBAT. This may be explained by the application of the training schedule. Teletherapeutic tasks were performed five to seven times a week, whereas outpatient therapy was performed only once a week. This is in line with Vu et al [36] who found significant differences in log-in frequency and learning activities between successful and unsuccessful learners in web-based training for teachers. The most remarkable improvements were detected in phoneme discrimination and speech tracking, which are closely related to interactive communication [6,37].

Overall, the Train2hear program was rated as highly usable by the participants. The fact that older participants rated usability worse than younger participants may be related to the lower level of technical experience among older people. This result was also mentioned by Ferguson and Henshaw [38], who stated that access to hardware and lack of skills in using hardware hinder access to computer-based training. Regardless of this age-related difference, all participants agreed that Train2hear is easy to use. Nonetheless, external support may be helpful for older users. This could be done either by the user's partner or family or friends or by therapists via videoconferencing.

In contrast, older participants had significantly higher scores on motivation and ease of adherence to the training schedule than did younger participants. In general, age did not significantly influence performance; the Freiburg monosyllabic test was the only speech understanding test in which older participants scored worse than their younger counterparts as compared with face-to-face therapy and CBAT (P=.004). Prolonged training intervals might have a positive effect because of a slower learning curve in older adults [6].

Nonusage has been known to be an important barrier in the field of web-based training [39], especially in interventions using automatic functions with minimal human involvement. In this study, 100% (20/20) of the participants completed the 3-week digital training program. As compared with other studies, this adherence rate can be interpreted as extraordinarily high [39].

A possible explanation for the high adherence rate could be that the Train2hear software is highly individualized, which includes a basic assessment of the user's demands and needs and automatically adapts the training schedule to their performance.

Furthermore, the Train2hear platform contains various motivational elements that might lead to better user adherence, for example, a close feedback system and reminders [38-40]. However, it remains to be seen if such levels of adherence would continue at a long-term follow-up. In a study on patients with stroke, Jurkiewicz et al [41] found that adherence in the initial period was significantly higher than that in the long-term follow-up. Previous works have shown that incorporating an avatar can increase motivation and engagement with a training application and the time spent in training [24,42,43]. With this observation in mind, we added a train conductor as an avatar to the new training platform.

Educational level had a significant impact on the handling of the software. This result is in line with Kriwy and Glöckner, who reported that the higher an individual's level of education, the better they could take part in computerized health programs [44].

Furthermore, significant correlations were observed between the total duration of hearing loss and improvements after T2. Generally, the shorter the duration of hearing loss, the greater the improvement in speech understanding. This result was also assumed by Ihler et al [45] in their study on home-based auditory training of speech recognition on the telephone in 20 CI users with postlingual hearing loss. Whether auditory training over a longer period can lead to greater improvements in speech comprehension, even in people with a long duration of hearing loss, has yet to be proven.

Participants' self-evaluated hearing abilities remained nearly unchanged after both face-to-face training and CBAT. Previous studies have reported this result. No, or only minor, self-reported improvements of listening abilities after auditory training periods have also been reported by Stacey et al [24] (after 5 days a week for 3 weeks) and Bernstein et al [6] (once a week for 8 weeks). The question is, if despite objectively shown improvements in speech understanding, a training period of 3 weeks is too short to have an impact on self-perceived hearing status.

There is currently an acute need to study the effectiveness of therapeutic interventions in speech language pathology and audiology. Studies designed and conducted in accordance with evidence-based criteria provide a rational basis for therapeutic approaches that are missing in large parts of auditory therapy [46]. CBAT might be an appropriate tool for future multicenter studies because the protocol is well defined (although highly individualized) and therefore comparable. In addition, CBAT enables a large amount of data to be obtained during the entire training procedure. This process can help speech and language pathologists to more precisely investigate the progress of CI users and to evaluate and refine the therapeutic approach.

Regarding the time- and resource-saving potential of CBAT, each therapist saved more than 5 hours per participant during the 3-week training period, including the time they would have needed to prepare the lessons. The participants saved a mean of almost 4 hours of traveling. Regarding the intense rehabilitation program that is regularly offered to CI recipients in Germany for 2 years and reimbursed by the general health insurance, home-based training might save an enormous amount of economic and human resources even if it might be suitable only for selected CI users and limited to only some parts of the rehabilitation process.

Furthermore, at the time of writing, much of the world is under lockdown or some form of restriction due to the COVID-19 pandemic. In such situations, people are not able to access office-based therapy; therefore, CBAT might be an appropriate and crucial tool for successful hearing rehabilitation, especially for older CI users and those with weakened immune systems.

Previous Studies

The few studies that exist on CBAT have a limited scope. They evaluated only a few aspects of auditory training [6,22,45] and generally had short or no follow-up assessments [19,23,25]. Previous studies have described improvements in speech comprehension and communication skills after several weeks of CBAT [20,47,48].

Overall, studies usually included only a small sample size [47]. Only Bernstein et al [6] compared the standard face-to-face regimen with digital auditory training. They conducted their study on speech tracking performance in CI users. Similar to our results, they found that CI users had an improved tracking rate (P<.001) and sentence recognition (P<.001) using both therapeutic approaches.

Limitations

Although this study is one of the largest on CBAT in terms of the number of participants, 20 participants were still a limited study group. In our study, we chose only a period of 3 weeks because of the regulations of the research project. It must be kept in mind that this period is short compared with the long rehabilitation period of 2 years, which is regularly performed in Germany after cochlear implantation. Furthermore, future studies would benefit from increasing the duration of the training period and analyzing the long-term effects to better evaluate how effective CBAT is and how well users adhere to the training program.

Due to the study design, it cannot be completely ruled out that the positive outcome after CBAT is partially due to the long-term effects of the conventional face-to-face training sessions. However, all participants had experience with face-to-face therapy before the study. This is a bias that all therapeutic studies are faced with. A complete stop of the training over a longer period would be necessary to rule out long-term effects, and this is not ethically justifiable.

Even the inclusion of a control group could not have solved this problem because CI recipients widely differ in terms of age, duration of hearing loss, socioeconomic status, etc. Therefore, we cannot completely rule out the effects of age, sex, duration of hearing loss, technical experience, and hearing experience on treatment outcomes. However, these correlations did not show a significant association. Large multicenter studies should be conducted in the near future to confirm the presented data.

Conclusions

Due to global demographic changes and the pressure under the current COVID-19 pandemic, there is an enormous and increased need for computerized therapeutic interventions in speech language pathology and audiology. Computer-based auditory therapy is an evidence-based and standardized yet highly individualized approach that has the potential to save human and economic resources. Outcomes seem to be quite similar to face-to-face therapy although due to the small number of participants, the results have to be confirmed. However, the promising results of this pilot study justify further investigation and evaluation of the Train2hear program in a large multicenter study over a longer period.

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Authors' Contributions

CV wrote the manuscript. C Stöckmann and C Schirmer contributed significantly to this manuscript. SD and CV initiated the project.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Subjective audiological self-rating based on Oldenburger Inventory-R score (Audiologie Initiative Niedersachsen, 2007).
[PNG File , 309 KB - rehab_v8i1e20405_app1.png]

Multimedia Appendix 2

Overview of exercises performed in Vienna (for example users had to count syllables and to differentiate vowels on a sightseening tour through Vienna).
[PNG File , 125 KB - rehab_v8i1e20405_app2.png]

Multimedia Appendix 3
Training schedule and calendar.
[PNG File , 103 KB - rehab_v8i1e20405_app3.png]

Multimedia Appendix 4
Results of each test at T1, T2 and T3 in n=20 (100%).
[DOCX File , 20 KB - rehab_v8i1e20405_app4.docx]

Multimedia Appendix 5
Test battery rank–ANOVA (analysis of variance).
[DOCX File , 13 KB - rehab_v8i1e20405_app5.docx]

Multimedia Appendix 6
System Usability Scale (Brooke, 1996); n=20 (100%) for each statement.
[DOCX File , 17 KB - rehab_v8i1e20405_app6.docx]

Multimedia Appendix 7
Bochum Usability Questionnaire; n=20 (100%) for each statement except in subtest "Videoconferencing" n=15 (100%).
[DOCX File , 26 KB - rehab_v8i1e20405_app7.docx]

Multimedia Appendix 8
Results of subjective audiological self-rating based on the Oldenburg Inventory-R score; n=20 (100%) for each test and interval.
[DOCX File , 16 KB - rehab_v8i1e20405_app8.docx]

Multimedia Appendix 9
Overview of the costs during the 3-week intervention study. (A) Patient's data. (B) Therapist's data.
[DOCX File , 16 KB - rehab_v8i1e20405_app9.docx]

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Abbreviations

CBAT: computer-based auditory training
CI: cochlear implant
EFRE: Europäische Fonds für Regionale Entwicklung
HSM: Hochmair-Schulz-Moser
SNR: signal-to-noise ratio
SUS: System Usability Scale

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Original Paper

Feasibility and Convergent Validity of an Activity Tracker for Low Back Pain Within a Clinical Study: Cross-sectional Study

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Abstract

Background: Low back pain (LBP) is a highly prevalent condition affecting individuals of all ages. To manage the symptoms and prevent recurrences and flare-ups, physical activity in conjunction with self-management education is recommended. Tools such as diaries and questionnaires have been the gold standard for tracking physical activity in clinical studies. However, there are issues with consistency, accuracy, and recall with the use of these outcome measures. Given the growth of technology in today's society, consumer-grade activity monitors have become a common and convenient method of recording physical activity data.

Objective: The aim of this study is to test the feasibility and convergent validity of a Garmin Vivofit 3 activity tracker in evaluating physical activity levels in a clinical trial of patients with LBP.

Methods: We recruited 17 individuals with nonspecific LBP referred from health care professionals or self-referred through advertisements in the community. The participants entered into a 12-week physical activity and self-management program. Physical activity was assessed using a self-reported questionnaire and the Garmin activity tracker. Activity tracker data (eg, steps taken, distance walked, and intensity minutes) were extracted weekly from the Garmin Connect online platform. Outcomes of pain and activity limitation were assessed weekly using a mobile app. A linear regression was conducted to evaluate if demographic factors (ie, age, gender, pain level) affected the adherence rates to the activity monitor. We also used Pearson correlations to evaluate the convergent validity of the Garmin activity tracker with the physical activity questionnaire.

Results: The mean daily adherence rate for activity monitors was 70% (SD 31%) over the 26 weeks of study. The mean response rate for the weekly physical activity measures using REDCap for the first 12 weeks of the study was 91% (SD 17%). None of the hypothesized variables or questionnaires were predictors of response rate.

Conclusions: The majority of participants were compliant with wearing the tracker, and demographic factors were not found to be predictors of adherence to wearing the device. However, there were poor correlations between the modified International Physical Activity Questionnaire Short Form (IPAQ-SF) and the activity monitor, demonstrating problems with convergent validity.

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KEYWORDS

activity monitor; activity tracker; low back pain

Introduction

Low back pain (LBP) is the most common musculoskeletal condition worldwide [1]. Approximately 85% of individuals with LBP will be diagnosed with nonspecific LBP, which refers to pain not attributed to a specific diagnosis such as sciatica, ankylosing spondylitis, and vertebral fracture [2-4]. Considering the high prevalence of LBP, treatment and management of the condition remain an important area of investigation.

Recent studies suggest that lifestyle modification and adherence to physical activity are crucial to preventing recurrences or back pain flare-ups and improving one's quality of life [5,6]. The majority of clinical practice guidelines recommend the use of education and exercise to manage LBP [7]. Exercise programs have shown to be successful at reducing pain, disability, and improving quality of life [8].

Levels of physical activity and exercise adherence are important outcome measures often used in clinical research. Traditional methods for tracking physical activity are diaries and questionnaires. However, these tools are unable to record real-time information and suffer from significant adherence problems and recall bias [9,10]. Studies that use diaries to track exercise patterns have lacked consistency, as participants often forget to make regular entries and frequently resort to recall for completing diaries post hoc [9]. It has been estimated that patients may fail to enter over 50% of requested physical activity data [9]. Questionnaires pose similar problems, where participants have a tendency to overestimate or underestimate values for question responses [10]. Factors such as day of the week when completing the questionnaire and self-esteem toward sensitive questions can influence the recall process [10]. Study participants often underestimate sitting duration up to 4.5 hours/day when solely relying on questionnaires to record the information post hoc [10]. Recent studies have shown that questionnaires have limited validity and reliability when collecting physical activity measures in the community [11]. Therefore, other stronger and more reliable tools may be needed for the collection of physical activity data within clinical studies.

Physical activity monitors such as pedometers and heart rate trackers have been used as alternatives for the collection of physical activity and exercise compliance data within clinical studies. Common measures that activity monitors can collect are steps taken per day, distance traveled per day, and intensity minutes obtained (amount of moderate and vigorous activities conducted). These activity trackers are exciting technologies that can collect and store a large number of data related to physical activity. These objective outcome measures evaluate physical activity and provide the opportunity to collect this information in the real world, during daily activities. Furthermore, activity monitors are less influenced by participant and evaluator bias; however, user reactivity to the activity monitor is a possibility, although the devices remain free of other biases. Research-grade activity trackers such as the ActiGraph are considered gold-standard tools for the collection of activity data [12]. Unfortunately, these trackers are costly, somewhat bothersome to wear, and require frequent uploads and charging, making its community use limited for collecting long-term data. Commercial-grade activity trackers represent an alternative for the collection of outcomes within studies [13,14]. Activity monitors such as Fitbit and Garmin devices tend to be more financially affordable, come in smaller and sleeker designs, possess a longer battery life (eg, up to 1 year), come in water-resistant forms, and can easily upload activity data to a mobile device [15,16]. These features make commercial-grade activity monitors appealing options, especially when compared with research-grade trackers that have shorter battery life and require more support for wear.

Commercial-grade activity trackers have been found to have some limitations in identifying low-intensity physical activity, particularly in older adults [12,17]. In addition, many activity trackers are worn on the wrist, which may present limitations in detecting activity from the lower limbs [18,19]. Clip-on activity trackers display similar issues in their limited ability to track movement from the entire body depending on their placement location. Although there are recognizable limitations for the use of commercial-grade activity trackers, the ease of using these activity trackers cannot be ignored when selecting outcome measures in research, especially when considering moderate and vigorous activities for which activity monitors have been found to have better validity [17]. They are economically priced for the public, employ user friendly systems, and can be easily worn on the wrist or clothing.

In addition to limitations related to the quality of the data collected, there are some concerns surrounding adherence rates in wearing and syncing activity monitors in clinical studies of long duration. Similar to diaries, participants are asked to wear activity monitors on a daily basis, charge the devices as appropriate, and sync with online platforms. To date, there is a gap in the literature on the feasibility of using a commercial-grade Garmin activity tracker in clinical studies. Understanding its value and usage in clinical trials can be beneficial in paving the way to more practical applications of commercial-grade products in scientific research. Thus, the primary objective of this study was to evaluate the feasibility of using a Garmin Vivofit 3, a consumer-grade activity tracker, to collect data in a clinical trial of patients with LBP. Feasibility will be measured in terms of adherence rates in wearing the monitor and whether there are differences in age, gender, or pain level in adherence rates. The secondary objective was to evaluate the convergent validity of the Garmin Vivofit 3 with the items of the modified International Physical Activity Questionnaire Short Form (IPAQ-SF) questionnaire.

We hypothesized that women and younger participants with higher levels of pain would be more likely to wear and sync their activity monitors. We also hypothesized that there would be a moderate correlation (Pearson correlation >0.6) of physical activity data with physical activity information collected using the IPAQ-SF.

Methods

Study Design

This is a project imbedded into a pretest posttest parent study aiming to evaluate the feasibility of a community-based physical activity program for patients with nonspecific LBP. The primary goal of the parent study was to observe whether the program could prevent recurrences of flare-ups of LBP and mitigate the negative consequences of the condition. The STROBE checklist used to report epidemiological studies was used in this report [20]. The study received ethical approval from the Hamilton Integrated Research Ethics Board (#2721) on June 15, 2017, and all participants signed a consent form prior to inclusion.

Recruitment for Parent Study

Participants were recruited to participate in the clinical trial from local physiotherapists, chiropractors, physicians, and community advertisements in Hamilton, Ontario, Canada. Participants were included if they met the following inclusion criteria: (1) discharged <3 months from physiotherapy, chiropractic, or osteopathic care following a course of treatment for LBP; (2) have nonspecific LBP; and (3) between 18 and 80 years of age. Participants were excluded if they met any of the following criteria: (1) ongoing high pain intensity, defined as pain intensity of 6 or more on a 0-10-point scale. The cut off of 6/10 is used in the literature to dichotomize low to high pain intensity [21,22]; (2) comorbidity preventing participation in physical activity as evaluated by the Physical Activity Readiness Questionnaire (PAR-Q) from the American College of Sports Medicine guidelines [23]; (3) inadequate English to complete outcome measures; (4) currently participating in an exercise program similar to the one we will evaluate; and (5) history of spine surgery.

Equipment

The Garmin Vivofit 3 is a commercial-grade activity monitor that that tracks steps taken, calories, distance traveled, intensity minutes, and sleep. It features a 1-year battery life, enabling it to track one's activity 24/7. The monitor is able to sync with the online Garmin Connect platform to provide further details of one's activities and connect with other users [16].

REDCap was the software used to create and send questionnaires to participants' emails as well as record their responses.

Procedures

Each individual participated in an initial appointment during which the research assistant gave an overview of the study, and participants signed consent forms. Baseline questionnaires were completed on the REDCap platform through a link sent to the participant's email address. Longitudinal data collection procedures were explained to the participant and their smartphones were set up to receive study notifications for weekly pain data collection through the MetricWire app. Garmin Vivofit 3 activity monitors were distributed to all participants and the research assistant instructed them on how to sync their tracker with a smartphone device or a computer. Participants were instructed to wear the activity monitor on a daily basis and only remove during swimming or showers. All participants underwent a 12-week exercise and education program and received 4 months free membership at a local YMCA gym.

Outcome Measures

Pain (Numerical Rating Scale), function (Patient-Specific Functional Scale), disability (Roland Morris Disability Questionnaire), health-related quality of life (EQ-5D-5L), and physical activity (activity tracker and modified IPAQ) levels were collected at baseline, at the end of the 12-week intervention, and at 6 months' follow-up. In addition, pain, disability, and mood outcomes and physical activity data were collected once a week for 26 weeks. Pain outcomes were collected once a week using a smartphone app that produced weekly notifications. All participants were asked to wear an activity monitor for the duration of 26 weeks and sync their devices biweekly with an online platform. One of the study investigators (LZ) logged into the Garmin website and extracted physical activity data for all participants. The activity monitor data extracted were steps taken per day, distance traveled per day, and intensity minutes obtained per day. Finally, once a week for the duration of the interventions (12 weeks), participants received a REDCap link to complete a self-management action plan and completed the IPAQ-SF from which responses about moderate, vigorous activity, and walking were extracted.

Statistical Analysis

Descriptive statistics of the population including age, sex, education level, pain, function, disability, and quality of life outcomes were presented as mean (SD) or n (%) when appropriate.

Response Rates

Response rates were calculated for the 12-week period of the intervention as well as for the 26 weeks of the study (intervention + follow-up period). Weekly adherence rates with wearing the monitor, how often participants synced their data to the mobile app, and how often researchers needed to send reminders regarding syncing were presented. Univariate linear regression and a multiple regression using backward elimination were used to identify whether age, gender, and baseline pain, function, and disability predict the number of times a participant "adhered" to the activity monitor protocol (wear and sync). A Bonferroni correction for multiple comparisons using an α level divided by the number of predictors (n=9) was conducted with α=.006.

Convergent Validity

A Pearson correlation was used to investigate the association between physical activity level reported weekly on the IPAQ-SF (self-reported amount of time per day spent engaging in moderate, vigorous physical activity, and walking) and the activity monitor (step counts, distance traveled, and number of intensity minutes). A 1-tailed hypothesis testing comparing the identified Pearson correlation with the expected null hypothesis of 0.6 was conducted. STATA (version 14.0; StataCorp) was used for all statistical analyses.

Results

Participants in this study were either referred from physiotherapists and chiropractors working in the Hamilton community or recruited from advertisements through the Les Chater YMCA's social media. A total of 21 individuals were referred to the study by health care professionals, and 10 participants contacted the investigators following a social media advertisement through the YMCA from December 2018 to February 2019. Of those 31, 20 individuals were deemed eligible to participate, and 17 were ultimately included. A lack of time was the justification provided by all 3 eligible participants who did not agree to participate in the study. A schematic of the study timeline can be found in Figure 1. A list of patient demographic information can be found in Table 1.

Figure 1. Schematic representation of study timeline.

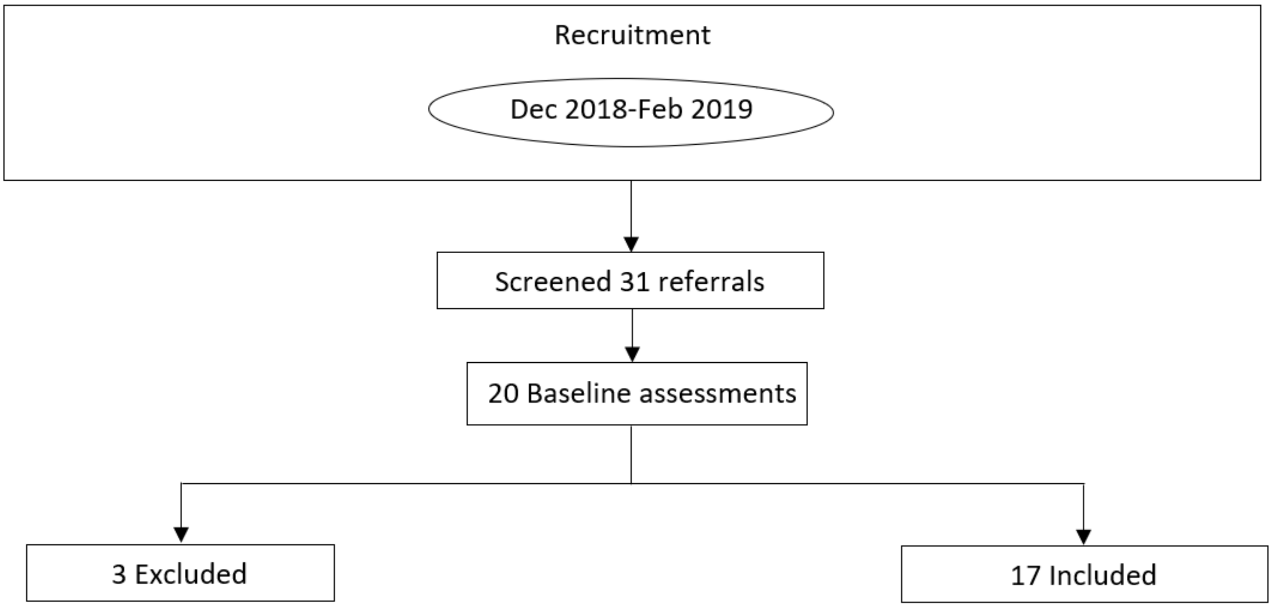

Table 1. Participant demographic characteristics and questionnaire scores (N=17).

Variable	Value
Sex, n (%)	
Female	9 (53)
Male	8 (47)
Marital status, n (%)	
Married	14 (82)
Divorced	1 (6)
Common Law	1 (6)
Single	1 (6)
Occupation, n (%)	
Not working[a]	4 (24)
Working	13 (76)
Employment, n (%)	
Full-time full duties	8 (47)
Full-time selective duties	1 (6)
Part-time full duties	2 (12)
Part-time selective duties	2 (12)
Not seeking employment	4 (24)
Smoking/medication, n (%)	
Smoking	1 (6)
Taking painkillers	2 (12)
Physical activity level, n (%)	
Moderate physical activity[b]	10 (59)
Education, n (%)	
High-school diploma	2 (12)
Diploma	5 (29)
Bachelor's degree	1 (6)
Postgraduate degree	3 (18)
Other	6 (35)
Characteristic, mean (SD)	
Age (years)	54.9 (11.7)
Weight (kg)	82.9 (18.5)
Height (cm)	175.1 (10.2)
BMI (kg/m^2)	26.9 (4.8)
Duration of low back pain (months)	62.9 (69.7)
Scale, mean (SD)	
Weekly pain rating	4.9 (2.5)
Patient-Specific Functional Scale	5.7 (2.5)
Roland Morris Disability Questionnaire	6.2 (4.)
Pain Self-Efficacy Questionnaire	48.5 (11.2)
Coping Strategies Questionnaire	11.9 (6.)

[a]At the start of the study, 3 participants were not working prior to their low back pain. Currently, 4 people are not working.

[b]At least 30 minutes of activity per day, 3 times a week.

Response Rates

The mean adherence rate (wearing and syncing) for activity monitors was 128 out of 182 (70%; SD 31%) total days, with a median of 141 days (77%; IQR 47%) over the 26 weeks of the study. Average response rate for the IPAQ-SF, which was collected during the first 12 weeks of the study, was 11 times (92%; SD 17%), with a median of 12 (100%; IQR 8%). Adherence rate of the activity monitors was highly skewed, as demonstrated by the histogram (Figure 2). There was 1 participant that did not respond to any of the activity measures or wear the activity monitor. In addition, there was 1 participant that lost the activity monitor and was thus unable to continue syncing. The participant with 0 weeks of data experienced log-in issues associated with his Garmin account. There were no significant differences in baseline characteristics between the compliant and noncompliant group of participants (P<.05 for all cases; see Table 2).

Univariate linear regression demonstrated that none of our hypothesized variables or questionnaires were predictors of response rate (Table 2). However, given the small sample size of this study, we were underpowered to identify significant associations. We were unable to build a multivariate model using our correct α level of .006. However, these results are likely due to a type II error.

Figure 2. Histogram of adherence rate and response rate to (A) activity monitor (B) modified IPAQ. IPAQ-SF: International Physical Activity Questionnaire Short Form.

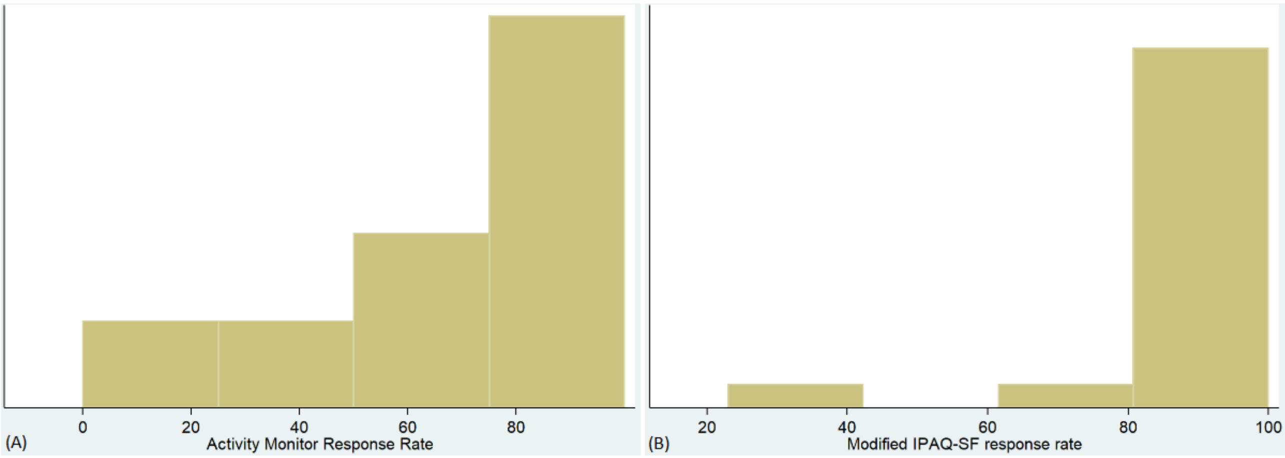

Table 2. Univariate linear regression analysis of participant characteristics and questionnaire responses as predictors of activity monitor response rate.

Predictor	Regression coefficient (95% CI)	P value	R^2 (%)
Age	–0.5 (–1.9 to 0.9)	.46	4
Gender	23.6 (–7.8 to 55.1)	.13	15
Education	4.4 (–5.3 to 14.1)	.35	8
Pain duration	–0.02 (–0.3 to 0.2)	.89	0.2
Weekly pain rating	5.8 (–0.1 to 11.7)	.05	23
Patient-Specific Functional Scale	4.1 (–2.4 to 10.5)	.20	11
Roland Morris Disability Questionnaire	–0.9 (–4.7 to 2.9)	.62	0.2
Pain Self-Efficacy Questionnaire	1.0 (–0.3 to 2.3)	.14	14
Coping Strategies Questionnaire	–2.1 (–4.5 to 0.2)	.08	20

Convergent Validity

Convergent validity was calculated for all data collected within the first 12 weeks of the intervention, meaning that 204 weeks of data were incorporated into the analysis (17 participants × 12 weeks). On the self-reported physical activity questionnaire, participants were asked to recall the amount of physical activity that they performed (vigorous, moderate, or walking) on an average day during the week, and thus, data represent minutes per day. Likewise, activity data such as step count, distance traveled (miles), and intensity minutes were entered into the analysis as averages per week, thus representing steps, miles, or minutes on an average day, respectively. If no data were collected for a specific day on the activity monitor (ie, 0 steps), then this data line was excluded from the calculations. Pearson correlation was poor and did not reach the threshold for validity in any of the outcomes (Table 3).

To further evaluate where inconsistencies may exist between physical activity data and the IPAQ-SF, individual patient data were observed (Table 3). The observed data demonstrated a variability in responses with some patients that underestimated self-reported activities while others overestimated self-reported activities. The results demonstrated poor correlations between the data collected from the activity monitor and the responses from the IPAQ-SF with correlations not statistically greater than the hypothesized r=0.6.

Table 3. Pearson correlation of average activity monitor data and IPAQ-SF[a] responses.

Measurement tool	Garmin			IPAQ		
	Step count	Distance traveled (miles)	Intensity (minutes)	Vigorous activity (minutes)	Moderate activity (minutes)	Walking (minutes)
Garmin						
Step count	1.000					
Distance traveled (miles)	0.99[b]	1.000				
Intensity minutes	0.76	0.77	1.0000			
IPAQ						
Vigorous activity (minutes)	0.32	0.31	0.24	1.0000		
Moderate activity (minutes)	0.32	0.30	0.29	0.82[b]	1.0000	
Walking (minutes)	0.10	0.08	0.04	0.24	0.39	1.0000

[a]IPAQ-SF: International Physical Activity Questionnaire Short Form.

[b]Denotes correlation is statistically significantly greater than the hypothesized r value of 0.6.

Discussion

Principal Results

The results of this study indicated that the mean adherence rate for wearing and syncing activity monitors was 70% (128/182) at 26 weeks, with an average response rate of 92% (11/12) for the IPAQ-SF collected using the REDCap survey. Other studies have found similar levels of engagement [24,25]. There were no variables that predicted response rate as per our univariate models. Given the poor adherence rates of self-reported physical activity questionnaires in the long term (eg, diaries), activity monitors represent a good alternative with moderate to high levels of compliance as illustrated in this study. This is especially true if some of the issues, such as replacing lost activity monitors and solving log-in errors to the online platform, can be addressed.

The correlation between the physical activity reported from the activity monitor and self-reported measures from the IPAQ-SF was poor and did not reach the threshold necessary for validity (r=0.6), thus indicating poor convergent validity between the 2 constructs. However, it is important to note that physical activity questionnaires suffer from overestimations and underestimations, which limit their ability to act as a comparison for the validity of activity monitor data.

Adherence Rates

Existing literature that employed tools such as pedometers, smartphone apps, and SMS text messages present a variety of findings on the relationship between participant demographic factors and adherence rates.

Age

Within our study, there was a wide age range among participants (18-80 years) but there was no difference for response rate among the ages, potentially due to the small sample size and a lack of power. However, it is interesting to note that all of the noncompliant individuals and those that experienced difficulties with the activity monitor were part of an older demographic group (>50 years). Other studies have identified different age groups with higher adherence rates with activity monitors, SMS text messages, or smartphone apps. In accordance with an article reporting on Australian adolescents, it was previously noted that there is low compliance among the participants in the study due to discomfort of wearing activity devices, the risk of receiving unwanted attention, and feeling embarrassed [26]. Similarly, another study of patients with LBP indicated that participants who withdrew from SMS text message studies were usually younger in age [27]. By contrast, a study concerning the use of medical apps by physicians for patient care demonstrated younger individuals using the app more than older individuals [28]. Similarly, younger individuals were reported to be more likely to use a wearable activity monitor in a US national physical activity survey [29]. The differing results in adherence rates among age groups may reflect the type of data collection tool used and preferences between age groups for a specific tool.

Gender

There has been no consensus thus far on whether males or females are more likely to adhere with using new methods of data collection such as activity monitors and smartphone apps. In this study there was no evidence of gender impacting response rates. A diabetes-related study requested participants to wear an Actical (Philips Respironics) accelerometer for a week to investigate diabetes, pulmonary, and cardiovascular disease risk factors, as well as morbidity and mortality. Results indicated that male participants demonstrated higher adherence rates [25]. However, a study on Swedish, Dutch, and Danish populations including patients with LBP in primary care reported that those who dropped out from studies that used SMS text messages were typically male [30-32]. The disagreement in the literature indicates that there is a lack of information and controversial results on the role of gender in adherence rates.

Levels of Pain

Participant's pain levels were not found to predict adherence to wear for the activity monitor used in this study. In line with our findings, pain levels were not predictors of response rate to an SMS text messaging system used to collect outcome measures within a study of LBP [33]. The poor correlation between adherence and pain levels in these 2 studies may be due to the ease of wearing the Garmin monitor or one's instinctive ability to send SMS text messages [33].

Correlation With IPAQ-SF

The Garmin Vivofit 3 activity monitor collected objective physical activity data in the form of step counts, distance traveled, and intensity minutes. These measures were collected in real time on an ongoing basis, with weekly averages calculated by the device. The IPAQ-SF was used to record subjective estimations of the participant's physical activity patterns over the span of a week. It specifically inquired about the number of days spent doing moderate and vigorous activity, as well as the amount of time spent during one of those days. The responses from the modified IPAQ-SF used in the analysis of our study were estimations of the number of hours of an activity an individual performed in 1 day on a particular week. However, the Garmin activity monitor provided daily measures of activity. Thus, to compare with an estimated average hour per day as presented on the IPAQ-SF, the activity monitor data entered in our validity analysis were averaged per week to represent daily averages. Pearson correlations were used to evaluate the convergent validity of the physical activity data from the Garmin Vivofit 3 in comparison with the IPAQ-SF. We were unable to find any studies that compared the IPAQ-SF with the same variables from a Garmin activity monitor. Of the studies that conducted comparisons between other activity monitors and the IPAQ, the findings presented weak correlations [34]. For example, in a study investigating the validity of the IPAQ-SF in measuring physical activity of patients with chronic fatigue syndrome, the Actical accelerometer measure of vigorous activity was identified to have weak correlations with the IPAQ-SF self-reported measure of vigorous activity [35]. These results are in line with our study, suggesting discrepancies between activity measures and the IPAQ. The weak correlations between the 2 may be the result of the Garmin tracker's inability to detect small-scale changes in activity, the recall bias in completing the IPAQ-SF post hoc, or a combination of these.

Limitations

Limitations to the study included a small sample size and the inclusion of patients with no smartphone or a tablet. Our sample size of 17 individuals did not provide enough statistical power to make definite conclusions about the analysis conducted. In addition, most people were compliant, and thus variety in response rates were low, also compromising some of our comparison's power. The IPAQ-SF was designed to ask participants about their physical activity levels averaging 1 day per week instead of collecting daily measures. This made it difficult to design accurate comparisons with the physical activity data collected by the Garmin tracker. Another limitation pertains to the inclusion of a participant in the study who did not have access to a smartphone or tablet with Bluetooth. This presented issues with Bluetooth syncing to the mobile app. Possession of a smartphone was not one of the criteria for inclusion into the study, thus the individual was enrolled into the study. To accommodate the lack of a mobile device, this participant was provided with an ANT stick to sync her activity monitor to a computer. However, collecting data from this individual was not ideal as her methods of syncing (the frequency of which was used as a measure of compliance) differed from that of the other participants. Finally, we did not collect information on the specific daily wear time for the activity monitors, which means participants could have used and synced information that was collected on a short period during the day rather than all day as expected.

Implications and Future Directions

With a constantly aging population and a high prevalence of the disease, LBP rates will continue to rise and require continuous health care resources. Moving forward, the results from this pilot study may be used to guide future studies and grant applications. Subsequent studies should use this information to develop strategies to boost adherence in older adults with longer back pain duration and poorer self-efficacy. The poor convergent validity between the IPAQ-SF and the Garmin Vivofit 3 raises questions about the validity of these measures in assessing physical activity. Other possible methods include using a commercial-grade activity monitor in combination with a physical activity diary as a more feasible method of tracking physical activity. Future studies could potentially use a research-grade activity monitor such as the ActiGraph to obtain more accurate measures of physical activity. Despite issues with validity, the majority of participants were compliant with wearing the tracker, and thus activity monitors may still be a useful tool in scientific research if used in combination with other measures.

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Conflicts of Interest

None declared.

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Abbreviations

IPAQ-SF: International Physical Activity Questionnaire Short Form
LBP: Low back pain
PAR-Q: Physical Activity Readiness Questionnaire

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