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Contents

Original Papers

Original Paper

Digital Versus Conventional Rehabilitation After Total Hip Arthroplasty: A Single-Center, Parallel-Group Pilot Study

Fernando Dias Correia[1], MD; André Nogueira[2], MPhysio; Ivo Magalhães[2], MPhysio; Joana Guimarães[2], MPhysio; Maria Moreira[2], MPhysio; Isabel Barradas[2], MPhysio; Maria Molinos[2], PhD; Laetitia Teixeira[3,4,5], PhD; Joaquim Pires[6], MD; Rosmaninho Seabra[6], MD; Jorge Lains[7], MD; Virgílio Bento[8], PhD

[1]Neurology Department, Hospital de Santo António-Centro Hospitalar do Porto, Porto, Portugal

[2]SWORD Health, Porto, Portugal

[3]Department of Population Studies, Abel Salazar Institute of Biomedical Sciences, Porto, Portugal

[4]Centro de Investigação em Tecnologias e Serviços de Saúde, Abel Salazar Institute of Biomedical Sciences, University of Porto, Porto, Portugal

[5]EPIUnit, Instituto de Saúde Pública, Universidade do Porto, Porto, Portugal

[6]Orthopaedics Department, Hospital da Prelada-Domingos Braga da Cruz, Porto, Portugal

[7]Physical Rehabilitation Medicine Department, Rovisco Pais Medical and Rehabilitation Centre, Tocha, Portugal

[8]Engineering Department, Instituto Universitário da Maia, Maia, Porto, Portugal

Corresponding Author:
Fernando Dias Correia, MD
Neurology Department
Hospital de Santo António-Centro Hospitalar do Porto
Largo Professor Abel Salazar
4099-001
Porto,
Portugal
Phone: 351 966557789
Email: fanacorreia@gmail.com

Abstract

Background: The demand for total hip arthroplasty (THA) is rising. In the face of rapidly increasing health care costs, ensuring widespread, cost-effective rehabilitation is a priority. Technologies allowing independent home-based rehabilitation may be the key to facilitate access, improve effectiveness, and lower costs of care.

Objective: The aim of this study was to assess the feasibility of a novel artificial intelligence–powered digital biofeedback system following THA and compare the clinical outcomes against supervised conventional rehabilitation.

Methods: This was a single-center, parallel-group pilot study, with an 8-week intervention program. Patients were assessed at baseline, during the program (at 4 and 8 weeks), and 3 and 6 months after surgery. The primary outcome was the Timed Up and Go (TUG) score and secondary outcomes were the Hip dysfunction and Osteoarthritis Outcome Scale (HOOS; a patient-reported outcome) and hip range of motion (ROM).

Results: A total of 66 patients were included: 35 digital physiotherapy (PT) versus 31 conventional. There were no differences at baseline between groups except for lower HOOS quality of life (QoL) subscale scores in the digital PT group. Clinically relevant improvements were noted in both groups at all time points. The digital PT group showed a retention rate of 86% (30/35). Per-protocol analysis revealed a superiority of the digital PT group for all outcome measures. Intention-to-treat analysis revealed the superiority of the digital PT group at all time points for TUG (change between baseline and 4 and 8 weeks: $P<.001$; change between baseline and 3 and 6 months: $P=.001$ and $P=.005$, respectively), with a difference between median changes of −4.79 seconds (95% CI −7.24 to −1.71) at 6 months post-THA. Between baseline and month 6, results were also superior in the digital PT group for the HOOS sports and QoL subscales and all ROM except for standing flexion.

Conclusions: This study demonstrates this novel solution holds promise in rehabilitation after THA, ensuring better clinical outcomes than conventional rehabilitation while reducing dependence on human resources.

Trial Registration: ClinicalTrials.gov NCT03045549; https://clinicaltrials.gov/ct2/show/NCT03045549

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KEYWORDS

THA; THR; digital physiotherapy; telerehabilitation; biofeedback; motion trackers; AI-powered rehabilitation

Introduction

The demand for total hip arthroplasty (THA) is rising [1,2]. By 2030, primary THA in the United States is estimated to increase by 174% and revision THA by 137% compared to 2005 [2], to approximately 572,000 primary and 96,700 revision procedures per year [2].

The efficacy of THA is well documented [3-5], and rehabilitation is key to optimize outcomes [6,7]. Furthermore, studies indicate that more intensive and early progressive exercise leads to better outcomes [8,9], greater satisfaction and adherence [10,11], and reduction of complications and expenses [11,12]. In an expert consensus on best practices for rehabilitation after THA, the greatest support was for 4 to 8 weeks of therapeutic exercise, two to three times per week [13].

In the face of rapidly increasing health care costs, ensuring widespread cost-effective rehabilitation is a priority, but putting this into effect constitutes a challenge, both in terms of logistics and costs.

In recent years, telerehabilitation solutions (ie, rehabilitation services delivered at home from a remote location through a telecommunication system and information technology [14]) have been developed that allow professionals to remotely monitor rehabilitation programs [15-17]. These solutions have demonstrated a potential to reduce health care costs associated with supervision, facility provision, and transport of patients [18-21], while yielding similar, but not superior, clinical outcomes as conventional physical therapy post-THA [22,23].

Using a different approach, several authors have compared unsupervised home-based programs with physiotherapist-led outpatient rehabilitation programs, with both cases showing similar results for patients who comply with their program [21,24-26]. However, in studies comparing supervised with unsupervised training, or no recommended training at all, there is high variability in adherence rates, which is a well-accepted key determinant to therapy success [27-29], ranging from 23% to 85% [8,27,30,31].

More advanced technological solutions have emerged that incorporate biofeedback systems with the intent of increasing both patient performance and adherence [17,32,33] to maximize outcomes. Promising as these may be, they are generally poorly interactive and show low-level evidence, with no long-term validation studies available.

In a previous study, we tested a novel digital biofeedback system based on inertial motion trackers that enables independent home-based physical rehabilitation with remote monitoring from a clinical team after total knee arthroplasty (TKA) [34]. In this study (N=59; NCT03047252), we compared the digital system to conventional, face-to-face, home-based rehabilitation post-TKA over an 8-week program. The results demonstrated that this solution was safe and very well-accepted, with high adherence and satisfaction levels and, most importantly, that the clinical outcomes were superior to conventional rehabilitation [34]. These encouraging results prompted further studies, with the intent of validating this solution in other therapeutic scenarios.

The aim of this single-center, parallel-group pilot study is to assess patient uptake and system safety in patients undergoing THA, as well as to compare the clinical outcomes of a home-based program using this digital physiotherapy (PT) system against conventional, in-person, home-based rehabilitation after THA.

Methods

Study Design

This was a single-center, parallel-group pilot study. It was designed to assess patient uptake and safety of a digital physiotherapy system, as well as to compare the clinical outcomes of a home-based program using a home-based digital program compared with conventional, in-person, home-based rehabilitation after THA.

Study Timeline

All consecutive patients admitted for THA between December 19, 2016 and January 16, 2018, were screened preoperatively and postoperatively for eligibility at Hospital da Prelada, Porto, Portugal, by the two orthopedic surgeons that oversaw the study (JP and RS). Completion date for the 6-month follow-up assessment was July 16, 2018.

Inclusion and Exclusion Criteria

All patients included in this study were referred to post-THA rehabilitation by two independent physicians. Patients were included if they were (1) aged 18 years or older and had (2) clinical and imaging (CT) evidence of hip osteoarthritis as assessed by the orthopedic surgeon, (3) indication for THA according to the patient´s orthopedic surgeon, (4) ability to walk (unaided or with assistive device), and (5) availability of a caregiver to assist the patient after surgery.

Exclusion criteria were (1) admitted for revision THA; (2) contralateral hip or knee osteoarthritis severely limiting patient mobility and ability to comply with a rehabilitation program; (3) aphasia, dementia, or psychiatric comorbidity interfering with communication or adherence to the rehabilitation process; (4) respiratory, cardiac, metabolic, or other condition incompatible with at least 30 minutes of light to moderate physical activity; (5) major medical complications occurring after surgery that prevented the discharge of the patient within 10 days after the surgery; (6) other medical or surgical complications that prevent the patient from complying with a rehabilitation program; and (7) blindness or illiteracy.

Patient Allocation

Patients were recruited at Hospital da Prelada, Porto, Portugal. Patient allocation was performed using patient address as the criterion. Those patients residing in areas outside the administrative limits of the city of Oporto were allocated to the digital PT group, whereas those residing within the city limits were allocated to the conventional rehabilitation group. Patient allocation was performed centrally by one investigator (FDC) and communicated to the responsible physiotherapist only after patient enrollment.

Blinding

The nature of the study did not allow blinding of the patients. Patient assessment was performed by two investigators (JP and RS), who were blinded to the study groups. Statistical analysis was performed by a blinded statistician (LT).

Intervention

After the initial assessment, all patients were submitted to elective THA. Surgical technique was the same for all patients—direct lateral approach under regional anesthesia.

Between day 1 postop and hospital discharge, all patients were taught how to safely get in and out of bed and were asked to perform alternate ankle flexion and extension exercises regularly. All patients performed initial gait training with canes.

After hospital discharge, both groups received an 8-week rehabilitation program starting between day 7 and day 10 after surgery (see Multimedia Appendix 1). These were designed based on the results of a Delphi panel on best practices for rehabilitation after THA [13] and the protocols published by SOFMER, the French Physical and Rehabilitation Medicine Society [35].

In the digital PT group, patients received an initial visit from the physical therapist to assess specific needs and to teach patients and caregivers how to set up and use the system. Patients then performed exercise sessions independently, using the system, under asynchronous remote monitoring from the physical therapist (see Multimedia Appendix 1 for more details). Patients were instructed to exercise 5 to 7 days per week, minimum 30-minute sessions, but they were not excluded in case of lower adherence. Each patient received a telephone call on weeks 2 and 6 to check on patient adaptation, review the program, and assess adverse events; a face-to-face visit on week 4 to perform an in-depth review of the program; and a termination visit to collect the system. Additional visits were performed when required.

The conventional rehabilitation group received a home-based supervised program provided by a physiotherapist, three times a week, for 1 hour (see Multimedia Appendix 1 for more details). Patients were also instructed to perform additional sessions on at least two other days of the week. These were nonmandatory, and no record of these sessions was kept.

Outcomes Assessment

Total Therapist Time

Total therapist time was calculated in both groups, considering the time spent on face-to-face contacts and spent in travel and on calls. For the digital intervention group, time spent per patient in the Web-based portal was also calculated.

Safety and Adverse Events

In the digital PT group, patients were asked to rate pain and fatigue on a scale from zero to 10 at the end of each session. These were available for remote monitoring through the portal. Patients were also given the direct contact of the assigned physical therapist to report adverse events: pain during exercise, falls, and other medical complications (eg, inflammatory signs or infection on the surgical wound or operated member; thrombophlebitis).

Patients in the conventional rehabilitation group performed supervised sessions by a physical therapist, enabling early adverse event detection and reporting.

Primary and Secondary Outcomes

For primary outcome, we chose a performance test—the Timed Up and Go (TUG) test [36], which measures patient mobility and consists of the time it takes to rise from a chair, walk 3 meters, turn around, walk back to the chair, and sit down. This test is among the most recommended outcome measures to routinely assess or monitor outcomes after primary THA [13]. It is simple, practical, and quick and easy to administer, plus it has been demonstrated to predict both short- [37] and long-term [38] function following hip arthroplasty. Importantly, it has also shown excellent interrater (intraclass correlation [ICC] ≥0.9) and very good test-retest (ICC 0.8-0.89) reliability in patients with elective hip replacement (N=100) [39], and higher sensitivity to change in performance after THA than other commonly used self-reported measures, such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Lower Extremity Functional Scale (LEFS) [40]. Moreover, Podsiadlo and Richardson [36] confirmed its content validity in elderly persons (N=60), in that it evaluated a well-recognized series of maneuvers used in daily life.

Secondary outcomes were (1) patient-reported outcomes, measured by the Hip dysfunction and Osteoarthritis Outcome Scale (HOOS) [41] and (2) hip range of motion (ROM).

The HOOS consists of five subscales: (1) pain, (2) symptoms, (3) function in activities of daily living (ADL), (4) function in sport and recreation (sport), and (5) hip-related quality of life (QoL). Patients are asked to answer this disease-specific questionnaire, based on the previous week, with standardized options for each question (each is assigned a score from 0-4). A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale. This scale has shown high test-retest reproducibility for people with hip disability with or without hip osteoarthritis, with ICC ranging from 0.75 to 0.97 for all subscales [41]. The HOOS content validity was tested by Nilsdotter and colleagues [42] in patients assigned to THA (n=90), by asking them to rate the importance of each item. All items were considered to be of at least some importance by more than 67% of the patients, the limit set to justify inclusion into the HOOS. All items included in the pain (10/10), ADL (17/17), sport (5/5), QoL (4/4), and most items included in symptoms (4/5), were considered at least somewhat important by more than 80% of patients.

The SWORD device was used in both groups to measure active hip ROM. This device has been certified for use as an angle-measurement tool, with a reported root mean square error of 3.5° compared with standard goniometry in the technical file. Active hip ROM was measured in degrees in the following exercises: lying and standing hip flexion, lying and standing hip abduction, and standing hip hyperextension. For each exercise, the patient was asked to perform three repetitions by itself; the best value of the three was recorded.

Patients were assessed at baseline (preoperatively), 4 weeks after initiation of rehabilitation, at the end of the 8-week program, and at 3- and 6-months follow-up evaluations.

Sample Size Estimation

Calculations were performed taking into consideration the primary outcome measure—TUG—and based on a minimal detectable change of 2.49 seconds, as reported by Kennedy et al [43] on a longitudinal study evaluating outcomes following total hip and knee arthroplasty. Considering an effect size of 0.65, a power of 80%, and a two-sided .05 significance level, 60 patients (30 in each group) would be necessary to detect a difference of 2.49 seconds between the two groups. Considering a dropout rate of 15%, the target recruitment was 70 patients.

Statistical Analysis

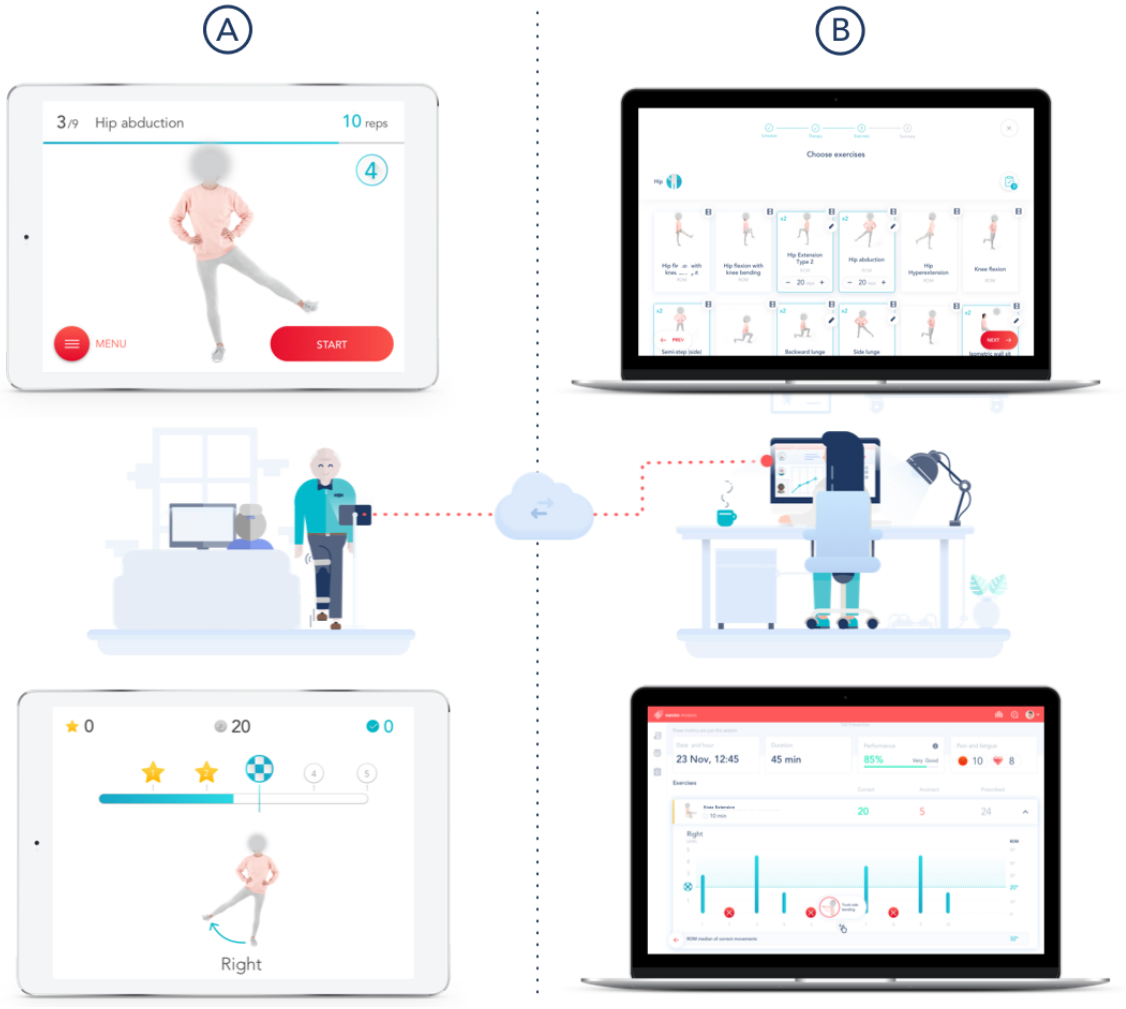
To assess differences in clinical and demographic variables of the patients allocated to the two study groups, independent samples *t* test or Mann-Whitney *U* test were used for quantitative variables. For categorical variables, chi-square test or Fisher exact test were used.

Outcome analysis was performed using both an intention-to-treat analysis and a per-protocol analysis. Differences between interventions were evaluated using independent samples *t* test or Mann-Whitney *U* test. For nonnormally distributed variables, the magnitude of the difference in the medians was assessed using Hodges-Lehman estimator. Additionally, a repeated measures ANOVA was also performed, with group as an independent factor and time as a within-subjects factor. When necessary, logarithm transformation was performed to obtain normally distributed variables. In all analysis, a significance level of .05 was considered. Statistical analysis was performed using IBM SPSS version 24.0.

System Technical Specifications

The system consisted of the elements described subsequently (Figure 1).

Figure 1. System components. (A) Mobile app. Preparation screen (top left): this screen displays video and audio instructions for each exercise. Execution screen (bottom left). (B) Web portal. Prescription screen (top right) displaying the exercise list and session layout. Results screen (bottom right) presenting (1) date, time, and session duration; (2) pain and fatigue scores; and (3) information on each repetition-range of motion and movement errors.



Inertial Motion Trackers

Each tracker consisted of a gyroscope, an accelerometer, and a magnetometer, which enabled precise movement quantification. The trackers were placed on body segments using Velcro straps in three specific positions: (1) over the sternal manubrium (red tracker), (2) on the anterior surface of the hip (green tracker), and (3) over the anterior tibial crest (blue tracker).

Mobile App

The app guided the patient through the session, providing video and audio instructions before each exercise, as well as real-time audio and video biofeedback during the exercise. If the patient performed a movement error or assumed an incorrect posture, an error message was displayed, allowing the patient to correct the movement in the following attempts.

Web-Based Portal

The portal enabled remote result monitoring and exercise prescription/edition by the clinical teams.

Ethics Approval of Research

The study was approved by the National Data Protection Commission (authorization number 1476/2017) and by the local ethics committee at Hospital da Prelada (Chair: Dr Juiz Conselheiro Almeida Lopes). The methods were conducted in accordance with the approved guidelines. All patients and caregivers were provided with information about the purpose and procedures of the study and provided written informed consent before inclusion. All patient data were anonymized and linked to the patient by a unique study number that did not contain any personal identifiers.

Data Availability

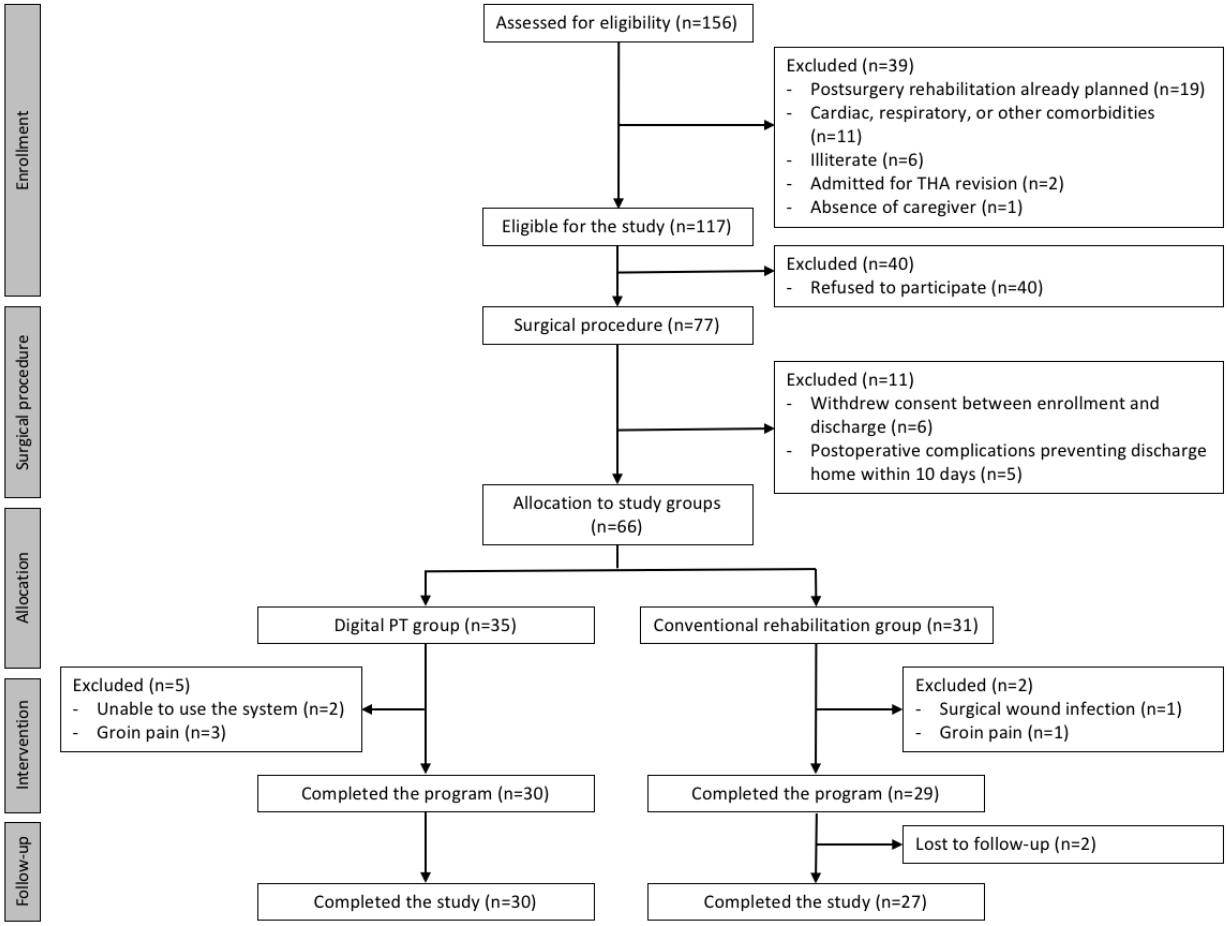
Individual participant data that underlie the results reported in this article will be shared after deidentification as supplementary information (Multimedia Appendix 2) of this paper. Other documents, namely the study protocol, Consolidated Standards of Reporting Trials (CONSORT) details, will also be made permanently available immediately following publication, either through the online version of this paper or at ClinicalTrials.gov (UI: NCT03045549).

Results

Overview

A total of 156 patients were assessed for eligibility between December 19, 2016 and January 16, 2018. Figure 2 shows the CONSORT diagram for the study (see also Multimedia Appendix 3). The study inclusion rate was of 42% (66/156). Between initial assessment and patient allocation, 90 patients refused to participate or withdrew consent, corresponding to 58% of all screening failures.

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) diagram. PT: physiotherapy; THA: total hip arthroplasty.



Overall, 66 patients were included (35 in the digital PT group versus 31 in conventional rehabilitation). The dropout rate in the digital PT group was 14% (5/35): two patients did not adapt to the system and withdrew consent in the first week and three were excluded due to groin pain. The dropout rate in the conventional rehabilitation group was 6% (2/31): two patients were excluded, one due to a surgical wound infection requiring readmission and another due to groin pain. In total, 59 patients completed the study (30 versus 29) and 57 completed the follow-up assessments—two patients in the conventional rehabilitation group were lost to follow-up between the 3- and 6-month assessments.

Study Population Characteristics

Baseline characteristics of study participants regarding demographics, comorbidities, and risk factors for adverse events, as well as data on hospitalization and surgery are summarized in Table 1 (divided by allocation group). There were no differences at baseline between the two study groups regarding any population characteristics.

Independence of Use

In the digital PT group, 13 of 35 patients (37%) required the assistance of a caregiver for tracker or strap placement or navigation. Patients requiring assistance were older (mean age 68.0, SD 7.6 years versus mean 57.7, SD 6.6; *P*=.001).

Table 1. Baseline characteristics of study participants (N=66).

Population characteristics	Digital physiotherapy group (n=35)	Conventional rehabilitation (n=31)	*P* value
Demographics			
Age (years), mean (SD)	62.4 (8)	66.6 (10)	.07[a]
Gender (female), n (%)	15 (43)	16 (2)	.64
Operated hip side (right), n (%)	16 (46)	12 (39)	.74
Comorbidities and known risk factors for adverse events			
Body mass index, mean (SD)	28.3 (3)	27.4 (4)	.31[a]
Smoking, n (%)	2 (6)	7 (23)	.07[b]
Hypertension, n (%)	14 (40)	12 (39)	>.99
Diabetes, n (%)	11 (31)	7 (23)	.59
Pulmonary disease, n (%)	1 (3)	1 (3)	>.99
Cardiac disease, n (%)	3 (9)	5 (16)	.46[b]
Stroke, n (%)	1 (3)	0.0	—[c]
Renal disease, n (%)	0.0	0.0	—
Bleeding disorders, n (%)	0.0	2 (6)	—
ASA[d] (class 3 or 4), n (%)	8 (23)	10 (32)	.56
Steroids for chronic condition, n (%)	0	0	—
Previous contralateral hip replacement, n (%)	7 (20)	5 (16)	.93
Previous knee replacement, n (%)	1 (3)	0	—
Hospital admission and surgical procedure			
Time between admission and surgery (hours)	<24	<24	—
Operative time (min), mean (SD)	63.7 (19)	59.9 (9)	.10[a]
Noncemented prosthesis, n (%)	2 (6)	2 (6)	>.99
Minor adverse events before discharge, n (%)	0.0	0.0	—
Length of stay (days), median (IQR[e])	6.0 (2)	6.0 (1)	.43[f]

[a]Independent sample *t* test.

[b]Fisher exact test.

[c]Not applicable.

[d]American Society of Anesthesiology physical status classification system.

[e]IQR: interquartile range.

[f]Mann-Whitney *U* test.

Adherence to the Intervention

Only five patients (17%) did not comply with the recommended session frequency of five times per week.

Patient Satisfaction

Patients in the digital PT group were asked to report their satisfaction level by answering the question: "On a scale from 0-10 ('0' meaning that you would not recommend and '10' that you would highly recommend), how much would you recommend the system to one of your friends or neighbors?" Of the 35 patients in this group, 32 (91%) rated the system as 10, two patients rated the system as 9, and one did not answer.

Therapist-Patient Interaction

Patients in the conventional rehabilitation group had 24 in-person sessions, whereas patients in the digital PT group had 3 face-to-face contacts with the therapist and, on average, 0.6 (range 0-2) extra contacts for technical assistance. Regarding telephone calls, in addition to the two scheduled calls per protocol, each patient received a median of four extra calls (range 0-7), the vast majority due to difficulties in interacting with the system.

Treatment Intensity

Total active treatment time was similar in both groups in both intention-to-treat (ITT) and per-protocol analysis (ITT: *P*=.11; per protocol: *P*=.24). In the ITT analysis, treatment intensity in the digital PT group was 20 hours (interquartile range [IQR] 11.0, range 1.0-59.0) and in the per-protocol analysis was 21 hours (IQR 10.3, range 8.0-59) versus 24 hours in the conventional PT group.

Outcomes Assessment

Total Therapist Time

Total therapist time was lower in the digital intervention group (mean 6.5, IQR 1.2 hours versus mean 32.1, IQR 5.2 hours; *P*<.001).

Safety and Adverse Events

For all patients enrolled in the study (66 patients), there was no significant difference between groups for safety and adverse events (*P*>.99).

In the digital PT group, the adverse event rate was 14% (5/35). Three patients were excluded due to significant pain during hip abduction, without inflammatory or other warning signs. All three patients recovered spontaneously within 2 weeks. One patient reported inflammatory signs over the surgical wound and another suffered a fall (not during system use), with no need for hospital assistance.

In the conventional rehabilitation group, the adverse event rate was 23% (7/31). One patient required hospital readmission and a revision procedure due to a surgical wound infection, one was excluded due to groin pain, two patients reported inflammatory signs over the surgical wound, one patient had a thrombophlebitis, one reported a unilateral lower limb edema (with spontaneous recovery), and one patient suffered a fall, with no need for hospital assistance.

Primary and Secondary Outcomes

Baseline

There were no differences between the two groups regarding outcome measures, except for the HOOS QoL subscale (*P*=.03; see Tables 2-4). The median difference between the TUG scores in the two groups was of 2.34 seconds (95% CI −0.69 to 5.17) in favor of the conventional rehabilitation group. Taking into consideration the 2.49 seconds reported as minimal detectable change for this test [43], this difference is neither statistically nor clinically significant.

Table 2. Primary outcome assessment of Timed Up and Go (TUG) test: intention-to-treat analysis (N=66).

Time point	TUG time (seconds), median (IQR[a])		*P* value[b]	Estimate difference between groups (95% CI)
	Digital PT[c] group (n=35)	Control group (n=31)		
Baseline	17.50 (6.33)	14.89 (9.42)	.12	2.34 (−0.69, 5.17)
Short term				
8 weeks	7.26 (2.15)	11.03 (6.84)	<.001	−3.34 (−5.14, −1.70)
Change baseline-8 weeks	−10.50 (7.45)	−2.90 (7.10)	<.001	−6.33 (−8.79, −3.42)
Medium term				
6 months	6.38 (2.30)	8.20 (4.22)	<.001	−1.87 (−3.02, −0.62)
Change baseline-6 months	−10.50 (7.39)	−5.10 (6.94)	.005	−4.79 (−7.24, −1.71)

[a]IQR: interquartile range.

[b]Mann-Whitney *U* test.

[c]PT: physiotherapy.

Table 3. Secondary outcome of patient-reported Hip dysfunction and Osteoarthritis Outcome Scale (HOOS): intention-to-treat analysis (N=66).

Time point and variable	Score, median (IQR[a])		*P* value[b]	Estimate difference between groups (95% CI)
	Digital PT[c] group (n=35)	Control group (n=31)		
Baseline				
Symptoms	35.0 (20.0)	40.0 (30.0)	.12	−10.0 (−20.0, 0.0)
Pain	33.0 (13.0)	33.0 (35.0)	.50	−3.0 (−13.0, 5.0)
Activities of daily living	29.0 (15.0)	28.0 (28.0)	.75	1.0 (−6.0, 7.0)
Sports	0.0 (6.0)	0.0 (19.0)	.34	0.0 (0.0, 0.0)
Quality of life	13.0 (13.0)	19.0 (25.0)	.03	−6.0 (−13.0, 0.0)
8 weeks				
Symptoms	100.0 (5.0)	95.0 (20.0)	.01	5.00 (0.0, 10.0)
Pain	100.0 (7.0)	98.0 (12.0)	.24	0.0 (0.0, 5.0)
Activities of daily living	93.0 (11.0)	82.0 (14.0)	<.001	9.0 (4.0, 13.0)
Sports	50.0 (18.0)	38.0 (19.0)	.004	12.0 (6.0, 19.0)
Quality of life	81.0 (19.0)	69.0 (31.0)	.08	6.0 (0.0, 18.0)
Change baseline-8 weeks				
Symptoms	60.0 (30.0)	45.0 (30.0)	.06	10.0 (0.0, 20.0)
Pain	60.0 (22.0)	60.0 (32.0)	.75	2.0 (−10.0, 10.0)
Activities of daily living	56.0 (23.0)	57.0 (27.0)	.63	−2.0 (−10.0, 6.0)
Sports	44.0 (25.0)	38.0 (25.0)	.26	6.0 (−6.0, 13.0)
Quality of life	63.0 (31.0)	50.0 (25.0)	.46	6.0 (−6.0, 13.0)
6 months				
Symptoms	100.0 (5.0)	95.0 (10.0)	.20	0.0 (0.0, 5.0)
Pain	100.0 (5.0)	100.0 (7.0)	.75	0.0 (0.0, 0.0)
Activities of daily living	96.0 (11.0)	88.0 (19.0)	.02	4.0 (0.0, 10.0)
Sports	75.0 (32.0)	50.0 (32.0)	.01	19.0 (6.0, 37.0)
Quality of life	94.0 (12.0)	81.0 (19.0)	.02	7.0 (0.0, 19.0)
Change baseline-6 months				
Symptoms	60.0 (25.0)	45.0 (30.0)	.06	10.0 (0.0, 20.0)
Pain	65.0 (18.0)	53.0 (30.0)	.21	7.0 (−5.0, 17.0)
Activities of daily living	63.0 (22.0)	56.0 (25.0)	.10	7.0 (−1.0, 15.0)
Sports	69.0 (31.0)	38.0 (38.0)	.004	25.0 (7.0, 37.0)
Quality of life	75.0 (32.0)	56.0 (31.0)	.01	19.0 (6.0, 25.0)

[a]IQR: interquartile range.

[b]Mann-Whitney *U* test.

[c]PT: physiotherapy.

Table 4. Secondary outcome of hip range of motion assessment: intention-to-treat analysis (N=66).

Time point and variable	Median (IQR[a])		*P* value[b]	Estimate difference between groups (95% CI)
	Digital PT[c] group (n=35)	Control group (n=31)		
Baseline				
Lying flexion	28.2 (19.1)	37.1 (20.0)	.07	−8.9 (−18.53, 0.67)
Lying abduction	12.2 (5.4)	15.9 (9.1)	.05	−3.7 (−7.48, 0.02)
Standing flexion	45.1 (15.9)	49.6 (16.7)	.27	−4.5 (−12.52, 3.53)
Standing hyperextension	−11.9 (7.0)	−15.4 (8.8)	.31	3.4 (−0.44, 7.33)
Standing abduction	23.5 (6.8)	25.8 (10.7)	.08	−2.2 (−6.78, 2.26)
8 weeks				
Lying flexion	84.0 (23.5)	66.6 (19.6)	.002	17.5 (6.78, 28.18)
Lying abduction	50.5 (17.5)	39.2 (15.2)	.01	11.4 (3.27:19.50)
Standing flexion	87.6 (21.2)	80.0 (19.8)	.14	7.5 (−2.58, 17.66)
Standing hyperextension	−36.7 (14.3)	−30.1 (8.2)	.03	−6.6 (−12.28, −0.96)
Standing abduction	52.2 (13.8)	40.3 (11.3)	<.001	11.9 (5.62, 18.13)
Change baseline-8 weeks				
Lying flexion	55.8 (27.4)	29.4 (25.6)	<.001	26.4 (13.32, 39.50)
Lying abduction	38.4 (17.3)	23.3 (15.7)	<.001	15.1 (6.91, 23.25)
Standing flexion	42.5 (21.3)	30.4 (20.3)	.02	12.0 (1.81, 22.33)
Standing hyperextension	−24.7 (12.7)	−14.7 (10.1)	.001	−10.1 (−15.75, −4.38)
Standing abduction	28.7 (13.4)	14.6 (13.5)	<.001	14.1 (7.51, 20.76)
6 months				
Lying flexion	80.7 (24.4)	70.0 (19.3)	.06	10.7 (−0.27, 21.6)
Lying abduction	49.8 (18.2)	41.6 (14.3)	.048	8.2 (0.06, 16.31)
Standing flexion	90.2 (23. 1)	84.8 (19.8)	.32	5.4 (−5.25, 16.03)
Standing hyperextension	−34.1 (15.1)	−28.8 (9.2)	.10	−5.3 (−11.36, 0.81)
Standing abduction	51.7 (15.1)	43.8 (11.8)	.02	8.0 (1.24, 14.69)
Change baseline-6 months				
Lying flexion	52.5 (26.6)	32.8 (25.6)	.003	19.6 (6.73, 32.50)
Lying abduction	37.6 (18.2)	25.7 (15.2)	.01	11.9 (3.57, 20.20)
Standing flexion	45.1 (22.6)	35.2 (20.6)	.07	9.9 (−0.79, 20.57)
Standing hyperextension	−22.2 (13.3)	−13.5 (11.1)	.01	−8.7 (−14.72, −2.59)
Standing abduction	28.2 (14.3)	18.0 (12.1)	.003	10.2 (3.64, 16.74)

[a]IQR: interquartile range.

[b]Mann-Whitney *U* test.

[c]PT: physiotherapy.

Short-Term Outcomes Assessment

4-Week Assessment

Differences between groups were found for TUG between the digital PT and the conventional group: mean 9.9 (SD 5.4) seconds versus mean 15.0 (SD 8.2) seconds, respectively (*P*<.001), (see Multimedia Appendix 4) and for all hip ROM exercises, except standing flexion (*P*=.05; see Multimedia Appendix 4). There were no differences between groups in terms of patient-reported outcomes (see Multimedia Appendix 4).

8-Week Assessment

The TUG scores were again lower in the digital PT group (*P*<.001; see Table 2). The median difference between the TUG scores in the two groups was 3.34 seconds (95% CI −5.14 to −1.70).

Regarding HOOS, the median scores in the digital PT group were superior to the conventional rehabilitation group for all subscales, except for pain and QoL (see Table 3). Importantly, in the symptoms and pain subscales, the median scores at the 8-week assessment were either the maximum score that can be attained (100) or close to that value in both groups, revealing a ceiling effect, which persisted over time (see Table 3).

Hip ROM was also higher in the digital PT group for all exercises, except for standing flexion (see Table 3).

Change Between Baseline and the 8-Week Assessment

The median difference between the changes in the two groups regarding the TUG score was 6.33 seconds (95% CI −8.79 to −3.42). The minimal detectable change was 2.49 seconds, which reveals a clinically significant difference (see Table 2).

No significant differences were detected in the median changes from baseline and week 8 for HOOS scores (see Table 3).

For hip ROM, significant improvements from baseline were noted in both groups, again with the digital PT group showing greater results (see Table 4).

In the per-protocol analysis, the change between baseline and week 8 was superior in the digital PT group for all outcome measures (see Multimedia Appendix 5).

Medium-Term Outcomes Assessment

3-Months Assessment

The TUG score remained significantly different between groups ($P<.001$), with patients from the SWORD group experiencing better results (see Multimedia Appendix 4).

For the HOOS, the median scores in the digital PT group were superior for all subscales except for pain ($P=.10$) and symptoms ($P=.08$; see Multimedia Appendix 4).

Hip ROM was also higher in the digital PT group for all measured exercises ($P<.001$), except for standing flexion ($P=.41$; see Multimedia Appendix 4).

6-Months Assessment

The median difference between the TUG scores in the two groups was 1.87 seconds (95% CI −3.02 to −0.62) in favor of the digital PT group ($P=.002$; see Table 2).

For HOOS, the median scores in the digital PT group were significantly superior to the conventional rehabilitation group for the ADL ($P=.02$), sports ($P=.01$), and QoL ($P=.02$) subscales (see Table 3). Importantly, the majority of patients from both groups reported the highest possible scores in the symptoms and pain subscales, and the ADL and QoL scores from the digital PT group nearly reached this same plateau (see Table 3).

Hip ROM was higher in the digital PT group for lying abduction ($P=.048$) and standing abduction ($P=.02$; see Table 4).

Change Between Baseline and the 6-Months Assessment

The ITT analysis revealed the superiority of the digital PT group in the TUG test, HOOS sports and QoL subscales, and all hip ROM exercises, except for standing flexion.

The median difference between the changes in the two groups for TUG was 4.79 seconds (95% CI −7.24 to −1.70) in favor of the digital PT group (see Table 2).

For HOOS, the difference between median score changes was both statistically and clinically significant in the sports (25.0 points, 95% CI 7.0-37.0) and the QoL (19.0 points, 95% CI 6.0-25.0) subscales (see Table 3).

For hip ROM, significant differences between the mean changes in the two groups were detected in all ROM exercises, except the standing flexion hip ROM ($P=.07$; see Table 4).

In the per-protocol analysis, the superiority of the digital PT group was verified for all outcome measures (see Multimedia Appendix 5).

Repeated Measures Analysis

A repeated measures ANOVA was performed only for variables with normal distribution—TUG (after log transformation) and hip ROM—and results are summarized in Table 4. Although both groups presented an improvement in every dimension evaluated, this analysis revealed a main effect of time, a main effect of group (here with the exception of the standing hip flexion ROM), and an interaction between time and group for all outcome measures in favor of the digital PT group (see Table 5 and Figure 3).

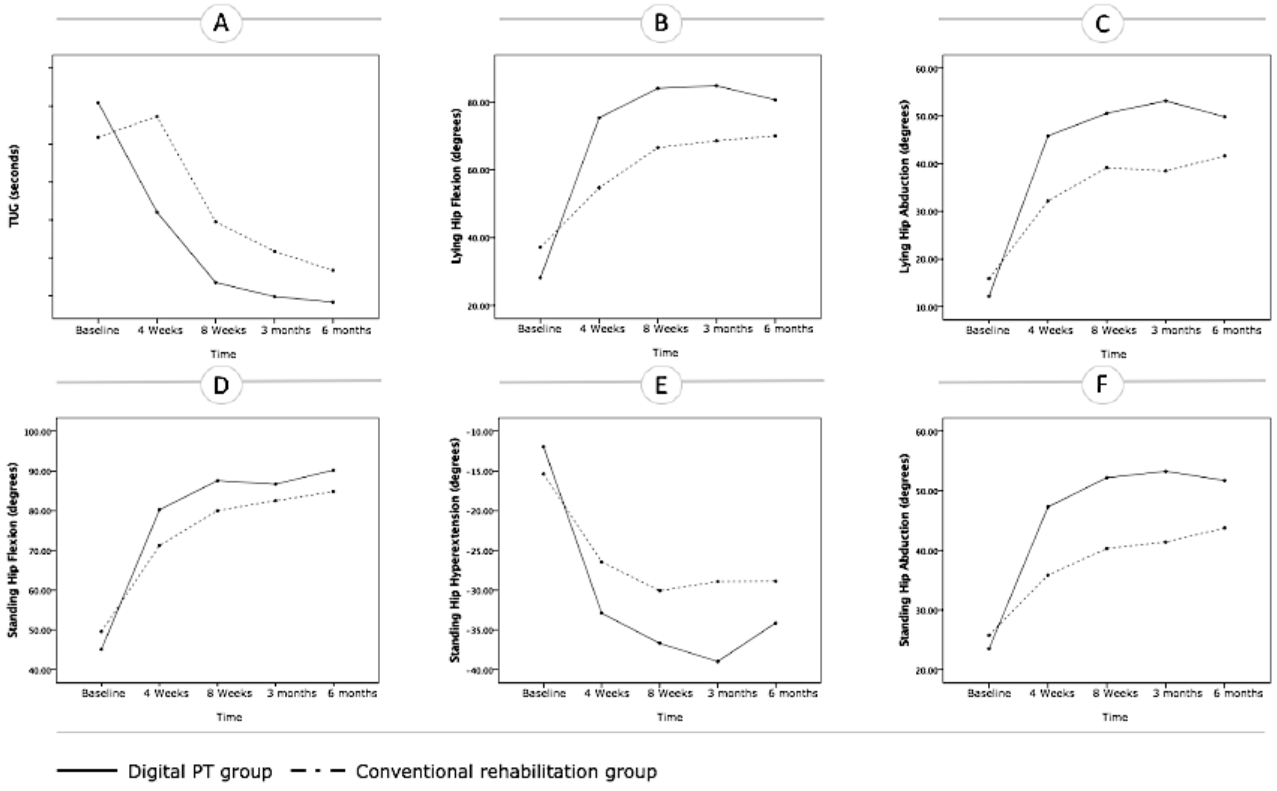
Table 5. Outcomes assessment: repeated measures analysis.

Outcome variable	Time		Group		Time*Group	
	F (df1,df2)	*P* value	*F* (df1,df2)	*P* value	*F* (df1,df2)	*P* value
Patient performance						
Timed Up and Go[a,b]	128.6 (2.5,159.6)	<.001	12.3 (1,64)	.01	14.9 (3.2,159.6)	<.001
Hip range of motion[b]						
Lying hip flexion	119.4 (1.9,121.6)	<.001	6.5 (1,64)	.01	12.0 (1.9,121.6)	<.001
Lying hip abduction	139.0 (2.9,188.1)	<.001	9.4 (1,64)	.03	10.4 (2.9,121.6)	<.001
Standing hip flexion	154.9 (1.9,123.1)	<.001	1.06 (1,64)	.31	4.0 (1.9,123.1)	.02
Standing hip hyperextension	91.1 (3.3,211.2)	<.001	4.6 (1,64)	.04	8.2 (3.3,211.2)	<.001
Standing hip abduction	125.5 (2.1,137.3)	<.001	10.0 (1,64)	.002	12.1 (2.1,137.3)	<.001

[a]ln transformation.

[b]Greenhouse-Geisser correction.

Figure 3. Evolution of the outcomes over time in both groups based on the repeated measures analysis (estimated marginal means are presented). (A) Timed Up and Go (TUG) score, (B) lying hip flexion, (C) lying hip abduction, (D) standing hip flexion, (E) standing hip hyperextension, (F) standing hip abduction. PT: physiotherapy.



Discussion

Patient refusal and consent withdrawal were the main reasons for screening failures in this study (57.7%, 90/156). The explanation for this high refusal rate resides in patient skepticism on the patient side, especially in an older population with little technological literacy. This same difficulty was reported by other authors in studies with similar devices [44] and is one of the challenges that these technologies need to overcome. The oldest patients in this study were also afraid of hidden costs, even though it was clear and thoroughly explained that participation in the study did not imply any cost.

There were two dropouts in the digital PT group, and a high percentage of patients needed assistance from a caregiver to interact with the system (37%, 13/35) or required assistance calls. This likely represents the challenges felt by an older population when dealing with technology and some issues with the user interface that need to be overcome. In particular, each physical interaction (ie, the need to calibrate sensors and the multiple touches needed to start a session) represent huge hurdles for elderly patients. This has been another challenge faced by similar technologies and is an aspect where there is still much room for improvement.

The patient satisfaction score was very high, with all but two patients rating the system with a 10/10. This is particularly interesting considering the high percentage of patients who needed assistance in using the system. When they were asked to elaborate on the reasons, almost all referred to the possibility of performing sessions at home, at their convenience. Still, it must be considered that patients who agreed to enter the study were more prone to use new technologies, and thus more likely to give high scores.

Regarding clinical outcomes, considering the reference values for the TUG [43], HOOS [45], and hip ROM [46], both groups attained clinically relevant improvements in all outcome measures in the short- and medium-term assessments. This is in line with the findings of other authors who reported the effectiveness of early exercise interventions post-THA [8,10,47-49].

Greater benefits were observed in the digital PT group, which was particularly evident in the per-protocol analysis, for all outcome measures. Furthermore, for TUG and hip ROM, these were confirmed in the repeated measures analysis. This is a major achievement for remotely assisted PT programs, considering no evidence exists yet on the superiority of a specific exercise intervention post-THA [13,50-52]. Indeed, this approach could be a game-changer on how rehabilitation programs are delivered following hip replacement. By offering a scalable solution that does not rely entirely on human resources and maximizes the reach of existing resources, while minimizing patient discomfort and the need for traveling back and forth, access to effective rehabilitation could be democratized.

A synergy of factors might explain the results obtained in this study. These have already been discussed in a previous paper [34] and can be summarized as follows: (1) beneficial impact of biofeedback and gamification on patient engagement and performance, namely on achieving a higher ROM and on a more effective correction of movement errors; (2) greater patient empowerment, coupled with the effect of monitoring on patient effort; and (3) program changes based on objective data.

In the absence of studies using technologies similar to this one, it was nearly impossible to establish interstudy comparisons. In fact, we found five reports on biofeedback systems designed to complement physical therapists' intervention following hip arthroplasty [17,32,33,53,54], of which only two were based on inertial motion tracking [53,54]. However, the aims of these studies were distinct from ours and did not propose any rehabilitation program. Furthermore, reports on PT interventions for THA recipients revealed high methodological variability regarding timing, duration and intensity, outcome measures, and timelines for assessment [5,6,51,55]. Thus, only broad comparisons can be made between this study and previous ones.

Despite being one of the most often used and recommended performance-based outcome measures [13], the TUG test was only found in four studies [24,25,30,56]. From these, one compared the change between baseline and 9 to 12 months postsurgery [30], and the others presented data on 4- [56], 8- [24], 12- and 26-week [25] assessments or on the change between baseline and 9 to 12 months [30]. All studies but one [56] reported similar significant improvements on the TUG test with time in both intervention groups. Overall, reported changes in TUG scores varied between 0.36 seconds [56] and −5.8 seconds [25]. The results in the conventional PT group from this study fall broadly within these values, whereas the results of the digital PT group were higher, even surpassing the scores previously reported for healthy, community-living older adults (mean 8 seconds) [57,58]. Additionally, although the pattern of recovery from the conventional group followed a similar trend to the ones found in other studies using conventional PT [59,60], patients from the digital PT group improved faster (38% at 4 weeks after surgery) and to a greater extent in the medium term (60% at 24 weeks). Indeed, in the study from Naylor et al [59], an Australian cohort of 44 THA recipients (mean age 65 years) with TUG baseline values similar to ours (18 seconds), patient recovery at 4 weeks was approximately 6% and plateaued at 36% 24 weeks after surgery. Additionally, Kennedy et al [60] reported a very slow recovery in a Canadian cohort of 68 patients (mean age 68 years), with a 78% TUG aggravation within the first 4 weeks following surgery (18 seconds) and a 21% improvement from baseline after 24 weeks. However, in this latter case, baseline values were oddly low (10.14 seconds), masking an actual 73% recovery after 24 weeks when the postoperative TUG (30 seconds) was set as the reference value.

Regarding HOOS, all subscales from both groups presented higher scores than those reported on a French (N=30; 37.5-55.3 points) [45] or Swedish HOOS validation study (N=90; 56.3-82.3 points) [42] 3 and 6 months after THA, respectively. In another randomized controlled trial (RCT; N=68) on the effect of a walking skill training program in THA patients, significant improvements were detected between 3 and 5 months. However, changes were much smaller than those we observed. Also, in terms of changes from baseline, both the digital PT and the control group improved significantly from baseline to 4 weeks postoperatively, which was sooner than what was reported by Mikkelsen et al (RCT; N=73) [8] and Heiberg et al (RCT; N=68) [61]. Importantly, a ceiling effect was observed on the HOOS symptoms and pain subscales, with patients from both intervention groups reporting the best possible score from 8 weeks onward. Ceiling effects have also been reported on all subscales in the Swedish HOOS validation study, 6 months after THR [42], and in the Dutch RCT by Mikkelsen et al [8]. Considering some sensitivity is lost using this scale, a revision and adaptation to the context of digital interventions, such as the one we presented, would be very useful in the future.

Regarding hip ROM, all reports use goniometry as a means to measure hip ROM, whereas we applied high-precision sensor-based technology to assess active hip ROM, enabling continuous remote monitoring [34,62], while eliminating operator errors [63]. In a retrospective study by Davis et al (N=1383) [64], a logistic regression model yielded three levels of postsurgery hip ROM: high (115° of flexion, 25° of abduction), average (90°-114° of flexion, 16°-24° of abduction), or low (<90° of flexion, ≤15° of abduction) motion. Considering these ranges, scores from our study revealed very high abduction amplitudes in both groups at month 6 postsurgery, particularly in the digital PT group. Indeed, we found no other reports

showing superior abduction results than those reported in this study [31,56,61,65,66].

On the other hand, flexion ROM values fell in the lower range reported, revealing some room for improvement. Notwithstanding, our results from the digital PT group at month 6 (median 80.7°, IQR 24.4) were comparable to the ones reported on another prospective study (N=15) [66] on THA outcomes 12 months postsurgery (flexion mean 93.3°, SD 18.7°).

Another study by Umpierres et al (RCT, N=106) [65] also reported on the improvement of hip flexion and extension ROM following THR, with an early 2-week inpatient supervised versus unsupervised intervention. Although closer to the values reported at the 4-week assessment in this study, results from the digital PT group in our study were superior to the ones reported in this RCT. Other studies were found in which flexion and extension ROMs were higher than those we reported [31,56,61]. However, even considering possible differences related to measurement methods, high baseline angles revealed that the population in these studies was not as disabled as the one in this study.

Although the improvements achieved in hip ROM are substantial, the values are still far from those reported for healthy individuals [67].

This study has several limitations that need to be acknowledged. This was a quasi-randomized study, in which patient allocation was performed according to geographical location. This implies that even if no differences were found in demographics, comorbidities, and risk factors for adverse and clinical characteristics (except for the HOOS QoL subscale), a number of factors (eg, socioeconomic) might have influenced the results. Still, almost all the patients resided in urban areas; therefore, the authors speculate that the impact of these aspects is small, but nonetheless needs to be controlled in ensuing studies.

There was a potential selection bias toward more technologically prone recipients, given the low inclusion rate. To address this, greater involvement of the clinical teams (doctors and nursing staff) in the wards is required to overcome natural patient skepticism.

The limited context of the clinical setting, which was a low-volume orthopedic hospital, may not reflect the reality of other settings. Thus, generalization of the results needs to be confirmed in larger hospitals and multicentric trials.

The study protocol depicts slight differences between the digital PT group and conventional rehabilitation group that could be confounders. First, the total active treatment time was similar between groups. However, the intensity in the digital PT group was highly variable, and unsupervised sessions in the conventional group were not taken into consideration. These aspects also need to be homogenized and controlled in future studies. Second, the exercise program was similar in both groups, with the exception of additional exercises that were possible only with a face-to-face intervention. In this sense, although the authors agree that these may be confounding factors, they benefit the conventional group and not the digital intervention group and therefore do not bias results toward the latter.

There was a notable absence of minor adverse events, in particular after 8 weeks, most likely due to underreporting. In future studies, in addition to direct telephone contacts at predetermined time stamps and specific questioning of adverse events in assessment appointments, event logs should be delivered to the patients for them to fill in.

In conclusion, this study demonstrates that home-based rehabilitation with this novel digital biofeedback system is feasible and safe following THA as previously demonstrated for TKA, and is associated with high patient satisfaction, albeit with room for improvement in terms of usability by elderly patients. Plus, to our knowledge, it is the first study demonstrating that a digital rehabilitation solution can reduce the dependence on human resources while ensuring better clinical outcomes than conventional rehabilitation in the short and medium term following THA. These promising results justify further investigation and prove the feasibility of larger RCTs to confirm these findings.

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Authors' Contributions

Study concept and design: FDC, AN, VB, JP, RS, and LT. Data acquisition: IM, JG, MM, and IB. Direct supervision of rehabilitation program: IM, JG, MM, and IB. Independent supervision of rehabilitation program: JP and RS. Outcomes assessment: JP. Analysis and interpretation of data: FDC, LT, AN, and MM. Critical revision of the manuscript for important intellectual content: all authors. Obtained funding: FDC and VB. Administrative, technical, and material support: IM, JG, MM, and IB. Study supervision: FDC, VB, JP, RS, and AN.

Conflicts of Interest

FDC and VB have a shareholder position at SWORD Health, a company that develops and commercializes SWORD-related products. AN, IM, JG, MM, and IB are employees of SWORD Health but do not have shareholder positions. LT and JL receive honoraria from SWORD Health. JP and RS have no conflicts of interest to report.

Multimedia Appendix 1

Rehabilitation protocol.

[DOCX File, 17KB - rehab_v6i1e14523_app1.docx]

Multimedia Appendix 2

Raw data.

[XLSX File (Microsoft Excel File), 260KB - rehab_v6i1e14523_app2.xlsx]

Multimedia Appendix 3

CONSORT‐EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 2MB - rehab_v6i1e14523_app3.pdf]

Multimedia Appendix 4

Intent-to-treat analysis.

[DOCX File, 43KB - rehab_v6i1e14523_app4.docx]

Multimedia Appendix 5

Per protocol analysis.

[DOCX File, 186KB - rehab_v6i1e14523_app5.docx]

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Abbreviations

ADL: activities of daily living
CONSORT: Consolidated Standards of Reporting Trials
HOOS: Hip dysfunction and Osteoarthritis Outcome Scale
IQR: interquartile range
ITT: intention-to-treat
PT: physiotherapy
QoL: quality of life
RCT: randomized controlled trial
ROM: range of motion
THA: total hip arthroplasty
TKA: total knee arthroplasty
TUG: Timed Up and Go

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Original Paper

Walking With a Robotic Exoskeleton Does Not Mimic Natural Gait: A Within-Subjects Study

Chad Swank[1*], PT, PhD; Sharon Wang-Price[1*], PT, PhD; Fan Gao[2*], PhD; Sattam Almutairi[1*], PT, DPT

[1]Texas Woman's University, Dallas, TX, United States

[2]University of Kentucky, Lexington, KY, United States

[*]all authors contributed equally

Corresponding Author:
Chad Swank, PT, PhD
Texas Woman's University
5500 Southwestern Medical Ave
Dallas, TX, 75235
United States
Phone: 1 2146897714
Email: cswank@twu.edu

Abstract

Background: Robotic exoskeleton devices enable individuals with lower extremity weakness to stand up and walk over ground with full weight-bearing and reciprocal gait. Limited information is available on how a robotic exoskeleton affects gait characteristics.

Objective: The purpose of this study was to examine whether wearing a robotic exoskeleton affects temporospatial parameters, kinematics, and muscle activity during gait.

Methods: The study was completed by 15 healthy adults (mean age 26.2 [SD 8.3] years; 6 males, 9 females). Each participant performed walking under 2 conditions: with and without wearing a robotic exoskeleton (EKSO). A 10-camera motion analysis system synchronized with 6 force plates and a surface electromyography (EMG) system captured temporospatial and kinematic gait parameters and lower extremity muscle activity. For each condition, data for 5 walking trials were collected and included for analysis.

Results: Differences were observed between the 2 conditions in temporospatial gait parameters of speed, stride length, and double-limb support time. When wearing EKSO, hip and ankle range of motion (ROM) were reduced and knee ROM increased during the stance phase. However, during the swing phase, knee and ankle ROM were reduced when wearing the exoskeleton bionic suit. When wearing EKSO, EMG activity decreased bilaterally in the stance phase for all muscle groups of the lower extremities and in the swing phase for the distal muscle groups (tibialis anterior and soleus) as well as the left medial hamstrings.

Conclusions: Wearing EKSO altered temporospatial gait parameters, lower extremity kinematics, and muscle activity during gait in healthy adults. EKSO appears to promote a type of gait that is disparate from normal gait in first-time users. More research is needed to determine the impact on gait training with EKSO in people with gait impairments.

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KEYWORDS

electromyography; gait; kinematics; lower extremity; muscle activation; range of motion; robotic exoskeleton

Introduction

Walking is a complicated process requiring optimal muscle activation and joint mobility to control dynamic balance and posture under different environments. Typified by characteristic muscle activity and kinematic patterns governed by predesigned central nervous system motor programs [1], walking consists of identifiable sequential patterns within a relative timing mechanism [2]. However, an injury to the neuromuscular system is likely to result in atypical walking patterns of both kinematics and muscle activity performance.

Recovery of walking continues to be the primary goal for persons with neurological deficits and a contributing factor to the quality of life [3,4]. Therefore, learning to walk is a major goal during rehabilitation [5,6]. Although the optimal therapeutic intervention to achieve full recovery of gait remains unknown

for many patients with neurological injuries, any rehabilitation effort intended to drive neuroplastic changes toward motor recovery should incorporate principles of neuroplasticity. Specifically, inclusion of factors (ie, loading the sole of the foot and attaining adequate hip extension movement) to facilitate appropriate electromyographic (EMG) patterns is thought to be crucial [7]. Locomotor training seeks to capitalize on these established principles [8-10].

Recently, robotic exoskeletons have been developed, and they offer a relatively new form of locomotor training. Robotic exoskeleton devices enable individuals with lower extremity weakness (ie, people with stroke or spinal cord injury) to stand up and walk over ground with a full weight-bearing and reciprocal gait. By adding actuators adjacent to the study participant's hip and knee joints, robotic exoskeletons provide an external source of controlled joint power. Several exoskeletons have been developed for gait restoration, with much variation in the actuator and sensing technologies. Although there are some commercially available devices, like the ReWalk or EKSO, the technology is not yet mature enough to produce unlimited community ambulation [11-13]. Although gait training with exoskeletons has been shown to be safe and well tolerated, with no significant complications [14] over distances of 40-100 m [15], it is unclear how closely the gait of a person wearing a robotic exoskeleton approximates normal gait. Recently, 2 case studies have highlighted the impact of wearing a robotic exoskeleton on gait characteristics. In the first case study, the lower extremity range of motion (ROM) was generally smaller, with greater hip and knee power generation, for the exoskeleton gait [16]. However, in the second case study, improved symmetry on temporospatial variables and increased gait speed were indicated after robotic exoskeleton gait training in a person with stroke [17].

A common goal of gait retraining is to promote locomotor features typical of normal gait. However, the current robotic exoskeleton devices may promote different nonphysiological walking characteristics. These differences in gait parameters may be accompanied by dissimilarities in kinematics and muscle activity typically observed in normal walking. It is crucial to identify the differences between exoskeleton walking and normal walking prior to using a robotic exoskeleton system for gait training. Therefore, the purpose of this study was to examine whether wearing a robotic exoskeleton suit affects kinematics and muscle activity of the lower extremities during walking. We compared healthy individuals' gait parameters under 2 conditions: normal walking and walking while wearing a robotic exoskeleton suit.

Methods

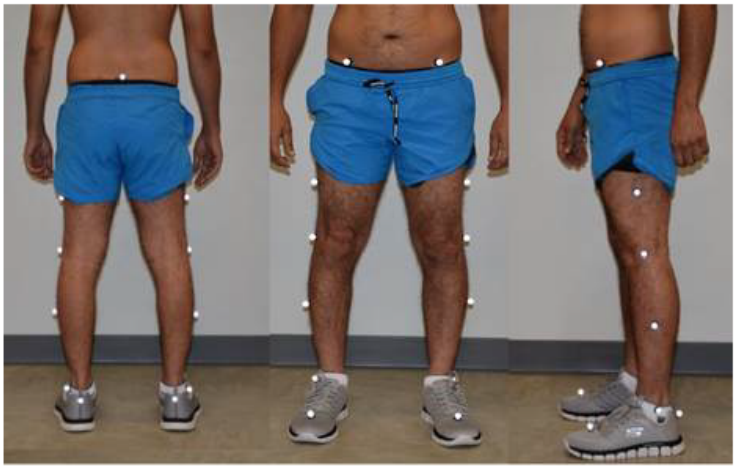
Participants

Healthy adults 18-70 years old without any neurological disorder were recruited from the local community. Exclusion criteria was based, in part, on the limitations of the robotic exoskeleton, EKSO (Ekso Bionics, Richmond, CA, USA) used in this study and included: (1) screening failure of EKSO frame limitations (weight ≤100 kg; 1.58-1.88 m tall; standing hip width ≤41.9 cm; near-normal ROM in hips, knees, and ankles; and leg length discrepancy ≤1.9 cm), (2) severe spinal instability, (3) unresolved deep vein thrombosis, (4) orthostatic hypotension, (5) skin integrity issues on contact surfaces of the device or sitting surfaces, (6) significant cognitive impairments (unable to follow 3-step commands), and (7) pregnancy.

Instrumentation

A 10-camera VICON Motion Analysis System (Vicon Motion Systems Inc, Centennial, CO, USA) was used to capture kinematic data. The sampling rate of the 10 cameras was set at 120 Hz, and the cameras were time-synchronized with 6 AMTI (Waterton, MA, USA) force plates, for which the sampling rate was set at 1200 Hz. The force plates were placed in the middle of the 9-m walkway. The threshold of the force plates was set at 10 N in order to determine gait events (ie, heel strikes and toe offs). A VICON Plug-In-Gait model with 15 reflective markers was used to obtain joint motions of lower extremities. Marker placements are shown in Figure 1.

Figure 1. VICON Plug-In-Gait model lower extremity marker placements.



EMG data were obtained from the right and left gluteus medius, rectus femoris, medial hamstrings, tibialis anterior, and soleus muscles with 10 wireless surface electrode pairs (Delsys Trigno EMG system (Delsys Inc, Natick, MA, USA)). The bandwidth of the EMG system was set at 20-450 Hz with a gain of 1000. The Delsys Trigno EMG system contains a notch filter to eliminate nonphysiological signals. The EMG signal was recorded at a sampling rate of 960 Hz and was time-synchronized with the VICON Motion Analysis System. The 10 surface electrode pairs were affixed with self-adhesive tape on the specific location for each muscle following the Surface ElectroMyoGraphy for the Non-Invasive Assessment of Muscles [18] recommendation to minimize surface myoelectric signal cross-talk [19]. Prior to electrode placement, the patient's skin in the areas of electrode placement was cleaned with isopropyl alcohol. If there were excessive hair, a new disposable razor was used to shave the hair to improve the quality of the EMG recording.

Procedures

After the participants signed a written consent form approved by the Institutional Review Board of Texas Woman's University, they completed an intake form for their demographic data (age, gender, and leg dominance); past medical history; past surgical history; and activity level. The investigator then took anthropometric measurements of each participant. These measurements, including height; weight; standing hip width; ROM in hips, knees, and ankles; and leg length, were used to ensure that the participants were able to fit the exoskeleton suit, EKSO. Other anthropometric measurements, including leg length, knee width, and ankle width, were taken as required for the VICON Plug-In-Gait model.

Preceding walking trials for each condition (with and without wearing EKSO), a static trial was captured to create a customized lower-body model for each participant based on the VICON Plug-In-Gait model. For walking trials, the participants were asked to wear a pair of shorts and a pair of tennis shoes, required for EKSO. Kinematic and EMG data were collected simultaneously. During each walking trial, each participant was asked to look straight ahead, if possible, and to walk at a self-selected speed on a 9-m level walkway. Participants stepped onto the force plates on their 4^{th} or 5^{th} steps after attaining a constant velocity. For each of the 2 conditions (with and without wearing the EKSO), data from 5 walking trials were collected from each participant. Prior to trials with EKSO, each participant was given instructions and allowed to practice walking with an EKSO-trained therapist for a minimum of 15 minutes and until the therapist was comfortable providing only close supervision to prevent loss of balance.

Signal Processing

First, the collected data were processed using the VICON Nexus software to label markers; interpolate, as necessary, for missing data points; determine the gait events; and, finally, generate C3D files. Each walking trial was divided into individual gait cycles that began and ended with the heel strike of the same foot, and then the data were normalized in time by the percent of the gait cycle. Each complete gait cycle was further divided into a stance phase (%) and a swing phase (%). Next, customized MATLAB (Mathworks Inc, Natick, MA, USA) scripts were used to process the C3D files and to generate sagittal joint angles of the hip, knee, and ankle as well as temporospatial variables.

Similarly, custom MATLAB scripts were used to process and produce surface EMG (sEMG) amplitudes for each walking trial. Root mean square (RMS) values of EMG were used to quantify the amount of EMG activity for each walking trial. EMG RMS values were obtained using a window size of 120 samples with 60 samples overlapping. Then, sEMG RMS values were normalized across a complete gait cycle (100%) with 101 data points over the corresponding phase. Finally, sEMG RMS values were further normalized with respect to the peak over the gait cycle. The peak EMG value of the corresponding stance or swing phase of each walking trial was used for the normalization of EMG values. We elected to use the peak EMG normalization approach in order to allow for comparison with previous studies and replication with different neurologically impaired patient populations (ie, stroke and spinal cord injury) [20].

During walking, joint motion predominantly occurs in the sagittal plane. In particular, when using an exoskeleton, motions in other planes are further restrained (reduced). Thus, we are primarily interested in the motion of the sagittal plane. It should be noted, however, that muscles typically cross joints with actions not strictly limited to certain anatomical planes. Hence, muscles routinely cause motion in all 3 planes. For example, frontal plane stability is critical in the single-leg support phase of walking. Therefore, we elected to look at muscle groups characteristically involved in walking regardless of their primary plane of action.

Statistical Analysis

All statistical analyses were performed using SPSS version 24 (IBM Corp, Armonk, NY, USA). Descriptive statistics were performed to describe participants' demographic data and gait parameters. Average values of all of the complete gait cycles and 5 walking trials were included in statistical analysis to minimize individual trial variations. Temporospatial parameters of gait were analyzed using paired *t* tests. With regard to kinematic data, because there were no significant differences between the left and right lower extremities, the averages of the right and left maximal sagittal ROM of the hip, knee, and ankle joints were used for statistical analysis. Therefore, 2 separate 2 (condition) ×3 (ROM) repeated measures analyses of variance (ANOVAs) were used to analyze kinematic variables: 1 for the stance and 1 for the swing phase. Due to significant left and right lower extremity differences in EMG, each limb was analyzed separately for stance and swing phases. Therefore, 4 separate 2 (condition) ×5 (muscle) repeated measures ANOVAs were used to analyze the EMG data: 2 for the stance and 2 for the swing phase, respectively. The alpha level was set at .05 for all statistical analyses.

An *a priori* power analysis using G*Power [21], with considerations of the use of *F* test, within factor design, and an anticipated large effect size (.4), indicated the necessary sample size was 15 participants to achieve a power of .80.

Results

The study was completed by 15 participants, 6 males and 9 females, with an average age of 26.2(SD 8.3) years (range, 19-50 years), average height of 171.8 (SD 7.9) cm (range, 161-184.5 cm), and average weight of 65.8 (SD 11.4) kg (range, 54.5-93.5 kg). Right leg dominance was reported by 12 patients. Participants demonstrated significant differences (P<.001) between conditions (with and without EKSO) on all temporospatial gait parameters (Table 1). Overall, participants wearing EKSO walked slower, with shorter steps and greater double-limb support time.

Table 2 lists the maximal sagittal ROM at the hip, knee, and ankle joints for the stance and the swing phases. ANOVA showed differences between with and without EKSO conditions. In the stance phase, there were significantly less hip and ankle motions but greater knee motions on both lower extremities for the EKSO condition. ANOVA results also revealed significant differences between the 2 conditions in the knee and ankle motions in the swing phase but not in the hip motion. Specifically, walking with EKSO produced equivalent hip motions but less knee and ankle motions bilaterally in the swing phases. Figure 2 demonstrates lower extremity joint motion across the gait cycle.

Table 3 lists sEMG RMS values (%) of the 10 muscles for the stance and the swing phases. In the stance phase, ANOVA results showed significant differences between with and without EKSO conditions for all lower extremity muscle groups bilaterally. In the swing phase, ANOVA results showed significant differences between with and without EKSO conditions only for the distal muscle groups (bilateral soleus and tibialis anterior) and left medial hamstrings. Figures 3 and 4 show lower extremity muscle activity across the gait cycle.

Table 1. Temporospatial gait parameters.

Parameter	Without EKSO[a], mean (SD)	With EKSO, mean (SD)	*P* value
Speed (m/s)	1.32 (0.16)	0.31 (0.04)	<.001
Stride length (m)	1.41 (0.12)	0.72 (0.14)	<.001
Double-limb support (s)	0.17 (0.02)	0.45 (0.06)	<.001
Left step length (m)	0.69 (0.06)	0.34 (0.01)	<.001
Right step length (m)	0.72 (0.06)	0.31 (0.16)	<.001

[a]Robotic exoskeleton

Table 2. Sagittal range of motion of lower extremity during gait with and without wearing a robotic exoskeleton (EKSO).

Lower extremity	Stance phase			Swing phase		
	Without EKSO, mean (SD)	With EKSO, mean (SD)	*P* value	Without EKSO, mean (SD)	With EKSO, mean (SD)	*P* value
Hip	44.33 (5.11)	37.90 (3.39)	<.001[a]	42.42 (4.92)	43.08 (4.55)	0.69
Knee	23.07 (4.52)	28.62 (5.39)	.006[a]	56.89 (8.24)	40.68 (4.07)	<.001[a]
Ankle	18.39 (2.44)	11.74 (2.21)	<.001[a]	24.07 (7.13)	6.85 (2.16)	<.001[a]

[a]Significant at P<.05.

Figure 2. Mean (SE) lower extremity joint motion across the gait cycle. y-axis: range of motion..

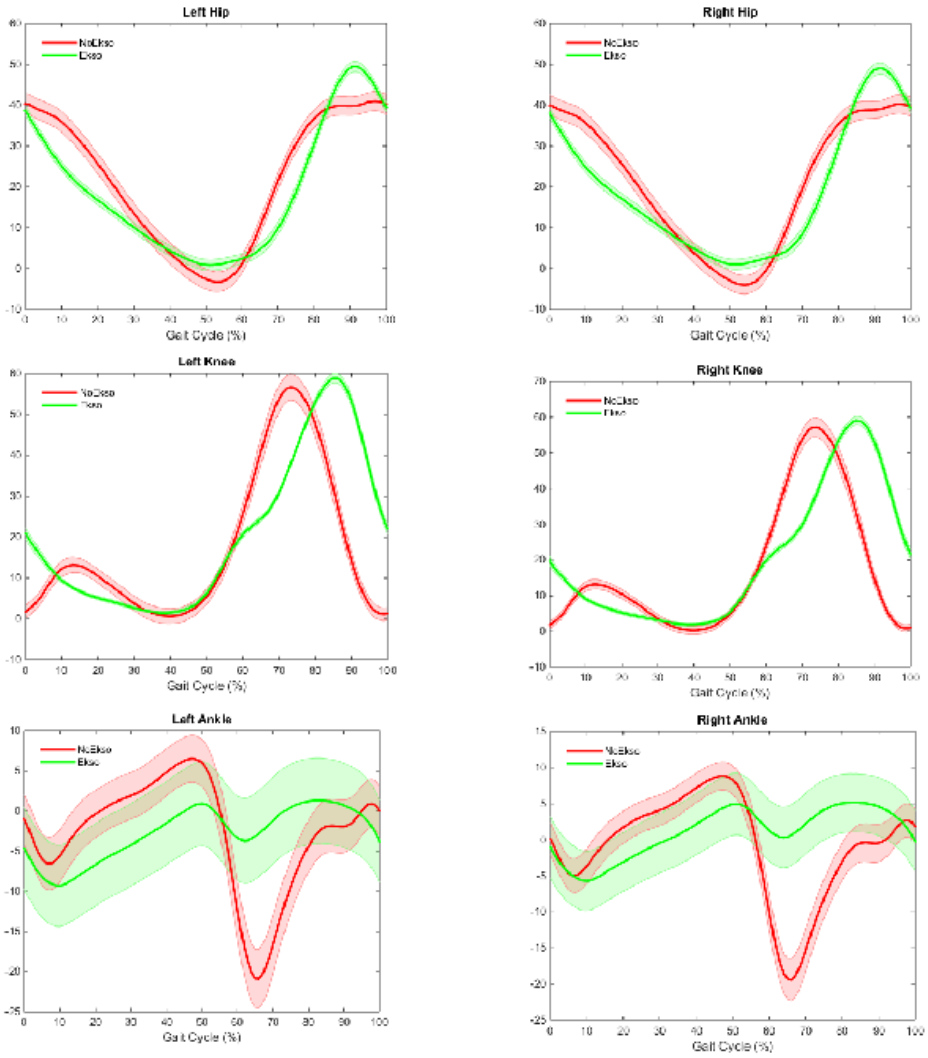


Table 3. Amplitude of lower extremity electromyographic muscle activity during gait with and without wearing a robotic exoskeleton.

Muscle	Stance phase				Swing phase			
	Without EKSO, mean (SD)	With EKSO, mean (SD)	*P* value	Difference, %	Without EKSO, mean (SD)	With EKSO, mean (SD)	*P* value	Difference, %
Right gluteus medius	0.62 (0.07)	0.55 (0.05)	.003[a]	−11.3	0.59 (0.13)	0.62 (0.10)	.47	6.9
Right rectus femoris	0.66 (0.08)	0.54 (0.07)	.001[a]	−18.2	0.59 (0.08)	0.56 (0.11)	.42	−5.1
Right medial hamstring	0.64 (0.070)	0.55 (0.09)	.01[a]	−15.6	0.42 (0.06)	0.41 (0.09)	.62	−2.4
Right tibialis anterior	0.61 (0.04)	0.49 (0.06)	<.001[a]	−19.7	0.59 (0.11)	0.68 (0.11)	.02[a]	15.3
Right soleus	0.61 (0.06)	0.54 (0.09)	.003[a]	−11.5	0.43 (0.15)	0.63 (0.13)	.004[a]	46.5
Left gluteus medius	0.63 (0.04)	0.560 (0.05)	.001[a]	−11.1	0.61 (0.08)	0.64 (0.07)	.22	4.9
Left rectus femoris	0.64 (0.06)	0.54 (0.09)	.003[a]	−14.3	0.57 (0.10)	0.55 (0.13)	.72	−1.8
Left medial hamstring	0.62 (0.09)	0.52 (0.09)	.007[a]	−16.1	0.59 (0.09)	0.52 (0.10)	.04[a]	−13.6
Left tibialis anterior	0.62 (0.08)	0.56 (0.10)	.03[a]	−9.7	0.60 (0.08)	0.71 (0.06)	<.001[a]	18.3
Left soleus	0.60 (0.04)	0.52 (0.07)	.004[a]	−13.3	0.42 (0.14)	0.62 (0.13)	0.01[a]	47.6

[a]significant at <.05

Figure 3. Mean (SE) right lower extremity electromyographic muscle activity across the gait cycle. med hams: medial hamstrings; y-axis: volt.

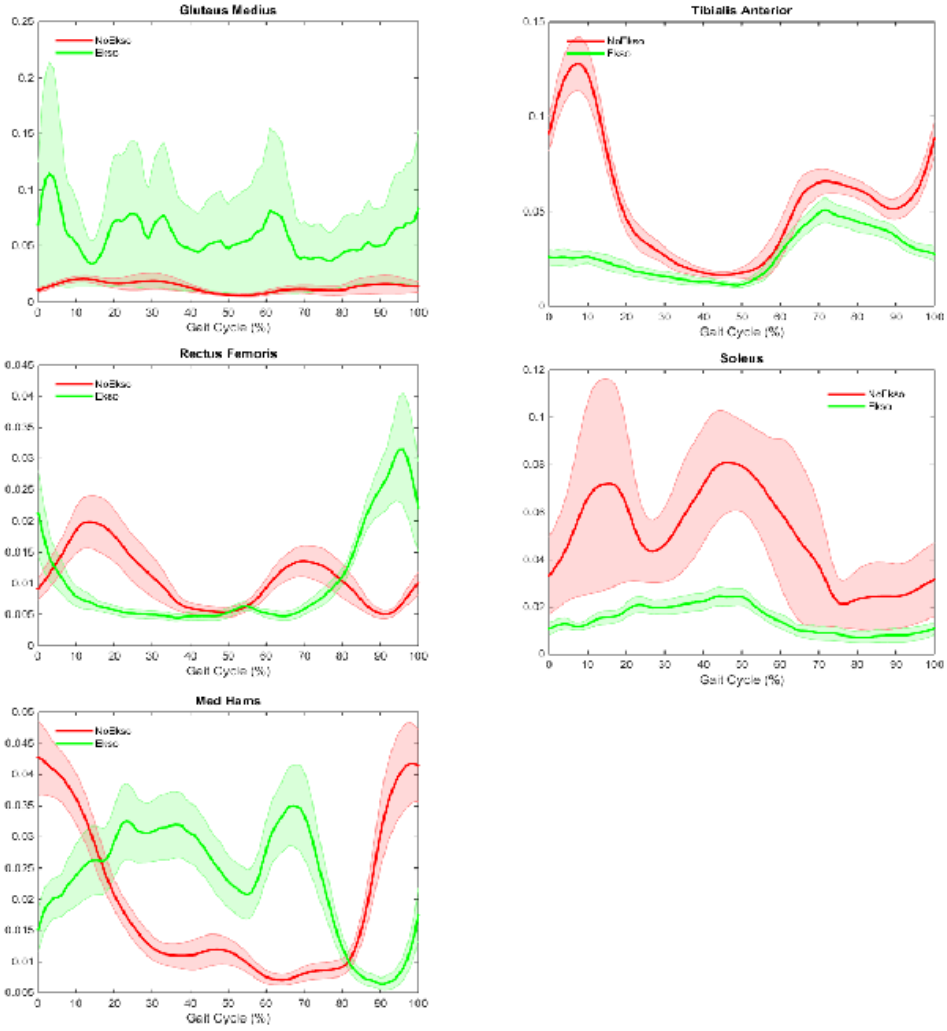
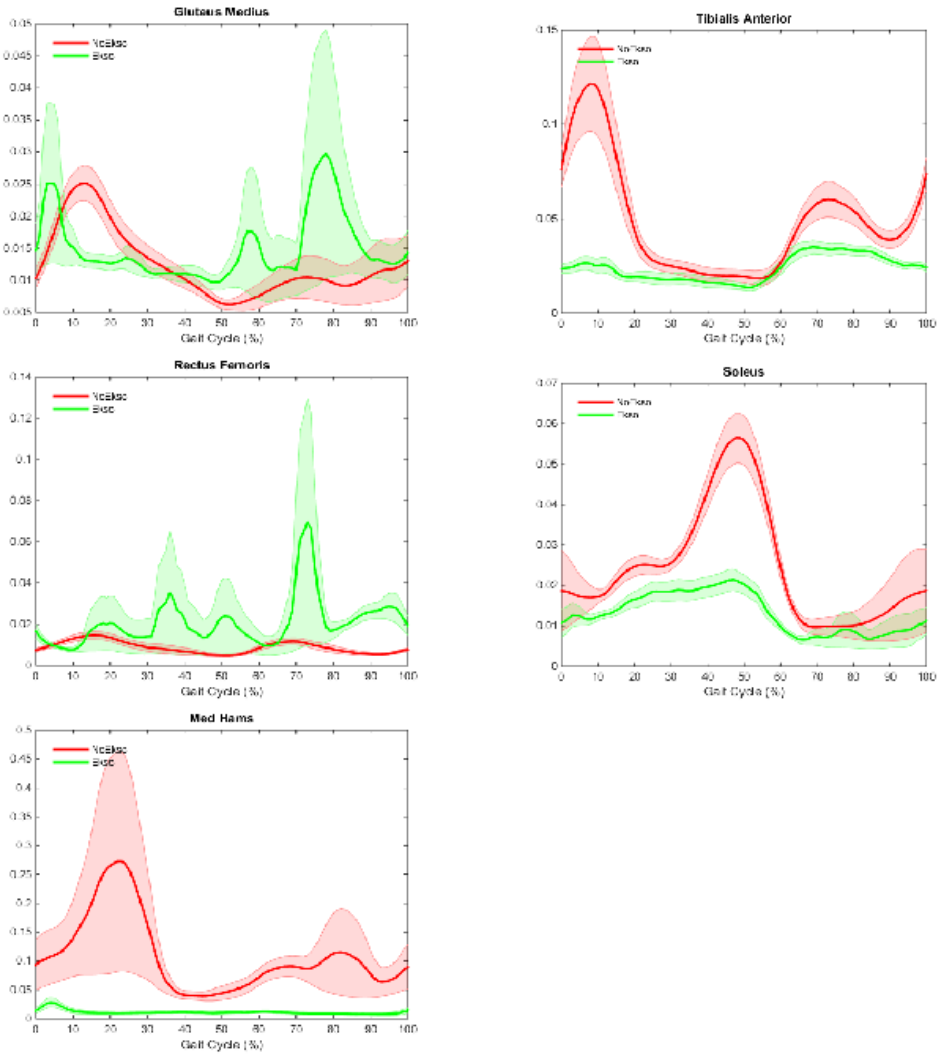


Figure 4. Mean (SE) left lower extremity electromyographic muscle activity across the gait cycle. med hams: medial hamstrings; y-axis: volt.



Discussion

Principal Findings

The results showed that walking with EKSO was dissimilar to typical walking with regard to lower extremity muscle activity and joint motions as well as temporospatial gait parameters. Overall, the participants in this study walked with EKSO at approximately one-fourth their average walking speed and with nearly half the stride length. These changes likely contributed to an increase in double-limb support time. Although the participants were instructed to walk at a self-selected pace during each condition, the participants were unable to match their typical walking performance when walking with EKSO. A possible explanation for these observed differences is the lack of training of our participants for walking with EKSO. Even though the participants were instructed on how to initiate a step and given 15 minutes of practice time, this short training may not have been sufficient to allow the participants to reach optimal exoskeleton gait performance. Moreover, a second possible explanation for the differences observed in temporospatial parameters is the technological limitations of the current robotic exoskeletons. Specifically, mechanical design and actuators of contemporary exoskeletons are known to limit gait performance and capacity [22]. For instance, actuators are located at the hip and knee joints but not at the ankle joints. Contemporary ankle joints are typically either a fixed solid plate or tension spring motion plates.

With changes in temporospatial parameters, it was expected that muscle activity would be impacted as well. It has been shown that walking at slower speeds resulted in decreased muscle activity of the lower extremities during both the stance and swing phases of gait regardless of age [23]. Similarly, we observed an average reduction of nearly 15% in muscle activity during the stance phase in both lower extremities (Table 3). This reduction may have been caused by the reduction in speed or by the structural support provided by the EKSO device. However, we did not see a similar reduction in muscle activity in the swing phase. On the contrary, an increase of 32% in muscle activity of the distal lower extremity was observed in our study. We speculate that the increase in muscle activity in our study was a result of EKSO's mechanical constraints [22]. In particular, the EKSO footplate limits ankle motion, and this may have required participants to compensate for the reduced ankle mobility.

Beyond limiting ankle ROM, we observed several changes in lower extremity kinematics when walking with EKSO as compared to when walking without EKSO. During the stance phase, we observed less hip and ankle motions but greater knee motion when wearing EKSO. In the swing phase, we observed less knee and ankle motions, but no difference in hip motion when wearing EKSO. Overall, it appears that gait with EKSO produced a pattern where shorter steps due to limited ankle motion contributed to a shortened trailing limb. While a typical swing phase ankle arc of motion moves from maximal plantar flexion in the initial swing to a near ankle neutral position in the terminal swing, EKSO-induced shortened steps minimized the potential for ankle plantar flexion in order to accommodate a relatively fixed footplate. Moreover, the limited ankle motion also likely required greater knee flexion during the stance phase. The EKSO footplate and corresponding upright support do not allow for optimal ankle joint motion. Rather, the mechanical constraints of EKSO ankle joint appear to influence lower extremity kinematics as well as corresponding muscle activity.

Our participants were without injury and, when not wearing EKSO, demonstrated walking parameters consistent with typical gait. For individuals with neurological dysfunction, return to walking is the primary focus of rehabilitation. As previously reported, gait training after neurological injury should include proper loading of the sole of the foot and attaining adequate hip extension to facilitate appropriate muscle activation [7]. The findings of this study question whether mechanical constraints in the current versions of robotic exoskeletons preclude the possibility of promoting kinematics suitable to induce satisfactory muscle activity. Our participants were novice EKSO users who were tested during their first session of wearing EKSO. It is possible that a longer training time with EKSO might have promoted more typical EMG patterns despite the mechanical constraints. Additionally, people with biomechanical limitations from various neurological and orthopedic injuries are able to walk albeit with an altered gait cycle and atypical muscle activity [24-26]. Although EKSO does not appear to promote normal gait, it may stimulate an altered functional gait. Although an altered gait is potentially less efficient [27], this functional gait may meet the mobility objectives of a person recovering from a neurological injury.

Limitations

There are several limitations in this study. First, our sample of 15 participants was primarily young, active individuals, and this may have limited generalizability of our conclusions. Second, the preferred EMG normalization method is to use a single maximum muscle test for each muscle group tested. We utilized a peak EMG normalization approach as this may be particularly appropriate when patient populations most likely to use a robotic exoskeleton (ie, spinal cord injury) are being studied because maximal muscle testing may be prohibitive [20]. Third, the intended user of EKSO is an individual with locomotion disabilities. Although outside the scope of this study, examination of gait parameters of individuals with locomotion disabilities is recommended for future studies. Further, EKSO requires the use of an assistive device (cane, walker, or forearm crutches) while walking. In this study with healthy individuals, we elected not to use an assistive device but provided close supervision to prevent a loss of balance. The use of an assistive device, as recommended by robotic exoskeleton companies, may have further altered gait kinematics and muscle activity. Lastly, walking speed was not controlled in this study. Future studies should consider exploring gait parameters and related asymmetries under normal walking and EKSO walking conditions while controlling speed.

Conclusion

EKSO appears to promote a type of gait that is disparate from normal gait in first-time users. Specifically, the mechanical constraints of EKSO appeared to alter joint motion and influence muscle activity throughout the gait cycle. These changes resulted in a walking pattern characterized by slower speeds, smaller steps, and less single-limb stance time. Given this foundation, more research will be necessary to determine the impact of wearing a robotic exoskeleton on rehabilitation in people with gait impairment.

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Conflicts of Interest

None declared.

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Abbreviations

EMG: electromyography
RMS: root mean square
ROM: range of motion

sEMG: surface electromyography

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Original Paper

Design Requirements for a Digital Aid to Support Adults With Mild Learning Disabilities During Clinical Consultations: Qualitative Study With Experts

Ryan Colin Gibson[1], BSc (Hons), MPhil; Matt-Mouley Bouamrane[1], BEng (Hons), MSc, PhD; Mark Dunlop[1], BSc (Hons), PhD

Digital Health and Well-Being Group, Department of Computer & Information Sciences, University of Strathclyde, Glasgow, United Kingdom

Corresponding Author:
Ryan Colin Gibson, BSc (Hons), MPhil
Digital Health and Well-Being Group
Department of Computer & Information Sciences
University of Strathclyde
Computer & Information Sciences, Livingstone Tower
26 Richmond Street
Glasgow, G11XH
United Kingdom
Phone: 44 (0)0141548318
Email: ryan.gibson@strath.ac.uk

Abstract

Background: Adults with mild learning disabilities (MLDs) face a plethora of obstacles when accessing effective health care. Central to many of these barriers is communication, with medical practitioners often remaining untrained on how to interact with patients who have learning disabilities (LDs). To date, research on how to promote this communication has largely centered on the development of low-tech aids.

Objective: The objective of this study was to assess the feasibility of utilizing tablet technologies to promote communication between general practitioners and patients with MLDs. We achieved this by identifying a set of design requirements from experts in LDs.

Methods: A set of design guidelines was formed during a 2-phase process. Phase 1 involved conducting a series of requirements-gathering interviews with 10 experts in LDs—the protocol of which emerged from the results of a separate scoping review. The interviews were subjected to a framework analysis to discern the key requirements discussed by the experts, and these were embedded within a technology probe. In phase 2, this probe was presented to a subset (n=4) of the experts during a round of usability studies, and the feedback received was used to update the requirements identified in phase 1.

Results: An initial set of design requirements has been produced that may assist in the development of clinical Alternative and Augmentative Communication technologies for adults with MLDs. Factors that must be considered range from the health, physical and cognitive needs of stakeholders, to the more individual needs of users.

Conclusions: The experts involved in the study were optimistic about the proposed app. They believe that such technologies can help to alleviate time constraints and promote communication by presenting information in a form understood by both practitioners and patients.

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KEYWORDS

learning disabilities; intellectual disability; communicative disorder; augmentative and alternative communications systems; primary care

Introduction

Background

Since the turn of the millennium, international policies [1] have been introduced that compel mainstream services to offer access to improved and unprejudiced care. Consequently, an increase in the well-being of those affected by learning disabilities (LDs) has been recognized [2]; however, their life expectancy remains far below that of the general population [3]. This suggests that the quality of care being administered remains suboptimal, with previous literature identifying a variety of barriers that patients with LDs face when accessing health care services [4,5]. One of the most widely cited barriers affecting this standard of care is the breakdown in communication between medical professionals and patients.

Howells suggests that the "art of general practice lies in the ability to communicate with patients" [6,7]. However, people with LDs have a variety of impairments that influence their ability to participate in conversations [8]. First of all, cognitive impairments affect an individual's ability to learn, meaning patients are likely to have a restricted knowledge of the human body and may be unable to recognize the presence of certain medical conditions [9]. Their expressive skills may also be affected, and this impedes their ability to comprehensibly describe the symptoms that they do acknowledge. On the other hand, people with LDs often have better receptive skills [8] and will have more success acquiring the information being conveyed by a general practitioner (GP), provided complex concepts such as medical jargon are avoided—an issue that is prominent throughout the clinical domain [10]. Impairments in abstract thinking and long-term memory [11] may hinder the patient's ability to provide an accurate medical history, with GPs relying on caregivers to provide this information. However, patients often object to this process [11], and there is evidence to suggest that it leads to inaccurate information being extracted [8].

Patients with mild learning disabilities (MLDs) may utilize Alternative and Augmentative Communication (AAC) devices [12] to assist them in conveying their needs. To explore the prevalence of these technologies within the clinical domain, the authors have conducted a separate scoping review. The finer details of the study have been described previously [13]; however, the results indicate that despite the call for digital support being made by practitioners as far back as 1997 [14], low-tech solutions continue to be the primary means used to supplement communication. This contrasts significantly with other vulnerable populations [15,16] where Information and Communication Technology is used copiously to advance health literacy.

Objectives

Moreover, 1 possible reason for this may be the lack of support available during the development of such technologies. We address this gap by investigating the potential use of tablet devices to promote communication between practitioners and patients with MLDs. Specifically, we have examined whether extracting information in advance of the consultation can have a positive impact on such communication. To achieve this, we used the results of the scoping review to shape 9 requirements-gathering interviews involving a purposive selection of experts in LDs. A technology probe was developed using this data and, subsequently, presented to a subset of the experts to further inform the extracted requirements. These requirements may be used to support researchers in the future development of medical AAC apps that cater to the complex needs of adults with MLDs. In addition, the findings made may also help to support the general population in communicating medical information to practitioners, as vulnerable patients are often considered as a litmus test to the effectiveness of interventions [17]. Throughout, we intend to answer the following research questions (RQs):

> RQ1: What do adults with MLDs and GPs require from an aid that aims to support them during clinical consultations?
>
> RQ2: What impact may mobile devices have on the clinical consultation process?
>
> RQ3: What are the design guidelines for medical AAC apps that assist adults with MLDs?

Methods

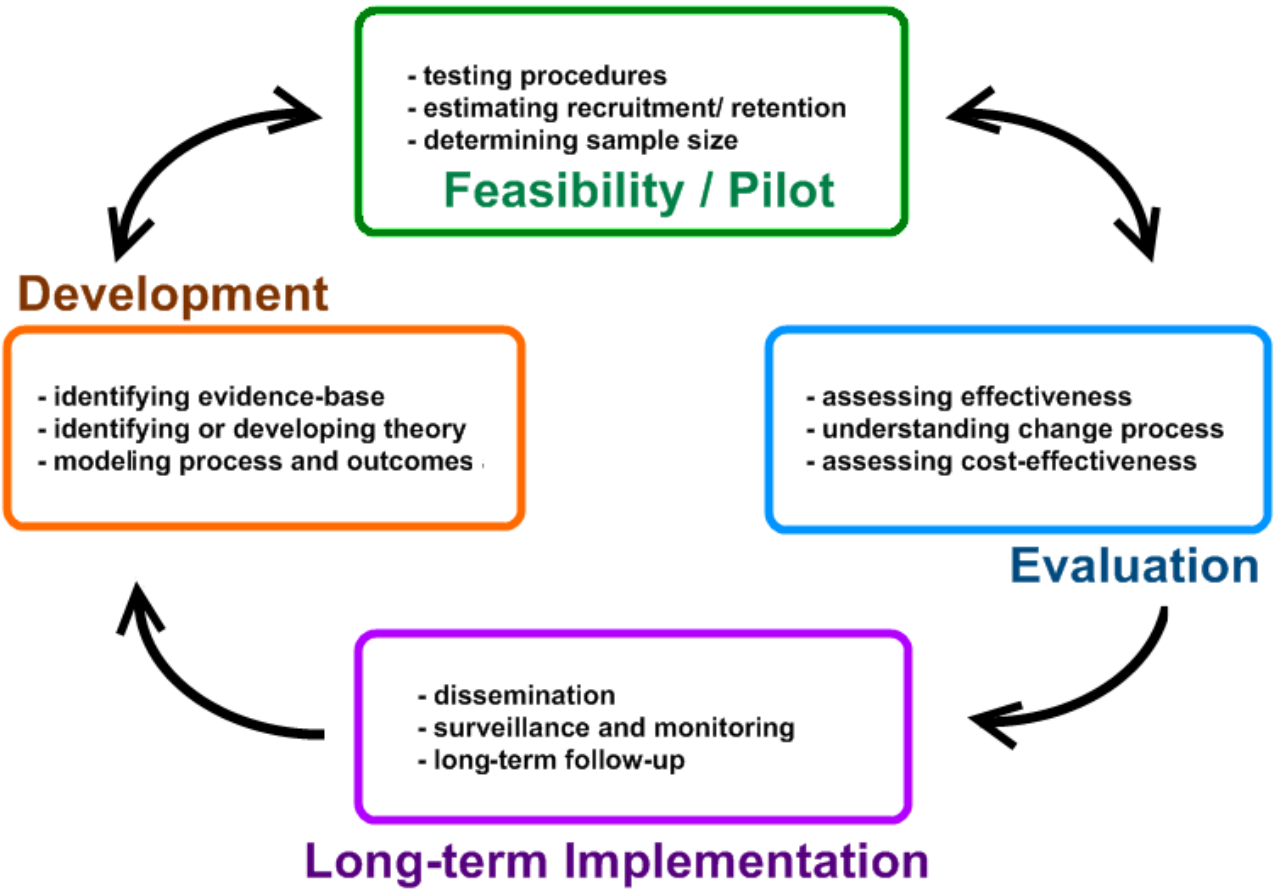
This study employed a 2-phase design process. The first phase focused on the development of a technology probe using the requirements extracted from experts in LDs during a round of semistructured interviews. In phase 2, the probe was evaluated by a subset of these experts to further inform the requirements identified. Both phases were conducted under ethical approval from the Department of Computer and Information Sciences Ethics Committee at the University of Strathclyde (ID CIS470, CIS614). We will first present an overview of the project before describing the design process used in more depth.

Project Overview: Medical Research Council Complex Interventions Framework

The research presented in this paper is part of a wider project to develop, in conjunction with the views of stakeholders, a tablet app to promote communication between GPs and patients with MLDs. In this context, the term "mild learning disability" may be applied to an individual if they satisfy the following criteria as listed by the World Health Organization [18]: "they have a significantly reduced ability to understand new or complex information and to learn and apply new skills. This results in a reduced ability to cope independently and begins before adulthood with a lasting effect on development." Those with MLDs are generally able to communicate their needs but may struggle with complex ideas such as medical symptoms.

To ensure the proposed aid is developed in a systematic manner, the authors are following the Medical Research Council's Framework for Complex Interventions [19], as shown in Figure 1.

Figure 1. Medical Research Council framework for complex interventions.



Our decision to utilize the Complex Intervention Framework may be justified via the following 3 criteria:

1. As discussed previously, people with MLDs tend to have impaired higher order cognitive skills [11] and may find it less challenging to discuss their requirements when interacting with artifacts as opposed to developing them from scratch. The iterative nature of the framework supports this process by offering multiple opportunities to present a probe to stakeholders for evaluation and subsequently update its design based on the results achieved.
2. Great emphasis is placed on the collection of evidence. This is important as it ensures that the researchers assess whether the developed product caters to the wide range of needs and impairments present in adults who have MLDs.
3. The framework is widely approved throughout the clinical domain, meaning that a product developed using these steps is more likely to be accepted within current practice.

The first stage ("Development") has almost come to its conclusion. We have established an evidence base for the proposed app via the aforementioned scoping review [13]. This review highlighted that low-tech AAC devices continue to be the primary form of support provided to patients with MLDs, despite the call for the implementation of high-tech devices being made as far back as two decades ago. Furthermore, AAC technologies are yet to be embedded within common practice, meaning even low-tech devices differ in terms of their availability and functionality across health boards and individual practices. As such, there is a clear need to develop a resource that can be adopted on a national scale.

The next substep is to establish how the intervention may fit into and improve current practice. This has been partially achieved via the research presented in this paper because it describes the development and evaluation of a technology probe based on the requirements identified by 10 experts in LDs. During future research, adults with MLDs will be given the opportunity to interact with and subsequently shape the design of the probe in preparation for stage 2. The "Feasibility and Piloting" and "Evaluation" stages will require the intervention to be embedded within the clinical domain and its performance monitored over a short period of time. This will allow the researchers to determine whether the app is having its desired effect and subsequently make improvements before a long-term evaluation study is carried out in stage 4.

Phase 1: Requirements Gathering

Design and Setting

Phase 1 involved identifying an initial set of requirements for a tablet app that supports adults with MLDs in communicating symptoms to their GP. To achieve this, the lead author conducted semistructured interviews with 10 experts in LDs. At the time, RCG was a master's student and had 1-year experience in conducting qualitative research. The protocol used was modeled around the themes that emerged from the aforementioned scoping review [13], and this will be discussed in the Procedure subsection. All interviews were carried out at

locations convenient to the participants, and no monetary rewards were provided because they occurred during working hours.

Our decision to include experts, as opposed to adults with MLDs, centered on the following reasons:

1. People with LDs often have impaired higher order cognitive skills such as abstraction [11] and may find it difficult to envisage how the proposed app can assist them in conveying information to their GP.
2. Stakeholders are often unaware of their needs during the early design stages of a product, and their true requirements do not become known until they have interacted with a concrete artifact [20].

As such, it was appropriate to involve experts first as they were able to identify various accessibility issues that may be mitigated before a concrete probe is presented to the people with MLDs. We plan to include participants with MLDs in future research and will update the guidelines presented in this paper accordingly. This process should lead to representative requirements being extracted from patients with MLDs.

Participants

The target sample size was set between 10 and 15 participants to account for data saturation [21] and to ensure a wide range of knowledge and expertise was utilized throughout the design stage. The recruitment process involved the first (RCG) and second authors (MMB) contacting various LD charities, academics, and government agencies via telephone and email throughout the city of Glasgow. A total of 10 participants consented to take part (6 females and 4 males), at which point recruitment ceased as we had reached our target sample size. All participants were interviewed separately apart from participants 1 and 2 (see Table 1), as it was convenient for them to be interviewed together.

Procedure

Before commencing, participants had all questions resolved by RCG, and written consent was obtained. The interviews were then conducted on a semistructured basis to allow stakeholders the opportunity to raise and expand upon topics outside of the protocol. RCG presented 6 sets of questions based on the themes that emerged during the scoping review [13], including potential communication barriers, the communication modalities utilized by people with LDs, the communication aids encountered by the experts, potential barriers to AAC technologies, professionals' attitudes toward people with LDs, and personalization. Additional questions relating to the aesthetics and features of the proposed app were also presented.

In addition, GPs were required to discuss their overall experience and confidence in consulting with patients with LDs. The question sets presented to the participants are provided in Multimedia Appendix 1. On completion of the interviews, the experts were asked to raise any topics that had not been addressed throughout. The sessions were recorded with participant consent, and the mean duration was approximately 34 min—ranging from 25 min to 1 hour.

Data Analysis

The lead author transcribed the recorded interviews to further their understanding of the captured data. The transcriptions were then subjected to a framework analysis [22,23] to produce a structured summary of the requirements discussed by the experts. First, an initial thematic framework was developed by RCG based on the themes and subthemes that emerged throughout the scoping review. On further inspection of the transcribed data, the lead author recognized that some of the concepts discussed did not conform to these topics, because of the semistructured nature of the interviews. Further codes were therefore created to address this information. RCG then grouped similar codes together to form overarching themes, at which point MMB (who has extensive experience conducting qualitative research) reviewed the developed framework, and any discrepancies were resolved by MDD.

Table 1. The demographics of the participants interviewed.

ID	Profession	Sex
1	Governmental advisor—gathers evidence for the Scottish Government on the health inequalities experienced by those who have LDs[a]; previous support worker for people with LDs	Female
2	Governmental advisor involved in the coproduction of policies affecting those who have LDs; previous support worker	Female
3	Full-time support worker for an LD charity	Female
4	Academic in social work and social policy	Female
5	Governmental advisor involved in promoting Scotland's "Keys to life" strategy	Male
6	General practitioner	Male
7	General practitioner	Male
8	Academic in inclusive education; previous deputy head teacher for a special needs school	Male
9	Academic in cognitive psychology; developed accessible information resources for the National Health Service	Female
10	Academic in aging, frailty, and dementia; previously involved with a national LD charity	Female

[a]LD: learning disability.

Table 2. The symptoms to be selected by the participants during the usability studies.

ID	Symptoms
1	The participant is suffering from toothache caused by tooth decay.
2	The participant is not in pain. Instead, they hear ringing sounds and feel dizzy and sick. They are experiencing tinnitus.

The resulting framework was utilized by RCG to code the transcriptions, and the tagged excerpts were transferred to their appropriate positions in the framework analysis table. This table has been made available in [13].

Phase 2: Usability Study

Design and Setting

In preparation for phase 2, the lead author used the design requirements identified in the previous phase to develop a technology probe of the proposed app. A technology probe may be considered as a representation of a device that is utilized by stakeholders to inspire the design process through exposure to new experiences [24]. These stakeholders are, therefore, able to shape the design of the final artifact by interacting with the probe and commenting on their experiences.

To ensure adults with MLDs can interact with the probe during future research, a subset of the experts described in Table 1 were required to participate in a usability study. The experts completed 2 tasks using the probe and commented on the features they felt were accessible to the LD population and those that may present barriers. This enables the researchers to mitigate potential accessibility barriers before the introduction of stakeholders who have mild LDs. Once again, the study was conducted by RCG at a location convenient to the participant, and no monetary rewards were provided.

Participants

On the basis of the guidelines for iterative design by Dumas and Redice [25], the sample size was set between 3 and 5 participants. This supports the researchers in addressing key design and flaws over a short period of time, rather than having to carry out an extensive number of studies to obtain similar information. Invitations to participate were sent out to the experts involved in phase 1, as they had prior knowledge of the project and understood what the probes goals were. Participants 1, 2, 4, and 8 in Table 1 consented to take part, at which point recruitment ceased as the target number of participants had been met.

Procedure

The participants were required to work through the questionnaire embedded within the probe and select symptoms relating to 2 distinct medical conditions. These conditions (shown in Table 2) were designed to ensure that the experts explored all features within the app. Furthermore, no assistance was provided during this process, except when the experts explicitly asked for help or were unable to advance within the app. This ensured that the lead author refrained from influencing the actions of participants and that key design flaws were naturally identified [25]. Any points of indecision were also observed and noted by RCG to be explored further at the end of the session.

Once the experts had finished selecting the symptoms for both conditions, they were prompted to give their views on the probe, and it is appropriateness for the MLD population. The feedback received was then used to refine the requirements extracted during the previous phase. Over 1 hour of audio data were captured with participant consent, with each session averaging 21 min. A copy of the questions presented and an explanation of the conditions chosen are provided in Multimedia Appendix 2.

Data Analysis

To extract the features deemed to be accessible to the LD population, as well as those that may be improved on, the transcriptions were subjected to the same framework analysis process described in phase 1. A copy of the framework analysis table may be found in [13].

Results

Requirements

Throughout the semistructured interviews, a number of requirements were discussed by the experts, which helped to shape the design of a technology probe for the proposed app. In this section, the key requirements will be introduced and are supported by the excerpts contained within the resulting framework analysis table found in [13]. The rows in the table are organized to reflect the participant IDs found in Table 2, with the exception that the views of participants 1 and 2 have been combined into 1 row (2) because they were interviewed together.

Communication Challenges

Barriers to Communication

Both of the GPs interviewed cited communication difficulties as the primary barrier to effective care for patients with MLDs. They suggested that 2 factors play a prominent role in this breakdown in communication, the first of which involves the patient's interpretation of a condition. People with LDs are often undereducated on both the human body [9] and their own health needs and may, therefore, misinterpret or fail to recognize the presence of symptoms. The second factor centers on the inability (of all stakeholders) to describe conditions in a clear manner [26], as discussed by participant 7:

> *The [patient's] understanding of their condition, their interpretation of symptoms, [and] their ability to communicate symptoms may be different. Our ability on the practitioner's side to elicit those symptoms may be different or more challenging. Ultimately a consultation is based around two-way communication and at times aspects of that communication can be difficult. Whether it be to do with comprehension or*

to do with abstract thinking or just basic communication.

Implementing Accessible Language

Potential strategies discussed by the experts to improve this communication focused largely on the language used by stakeholders. First, 4 of the participants stressed the need to utilize clear and simplistic language and avoid medical jargon where possible. Strydom et al came to a similar conclusion while evaluating the accessibility of medical information leaflets; however, they established that some complex terms (such as brand names) were crucial to patient's comprehension [27]. This suggests that developers of medical AAC apps should consider the views of potential users when creating this information to ensure it is understood as intended.

Moreover, 3 further participants revealed that people with LDs often find it difficult to answer broad, open-ended questions such as "How have you been feeling?" Instead, the questions presented should be closed and focus on solitary ideas to first break the consultation down into manageable chunks and then ease the cognitive load placed on patients.

Utilizing a Range of Modalities

People with LDs are at an increased risk of being unable to understand the language used to describe concepts; thus, technologies must use alternative formats to represent this information [27]. The experts cited several communication modalities that, when combined, may be effective in achieving this, and these will be described in the next subsection.

Communication Modalities

Adults with MLDs are heterogeneous in nature and may not respond to information in the same manner as others [28] - for example, 40% have hearing impairments [29] and can find it difficult to understand data transmitted via sound. To overcome this issue, the experts suggested targeting a variety of communication modalities to ensure an individual's complex needs are catered to.

Pictures

The bulk of the experts suggested that imagery is the most effective modality used to convey information (and therefore promote discussion) providing it immediately captures the concept being depicted. Furthermore, 2 primary reasons that were suggested for this included being easier to process than words alone [30] and being available throughout the entire process. In a variety of health-related studies, patient comprehension has been proven to increase when resources conveyed information using both imagery and text [27,31,32]. In addition, participant 9 revealed that pictures can act as a referent and assist in overcoming potential short-term memory impairments:

[By] having a kind of visual record in front of somebody [it helps to] keep track of where they are. Concrete things are very helpful if there's something there that can be pointed to as a reminder or help to keep a focus.

Speech

A multitude of requirements will have to be met by the images embedded within the app to be effective for all users. As such, this information will have to be conveyed in an alternative format to cater to those users who do not understand the meaning behind a particular image. Of the useful modalities described by the experts, 1 was speech, providing the individual needs and abilities of adults with MLDs are taken into consideration. Participant 3 revealed that the communication skills of this population can vary widely but suggested that the use of accessible language guidelines can help to mitigate this issue.

The experts discussed 2 ways in which speech may be incorporated into the digital aid: (1) accepting speech as user input to forgo the reliance on touch screens and (2) playing back the text displayed on the screen. To ensure this process is accessible, the volume, style, and pace in which the speech is returned should be made customizable.

Accommodating for a Range of Users

Combining speech, text, and imagery to represent medical conditions should increase patient comprehension as they may use the modality that makes sense to them when presented with each potential option. This can lead to an increase in the accuracy of the data being collected and may also be beneficial to the general population, with many patients concluding that the language used by practitioners is both inappropriate and confusing [33].

Simplistic Interface

Limiting Clicks

Operational difficulties [34-36] have resulted in AAC abandonment rates rising to as high as 53.3% [35], with users preferring to revert to traditional forms of communication as opposed to persisting with complex technologies. The experts, therefore, stressed the need to develop simplistic user interfaces and suggested that a reduction in both the complexity and number of steps involved in a process could assist in achieving this, as discussed by participant 10:

It would depend on how easy the [tablet application] was to use but the quicker the better I would say. The shorter the better in terms of how much time someone would have to [complete it]. So, easy to use absolutely, [with] as few steps in the process - as few clicks in the process as possible.

The experts highlighted 1 method to reduce the number of steps involved in the app, which involved mitigating the number of irrelevant questions being presented. Consequently, a dynamic-based questionnaire should be implemented, with questions being adapted to suit the specific health needs of the patient. This closely mimics the consultation process described by participant 7:

I think the first question would be hi how can I help you today? How are you getting on? How are you managing? And then each subsequent question depends on that.

Limiting Choice

All experts agreed that the amount of choice available to adults with MLDs should be reduced to ease the cognitive load placed on users. Nevertheless, they had conflicting views on the maximum number of options present at any 1 time. Participant 9 suggested that this population is often excluded from the decision-making process and are more inclined to answer yes or no questions. As such, the number of options available should be reduced to a minimum and built upon a consistent framework:

> *So maybe keeping [the] options limited and building [the questionnaire] out in a kind of structure so that when you get to the end point you might have to go the long route rather than the shortcut.*

In contrast, several of the other experts felt that this population could cope with greater choice, with up to 4 potential options being cited. Furthermore, participant 8 discussed the need to prioritize adaptable technologies that alter the number of options displayed on screen:

> *Some people might cope with quite a large volume of information and some might need very little - you know two or three items...My recommendation would be that [the app] was very flexible [and] could adapt to the individual needs of a person.*

Individualization

In this study, 7 of the experts stated that AAC technologies should be able to adapt to the characteristics of the user, as summed up by participant 1:

> *I think just to highlight one of the things that was said is that it's not a one size fits all approach, you should tailor it to each individual's needs.*

Some of the requirements described previously strive to achieve this. For example, conveying information via speech, text, and imagery will enable patients to use the modality best suited to their needs. In addition, implementing an adaptive questionnaire will ensure that the questions being presented are suited to the patient's individual health needs. Finally, modifications to the tablet device itself can help cater to more individual needs, such as updating the screen sensitivity settings to account for motor impairments [37].

Adapting the Look of the App

Further opportunities for customization centered on the ability to change the aesthetics of the aid, which includes adapting the number of options displayed on screen, as discussed by participant 9. In addition, 4 of the experts revealed that many adults with LDs have an impaired perception of color and may require specific color schemes to assist in the comprehension of text, as summed up by participant 4:

> *Yellow is the kind of standard [background color]. But normally if someone needs a different color for whatever reason they'll tell you. So, I don't know if that's something that you [can] change [in the app].*

Overcustomization

Although there are great benefits to adapting technologies to cater to the individual needs of users, participant 8 emphasized the dangers of overcustomization:

> *I do worry about things getting too individualized, you know, so that it can't be shared in any way.*

Developers should, therefore, consider the ability to share such technologies across a range of stakeholders and refrain from simply tailoring the app to address the needs of 1 user group. Vanderheiden et al [38] have explored this issue in the past and have concluded that the characteristics and needs of potential subgroups of users can be readily identified. As such, they advocate for interfaces that adapt to the type of user operating the system to mitigate the accessibility issues common to that population. This could potentially entail saving the accessibility preferences of an individual and reloading them during future interactions with the device.

Questions

Target-Specific Health Demographics

The health demographics of adults with MLDs differ dramatically from that of the general population [29,39]. Consequently, this evidence must be used to justify the symptoms that are embedded within the aid to ensure the questions presented are relevant to the user's condition, as discussed by participant 2:

> *The content needs to be informed by the specific health experiences of people with learning disabilities. People with learning disabilities have different patterns of diseases to people in the general population…different kinds of cancers for example are more prevalent.*

GPs often overshadow many of the common conditions experienced by people with LDs, for example, hearing impairments [39,40]. The app, therefore, has the potential to draw greater attention to these conditions and increase their rate of diagnosis.

Question Types

The GPs interviewed also discussed a range of information they deemed essential to the formulation of a diagnosis. Participant 6 briefly described the first 5 questions they would explore during a consultation:

> *The first thing I'd ask is why are they here today? Then whatever they describe you ask for duration, if that has happened before and if there are any other symptoms. And [then finally] how they are in general.*

This led to the development of 4 question sets that should be explored by medical AAC technologies:

1. Questions to extract the symptoms experienced by the patient
2. Questions to determine the duration and intensity of symptoms
3. Questions to extract the history of symptoms
4. Questions that extract the overall health of patients, particularly focusing on their mental well-being as the

National Institute for Health and Care Excellence estimates that 40% of adults with LDs have undiagnosed mental health problems [41]

Patient Histories

Besides effective communication, the success of consultations involving adults with MLDs may rely heavily on the availability and accuracy of patient histories, as described by participant 6:

> *...the second thing you tend to utilize is previous records. For example, if they have [had] a particular health problem then you can anticipate certain problems [occurring]. History from their carer or family members often gives you cues to work beyond.*

From this excerpt, you may assume that all symptoms selected throughout the aid should be stored for subsequent retrieval. However, participant 7 believes that this is not necessary and instead only the most significant symptoms should be stored:

> *Our role is largely an interpretive role translating people's symptoms, alongside any investigations [and] what we know about the probability of a conditions prevalence etc. into a formulation of what's going on. So to that extent I don't always document every single symptom and I don't know how helpful that might be.*

The GP must, therefore, have access to the most significant symptoms selected by the patient when using the app.

Requirements Gathering Summary

Further requirements are presented in Multimedia Appendix 3 and a summary of those discussed in depth are presented in Table 3. The participant ID of the experts who raised each requirement is also included to highlight the frequency in which they were proposed.

Technology Probe Design

The Complex Intervention Framework states that a product must first be piloted before a long-term evaluation is carried out within its target environment. In preparation for this pilot study, a technology probe was developed using the requirements listed in Table 3 and subsequently evaluated by 4 of the experts listed in Table 1. This allows us to mitigate potential accessibility issues before the probe is introduced to stakeholders who have mild LDs. The decisions made during the development of the probe will be now be discussed; however, it is important to note that its functionality focuses solely on the features utilized by patients, meaning that features used exclusively by practitioners have not been implemented. This section is presented in 2 parts: (1) a description of the techniques used to adapt the probe to the individual needs of users and (2) a discussion on the development of a specialized user interface.

Adaptability

Portability

From the offset, portability was prioritized as 1 of the most important features of the app. Consequently, we developed the probe using HTML5, CSS3, PHP, and JavaScript to be cross-platform. As a result, 1 version of the code may run on any device, and this has a considerable advantage over native apps as stakeholders are not restricted by the type of tablet in use. As such, they may utilize the device best suited to their needs, for example, those who have significant visual impairments may require a larger tablet to allow for objects to be increased in size. Medical practices may also purchase the tablet they deem to be most appropriate, thus increasing their likelihood to invest in the intervention.

Stack-Based Questionnaire

The need to limit the number of irrelevant questions being presented to patients with MLDs was also discussed in depth by the experts. To achieve this, an adaptive stack-based questionnaire has been implemented similar to that proposed by Bouamrane et al [42]. A main questionnaire stack is created based on the primary symptom selected by the patient—for example, pain in their eye. This stack contains the questions deemed vital to extracting the current health status of the patient, which means all the questions are presented to the user. The questions are removed one at a time from the top of the stack and presented, in order, provided the user upholds certain preconditions. The answers provided by the patients may then result in additional questions being added to the top of the stack. For example, the questions that have been designed to extract the symptoms of blepharitis may only be presented if the patient indicates that they have itchy, red eyes. Consequently, the adaptive questionnaire can reduce significantly the number of irrelevant questions being presented, as many are only added to the stack once the user has selected a specific symptom.

User Interface

To present the questions contained in the stack to the patient, a specialized user interface was developed using the requirements listed in Table 3. This subsection presents a brief overview of the key design decisions made while developing this interface.

Trimodal Options

As shown in Figure 2, all options available to stakeholders have been conveyed via the use of 3 communication modalities. This includes pictures that closely match the options available, simplified text that provides a description of the symptoms presented, and audio that may be accessed in 2 manners. The user may request the program to sequentially highlight and playback all passages of text displayed on completion of page loads or simply select a particular audio button to have an individual passage played back. Patients may then utilize the modality that makes sense to them when presented with an option, thus increasing user comprehension. However, it is important to note that the images embedded within this probe are considered as placeholders. We intend to develop a set of resources in conjunction with the views of target stakeholders (during future studies) to ensure their complex needs are met [43].

Table 3. A summary of the requirements identified during the semistructured interviews.

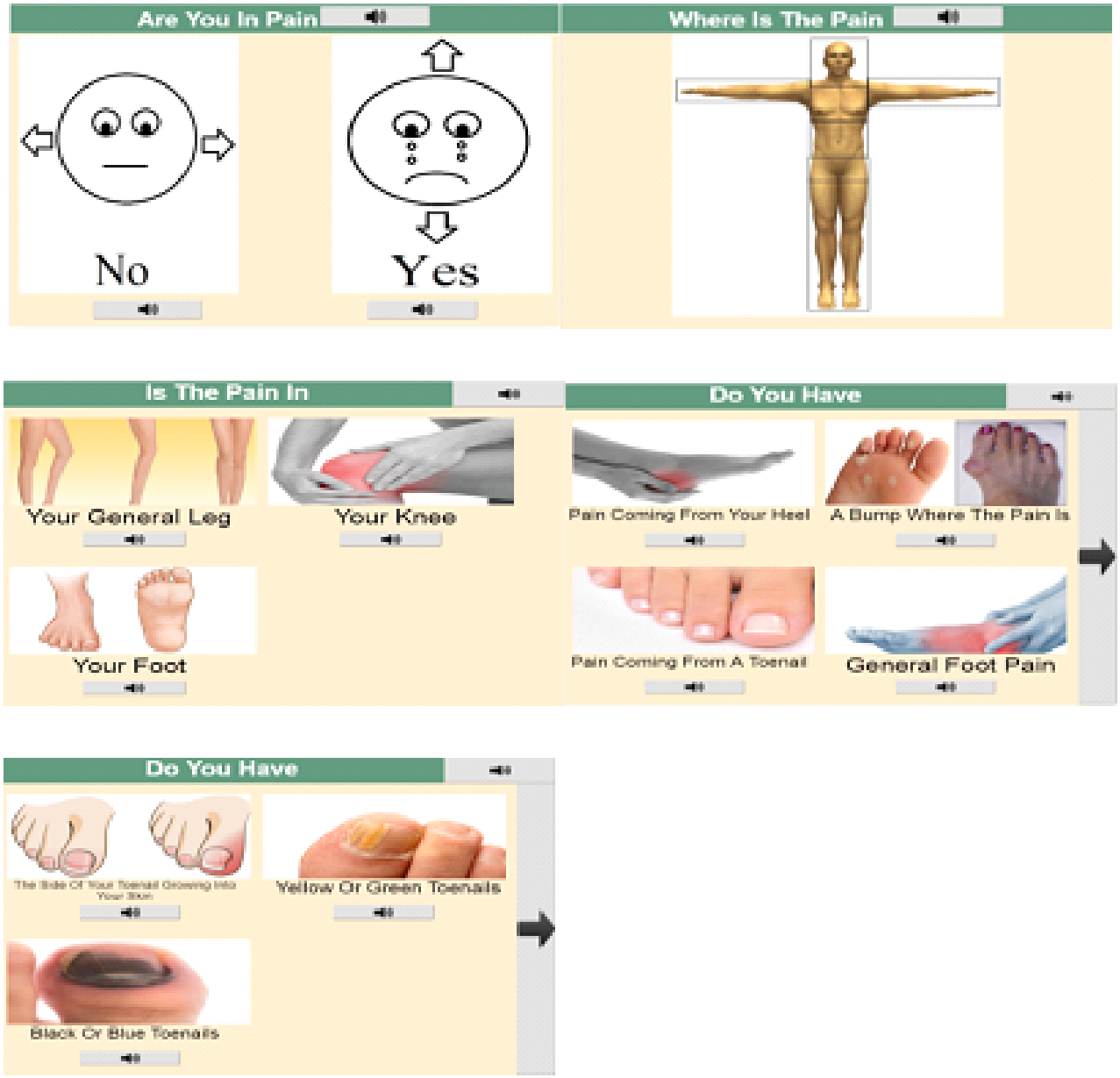
ID	Requirement description	Participant ID
1	Text used to convey symptoms should be developed in conjunction with the views of target stakeholders. Medical jargon should primarily be avoided but some phrases (such as brand names) may be crucial to user comprehension.	2, 3, 8, 10
2	A variety of communication modalities should be targeted. As a result, symptoms should be represented by text, speech, and images where appropriate.	1, 3-5, 7-10
3	Images should be immediately identifiable to the user and subsequently developed in conjunction with the views of target stakeholders.	5, 8
4	The user should have the option to have text played back to them. The pace, style, and volume in which the text is played back should be customizable to suit an individual's needs.	2-5, 8
5	The design of the app should be consistent throughout. An example may be embedding a help button at the top left-hand corner of all pages.	4, 9, 10
6	Questions presented to the user should be concise, straightforward, and focus on solitary ideas. All potential options should focus on a single subject.	1, 2, 4
7	The number of clicks used throughout the aid should be reduced to a minimum to aid users who have limited attention spans, etc.	10
8	A dynamic questionnaire should be implemented. Future questions should be shaped by the information previously supplied by the user.	7, 9
9	The number of potential options displayed on screen should be limited to a maximum of 4.	3, 4, 9, 10
10	The aid should port easily across various operating systems and screen sizes.	8, 10
11	The aesthetics of the aid should be made customizable to address the complex needs of stakeholders. The content should remain unchanged.	4, 5, 8, 10
12	The symptoms presented to stakeholders should be informed by the specific health needs of adults with learning disabilities, rather than that of the general population.	1, 2, 10
13	Questions should aim to extract the symptoms experienced by patients, the duration and history of these symptoms, and the overall health of patients.	6, 7
14	Questions should be presented one at a time.	3, 4, 9, 10
15	A minimum font size of 14 should be used throughout. Text should be made as large as possible.	3-5, 8, 9
16	Contrasting colors should be used to ensure information stands out and can be processed easily. The user should be able to select the color scheme that addresses their needs best.	3-5, 8, 10
17	The aid should provide symptoms experienced by patients in advance of consultations.	2, 4, 5, 7
18	Significant symptoms identified by the app should be stored for future retrieval by general practitioners. This will require the personal details of patients to be captured to act as keys within a database.	6-7
19	All feedback provided should be simple and constructive with a consistent help feature available to increase autonomy.	9
20	The overall consultation process should be broken down into manageable chunks.	1,2, 4

Simplifying the Consultation Process

To be effective, the experts suggested that the app should target those conditions commonly experienced by people with LDs. However, this could result in an overly complex questionnaire containing an abundance of questions, as there is evidence to suggest that this population is susceptible to a wide range of medical conditions [29,39,40]. The adaptive questionnaire described previously assists in reducing the number of questions presented as only those relevant to the patient's condition are considered. 2 further strategies are used to reduce the cognitive load being placed on the user. The first image in Figure 2 contains a page that determines whether the patient is in pain. This enables a host of conditions to be disregarded immediately as many are placed exclusively into a pain or nonpain category.

In addition, different combinations of symptoms may be used to deduce the presence of a condition. Presenting all possible symptoms on screen at once could be cognitively challenging for people with LDs due to the amount of choice available to them. As such, the app restricts the maximum number of options displayed to 4, as shown in the fourth image of Figure 2. As a by-product, this strategy caters to those stakeholders who have significant motor or visual impairments as the area of space allocated to text/clickable objects may be increased. All questions presented also focus on solitary ideas to allow patients to focus on the particular areas of their health that are a cause of concern for them.

Figure 2. Specialized interface developed using the requirements listed by experts.



Designating an Area of Concern

As discussed in the previous section, adults with MLDs respond particularly well to concrete objects that they may point to. Hence, when a patient is required to indicate the body part causing them distress, an image of the body is presented. Nevertheless, this process relies heavily on the user possessing the motor abilities required to tap on small sections of the screen, for example, when selecting the left foot. Due to the prominence of motor impairments in those who have LDs, the probe prompts the user to confirm their selection by presenting all body parts situated in the proximity of the tap (shown in image 3 of Figure 2). This also enables those that were unavailable for selection in the original image, for example, the back, to be presented.

Skipping Questions

Forcing patients into selecting 1 of the options displayed may result in practitioners using incorrect information to form a diagnosis. Consequently, a skip button (shown in the right-hand side of image 4 in Figure 2) has been developed with the needs of the majority of stakeholders taking into consideration. As text may not be relied upon to convey information [27], the button makes use of an arrow to represent naturally the ability to move onto the next question/page. The success of this image will be discussed in depth in the next section. Once the questionnaire has been completed, a summary page will be presented for use by the GP. A more detailed description of the interface may be found in the study by Gibson et al [44].

Technology Probe Evaluation Results

To update the extracted requirements, a series of usability tests were carried out on the probe by a subset of the experts described in Table 1. Participants 1, 2, 4, and 8 partook in the study, and the resulting framework analysis table has been made available in [13]. Row 2 reflects the views of expert 8, row 3 experts 1 and 2 (as they were interviewed together), and row 4 expert 4. Throughout this section, we will discuss the features

deemed to be appropriate for people with MLDs, as well as those that may be improved upon.

Focus

One of the primary barriers expressed by the experts was the overall complexity of the consultation process. To gauge the patient's health needs, GPs often use general open-ended questions such as "How may I help you?"; however, people with LDs tend to find it difficult to answer this style of question. Participant 4 believes that the probe can mitigate this issue by presenting short, closed questions that allow the patient to focus on a particular aspect of their health:

> *If you give someone [with LDs] a blank canvas to start off with their mind just goes blank and they don't know where to begin. I think this is a good way to focus people for the conversation...I just think it would really help someone to clarify what points they want to convey.*

Participant 4 also suggested that the app could help patients to rehearse the information they wish to convey, thus increasing their confidence to address the practitioner:

> *The carer [and the individual] could sit and go over this together and it could actually give them more confidence when they went in [to the appointment] 'cause I think sometimes people feel quite intimidated. Some GPs don't have the best bedside manner, so it gives someone the confidence to actually get their points across.*

Consultation Times

There is evidence to suggest that consultations involving patients with LDs are heavily restricted by time [45], and this may affect the standard of care being provided. A total of 3 experts felt that the aid could alleviate time constraints by allowing the GPs to shape their questions based on the information collected outside of the appointment, as described by participant 4:

> *I think a lot of GPs now have extended consultation times for people with learning disabilities but that would mean they could make the most of that time rather than spending the first half of it trying to figure out what the person's symptoms were.*

Accessible Summary Page

Participant 4 discussed the need to include a second summary page in a format that is accessible to people with LDs:

> *It would be quite a respectful [and] empowering thing for the patient to have a summary of [the symptoms to] use when they go in for the consultation. So, the GP gets the summary, but the person also has a little prompt for themselves in terms of all the things they were feeling.*

One way to achieve this is shown in Figure 3, where the options are represented by the 3 modalities discussed previously.

Communication Modalities

The placeholders used throughout the probe were deemed on the whole to be appropriate for adults with MLDs. All of the experts agreed that the combination of pictures, text, and speech is crucial to the patient's understanding of the symptoms displayed. However, some aspects may be improved upon. Expert 8 believed that some patients could have difficulty understanding the more abstract symptoms, such as tinnitus:

> *...the one about tinnitus, for example, "do your ears feel stuffed up" they might not know how to describe it."*

This quote emphasizes the need to develop the resources used to convey symptoms in conjunction with target stakeholders to ensure they are understood as intended.

Conveying a Range of Conditions

A total of 2 experts were concerned about the meaning conveyed by various images and felt that some could be taken literally by patients with MLDs, as highlighted by expert 1:

> *...the skin one though...people might be very literal in their interpretation i.e. [my condition] doesn't look like that, [so] it's wrong to click that.*

Figure 3. Summary pages for general practitioners and patients.

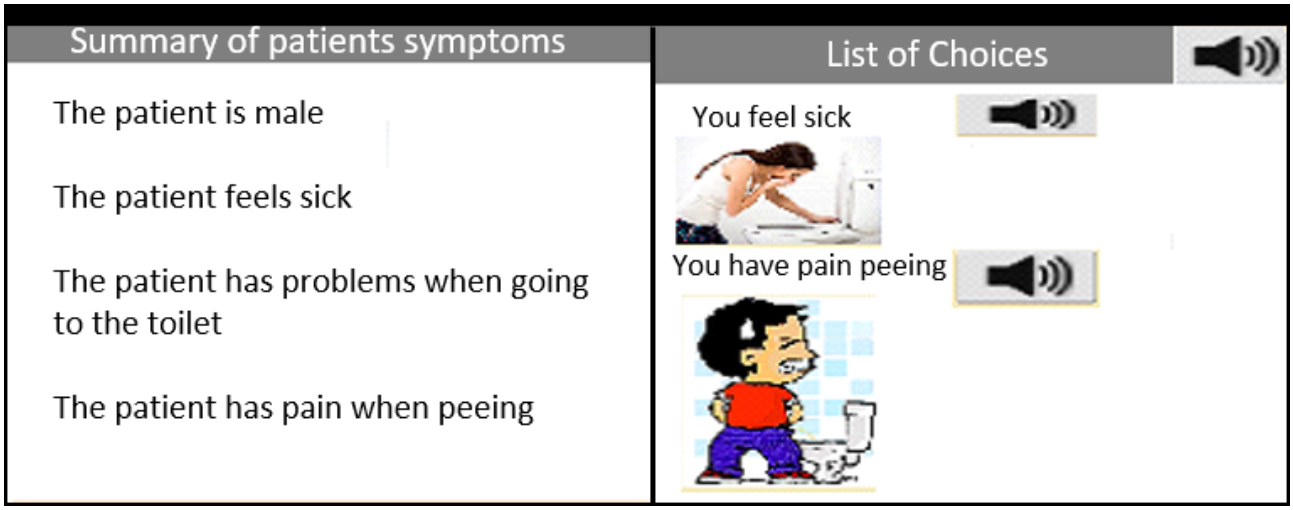
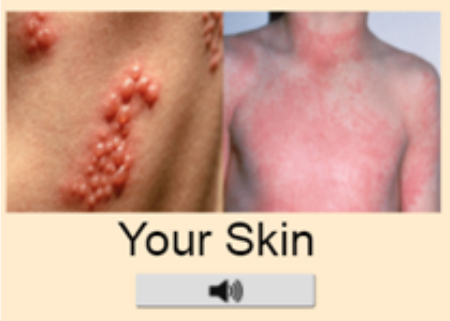


Figure 4. Image originally used to depict skin conditions.



Patients who have other skin conditions, such as eczema, may refrain from selecting the image shown in Figure 4 as their condition looks different to those displayed. Therefore, a more appropriate alternative would be to display a general image of skin to encourage individuals with any skin condition to select the option.

Highlighting the Skip Buttons Purpose

One feature within the app was deemed inappropriate for people with LDs. The skip button (shown in Figure 2) was developed with the use of an arrow to ensure all stakeholders, including those who have difficulty reading, could profit from its use. However, all 4 experts failed to select the button when required to do so, citing that its purpose was unclear. This led to the first author intervening and explaining that the button is used to skip the current question and subsequently present further options, at which point, its intention became clear, as discussed by participant 4:

> *See when you point it out it's like of course it's obvious but I suppose I didn't automatically register that arrow was there. I do think that someone with a learning disability might find that tricky. So, you look at the options and then you have to make a connection between none of them and knowing that you have to press that button to get more options.*

Much of the advice on how to improve the skip button, therefore, focused on making its purpose clear. Participant 4 suggested that a help feature should be implemented across all pages to ensure patients are able to obtain advice when unsure about how to progress, and this matches previous accessibility guidelines such as those provided by Medhi et al [46]. Once again, the information should be presented in an appropriate format with previous literature proposing the use of avatars and videos to deliver such content [15,47]. Further suggestions on potential improvements are presented in Multimedia Appendix 3.

Individualization

A total of 3 participants revealed that the opportunity to change the color schemes used is crucial to addressing the more individual needs of patients, as highlighted by participant 4:

> *That might be a good idea [changing the background color] because, depending on what the persons particular issue/condition is, there are certain colors that work better.*

A range of impairments may also be catered to by altering the pace, style, and volume in which speech is returned. However, it is important to note that the content within the questionnaire should remain the same to all users, and this will be presented in greater depth within the Discussion section.

Additional Features

Return Function

All participants disclosed the need to supply a return function to ensure any mistakes made by the patients can be rectified. Experts 1 and 2 suggested that a confirm function could be embedded that enables patients to corroborate their choice, as discussed by expert 2:

> *I was wondering [if you could include] a box that says, "did you mean your sight, is that correct yes or no" and if no it would go back.*

However, participant 4 felt that this strategy could become irritating for those users who are consistently selecting the correct option and instead advocated for a traditional return button that displays the previous page.

Guidelines for Medical Alternative and Augmentative Communication Apps

Overall, the experts discussed 5 main improvements to the developed probe: (1) the implementation of an accessible summary page for patients, (2) utilizing general pictures to represent a range of permutations, (3) providing audio feedback for all functional units, (4) allowing the user to return to a previous page, and (5) using a pain scale to distinguish between pain and discomfort. These requirements have been combined with the most significant of those found in Table 3 to form a set of guidelines (Table 4) for the development of medical AAC apps that target the needs of adult patients with MLDs.

Table 4. Developed guidelines for the implementation of medical Alternative and Augmentative Communication apps that target adults with mild learning disabilities.

ID	Guideline description
1	The overall consultation process should be broken down into manageable chunks by presenting small, closed questions that focus on solitary ideas.
2	Questions should focus on the health needs of target stakeholders rather than that of the general population as these may differ greatly.
3	Questions should aim to extract the symptoms experienced by patients, the duration and history of these symptoms, and the overall health of patients.
4	Information provided by stakeholders should be used to shape future questions in an attempt to limit the number of irrelevant questions being presented.
5	Information should be conveyed via a range of communication modalities including simplified text, immediately identifiable imagery, and speech.
6	The language and imagery used to convey information should be developed in conjunction with target stakeholders to ensure they are understood as intended. In general, medical jargon should be avoided but this may not be the case for all situations, for example, the use of brand names.
7	General pictures should be used to represent options that have a range of permutations. For example, a picture of eyes may be used to represent visual deficiencies.
8	Appropriate pain scales (such as the Wong Baker Smiley Face Pain Scale) should be used to distinguish if the patient is experiencing discomfort or is in pain.
9	The number of options available to the user should be limited. We recommend a maximum of 4.
10	Elements should be large in size and spaced far apart to accommodate for potential visual and motor deficiencies.
11	Key navigational and decision points should not be conveyed solely with the use of text.
12	A consistent layout should always be provided including the option to access a help feature. The user should be able to navigate across the interface, in both directions via skip and return buttons.
13	The aesthetics of such aids should be customizable; however, the content should remain the same.
14	A record should be kept of all the key activities made within the aid. Both patients and medical staff should have access to this information, represented in a format suitable to them.
15	The software should be portable to ensure stakeholders use the device most suited to their needs.

Discussion

Current Use of Communication Aids in Medical Domains

An extensive amount of research has been carried out to identify the barriers to effective health care experienced by patients with MLDs [2,4,39,48]. This literature highlights the important role communication has throughout primary care, yet surprisingly, little scrutiny has been placed on the impact digital technologies may have in advancing the health literacy of this population. Related studies have instead focused on specific aspects of the care process, for example, gaining consent [49], administering medication [50], and preparing for a stay in hospital [51] or have focused on other medical fields/populations, for example, dentistry [52] and children with LDs [31]. Nevertheless, this cohort of research has produced some similar findings to our own, thus enhancing the impact of the guidelines proposed in Table 4.

Utilizing the Most Appropriate Communication Strategy

The experts interviewed throughout this research (particularly the GPs) have highlighted that a breakdown in communication can occur when information is presented in an inappropriate manner. Both Furberg et al [49] and Menzies et al [52] came to a similar conclusion and suggested that this process can have a detrimental impact on the patient's ability to give consent as the individual may not fully comprehend the options available or why a specific action is required. As with our app, these studies have therefore focused on simplifying the information to be presented and customizing the delivery of content to suit the individual requirements of the user.

In addition to implementing speech, identifiable imagery, and accessible language, Menzies et al [52] found that animation and video can be effective in conveying how procedures are carried out, including the tools used within them. This concept could also be used to capture those conditions that involve movement, such as pain when raising your arm, to ensure they are identifiable to patients with LDs. Furberg et al [49] also investigated the most effective style of imagery to embed within their decision support tool and found that over 40% of participants preferred cartoon graphics. The remaining participants were split between simplistic images and those that followed a graphic novel design, and this emphasizes that a range of needs must be considered when developing technologies for stakeholders who have LDs.

In addition to presenting data in an accessible manner, the dentists involved in [52] requested that such aids extract the patient's likes, dislikes, and previous dental history in a manner similar to that of patient passports [53]. This strategy may

promote communication significantly as the medical professional will be able to use the techniques most suited to the patient's needs and has been explored in depth by Prior et al [54]. One final novel way of enhancing the capacity of a patient with LD to converse with a medical professional was explored by Hall et al [51]. They used virtual reality to embed the patient within a clinical environment, and this process resulted in participants retaining health-related information weeks after their exposure to the technology.

Customization

Many of the modalities discussed in the previous subsection were also targeted by Salgado et al when identifying features for a mobile app that supports users in the management of medication [50]. Nevertheless, these authors explored the concept of customization in further depth. Interestingly, they recognized the need to change the interface based on the category of user interacting with the app. This property could be extremely useful for the proposed app as different and more complex information may be presented to the medical professional or caregiver supervising the patient. With regard to personalizing features to suit the needs of an individual, Salgado et al [50] agreed with our experts by suggesting that this process should be balanced with the development of features that promote independence and comprehension for a wide range of users.

Traditional AAC technologies often afford the user the ability to customize the number of options displayed on screen [55,56]. In contrast, several of the experts interviewed suggested that this population is often unaware of their information needs, and the customization process may be too complex for people with LDs. As such, they proposed that the maximum number of options displayed should be capped at 4 to ease the cognitive load placed on the individual. Further benefits of this include catering to visual and motor impairments as elements may be increased in size because of the screen space available and reducing the need for technology-specific actions such as scrolling. However, 1 downfall is the need to present additional questions to ensure the range of potential symptoms is displayed. In addition, the questionnaire should be based on the evidence available on the health demographics of people with LDs. Consequently, enabling the user to change the number of options displayed may result in the path to certain conditions being altered, meaning erroneous information could be captured.

Furthermore, the resources used to convey symptoms should be developed in conjunction with stakeholders to ensure their complex needs are catered to. As such, it does not make sense to allow users to edit these at will, and instead, a range of resources should be developed and made interchangeable to suit certain subgroups of users. Moreover, 2 further opportunities for customization include adapting the color schemes employed as well as the style, pace, and volume in which speech is returned. We plan to develop the features discussed with the use of participatory design techniques to ensure they are effective in achieving their goal. Stakeholders may then customize the interface to suit their own individual needs and impairments.

The aesthetics of the aid is certainly an important factor; however, it is not the sole driving force behind its success. The experts revealed that the questions presented to the user should be based on their own health needs. Consequently, a static questionnaire would be inappropriate as the patient would be required to answer an abundance of irrelevant questions when providing information about their condition—a process that may be particularly detrimental to those who have limited attention spans. Instead, a dynamic questionnaire was developed that adapts to the needs of the user, and this will be discussed in the next subsection.

Presenting Appropriate Questions

The work presented in this paper is somewhat similar to that of the research carried out by Bostrom and Eriksson [31]. Consequently, many of the requirements identified across both studies were similar including simplistic screens that employ minimal information, the need to present 1 question at a time, limiting the number of interactions required to operate the aid, supplementing textual information with speech and images, implementing accessibility guidelines, and avoiding technology-specific actions such as swiping. Further requirements identified by these authors include offering breaks when the user is required to complete a lengthy process and supporting navigation via buttons that utilize left and right arrows [31].

The primary difference between the 2 studies is the length of the developed questionnaires. Bostrom and Eriksson included 43 questions within their aid, yet the experts interviewed by us suggested that such a length could be problematic for people with LDs because of a variety of reasons including cognitive impairments and short attention spans. Prior et al attempted to solve this obstacle in a project that aimed to extract the needs of adults with LDs during their admission to hospital [54]. They restricted the questions presented based on the user's personal information such as their gender. We have built upon this concept by utilizing the symptoms extracted from the patient to shape future questions, and this was achieved via a dynamic stack-based questionnaire similar to that proposed by Bouamrane et al [42]. This process significantly reduces the number of irrelevant questions being presented as many are only asked provided a certain option has been chosen. It can also assist professionals in meeting current and future guidelines such as those presented in Sullivan et al [57]. Any new conditions found in these documents may be added to the stack via a subquestionnaire and subsequently brought to the attention of the GP when appropriate.

Feasibility of Using Mobile Devices

By discussing the requirements listed by both previous literature and the experts interviewed, we have answered 2 of the research questions proposed. The final question centers on the feasibility of embedding mobile devices within consultations involving patients with LDs. This question may be split into 2 parts: how GPs will react to the use of mobile devices, and how accessible are mobile technologies to adults who have mild LDs.

The GPs involved in the study disclosed that they had never used mobile devices to obtain information; however, they were

open to doing so provided it benefited the patient. Their main concern during this process was the accuracy of computer algorithms in discerning the current health status of an individual, yet this apprehension may be mitigated provided these algorithms are developed using robust methods. They also advocated for receiving information in advance of the consultation although they suggested that a diagnosis should not be provided as the final decision should be made by medical professionals.

In addition, 2 main barriers to the use of tablet technologies were discussed by the experts: the presence of motor/visual impairments and digital exclusion. These impairments may hinder the user's ability to carry out touch screen–specific actions such as swiping, as well as their ability to tap on objects with the required accuracy. Rocha et al discussed these barriers in depth when exploring the accessibility of an iPad mini [58]. They found that the participants were able to learn how to operate the device relatively quickly; however, they struggled to grasp the concept of less intuitive operations. Furthermore, they experienced difficulties when performing actions that required fine motor skills, but their motivation to complete the tasks presented did not detract. Rocha et al also measured the error rate and time taken to complete 2 tasks on the tablet device in comparison to a traditional desktop setup [58]. They found that people with LDs were able to complete the tasks at a significantly faster rate and with greater accuracy while using the tablet. This bodes well for the potential use of such devices within clinical consultations.

Limitations and Future Work

The authors made a deliberate decision to interview experts, as opposed to adults with MLDs, and the rationale behind this has been justified in the Methods section. As such, we argue that this is not a limitation of the study. However, we recognize that the number of GPs involved was restricted and that data saturation for this population has not been achieved. Although GPs may not be considered as experts in LDs, as many are undertrained on the needs of this population, it is important to consider their requirements during the development of the app. As a result, there is scope to interview further GPs until data saturation has occurred. Further opportunities for future work include creating an ontology to represent the conditions common to people with LDs and conducting codesign workshops with adults who have LDs to update the guidelines presented in this paper. Finally, a concrete representation of the aid should be embedded within the medical environment to determine the impact it may have, for example, in reducing consultation times and increasing the diagnosis of certain conditions.

Conclusions

Our study has demonstrated the potential use of tablet technologies to promote discussion between practitioners and adults with MLDs. We developed the first representation of a high-tech research-based aid to achieve this by utilizing the extensive knowledge held by a variety of experts in LDs. This has resulted in the creation of a set of guidelines that will be instrumental in assisting developers in the future implementation of medical apps that cater to the complex needs of adults with MLDs.

It is important to consider a number of factors during the development of such technologies. First, the conditions embedded should exploit the evidence available on the health needs of people with LDs as their demographics differ significantly from that of the general population. Several modalities (including text, speech, and imagery) should be targeted to represent this information and should be developed in conjunction with the views of target stakeholders to increase user comprehension. Both the questions and options presented to patients should be limited to ease the cognitive load placed on adults with MLDs.

It is also important to develop features that cater to the wide range of physical and cognitive impairments that may be present in people with LDs. This process should be restricted to the customization of the aesthetics of the app and should refrain from extending to the content embedded within. Symptoms should be extracted in advance of the consultation to assist in mitigating time constraints, and the app should be portable to ensure patients are able to use the device best suited to their complex needs.

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Authors' Contributions

RCG is the lead author of the paper and conducted both studies reported here. In addition, he developed the initial thematic frameworks used to encode the transcripts that emerged throughout the design phases, as well as the probe used in phase 2.
All authors contributed to the study methods and design development. M-MB assisted in recruiting potential participants along with RCG, and both MMB and MDD confirmed the aforementioned coding and provided supervisory input on the paper writing process.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Question sets presented to participants during semistructured interviews.

[PDF File (Adobe PDF File), 120KB - rehab_v6i1e10449_app1.pdf]

Multimedia Appendix 2

Description of the conditions selected by the experts during the usability study and the questions proposed throughout.

[PDF File (Adobe PDF File), 113KB - rehab_v6i1e10449_app2.pdf]

Multimedia Appendix 3

Less relevant results discussed by experts.

[PDF File (Adobe PDF File), 259KB - rehab_v6i1e10449_app3.pdf]

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Abbreviations

AAC: Alternative and Augmentative Communication

GP: general practitioner
LD: learning disability
MLD: mild learning disability
RQ: research question

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Original Paper

Video Remote Interpreting Technology in Health Care: Cross-Sectional Study of Deaf Patients' Experiences

Poorna Kushalnagar[1], PhD; Raylene Paludneviciene[1], PhD; Raja Kushalnagar[2], JD, LLM, PhD

[1]Department of Psychology, Gallaudet University, Washington, DC, United States

[2]Department of Science, Mathematics, and Technology, Gallaudet University, Washington, DC, United States

Corresponding Author:
Poorna Kushalnagar, PhD
Department of Psychology
Gallaudet University
800 Florida Ave, NE
Washington, DC, 20002
United States
Phone: 1 5856660818
Email: poorna.kushalnagar@gallaudet.edu

Abstract

Background: The advent of new rehabilitation and assistive technologies has led to the creation of video remote interpreting (VRI) as an accessible communication technology for deaf patients. Although there has been a rapid growth in the use of VRI technology by health care providers, there is scant published information on VRI users and their satisfaction. Current, timely data are needed to understand deaf patients' use and satisfaction with the quality of VRI technology in health care settings.

Objective: This study aimed to investigate the national trends of deaf patients' satisfaction with the quality of video remote interpreting (VRI) in health settings and recommend actions to improve VRI quality and deaf patients' satisfaction with VRI in health care settings.

Methods: Secondary data related to deaf adults' experiences of using VRI service in a medical setting were obtained from the Health Information National Trends Survey in American Sign Language, which was administered to a US sample of deaf adults between 2016 and 2018.

Results: Among our VRI users (N=555, all in the United States) who answered questions about VRI usage in health between 2016 and 2018, only 41% were satisfied with the quality of the VRI technology service. Respondents with fewer years of education or those who were male were more likely to rate the VRI quality as acceptable. After adjusting for covariates in a binary regression analysis, deaf patients' self-reported interference (ie, VRI interpreter's interference with disclosure of health information) increased patient dissatisfaction with the quality of VRI technology service by three-fold.

Conclusions: To increase satisfaction with VRI technology service in health care and rehabilitation settings among deaf patients, special attention needs to be given to video technology, as the use of sign language requires high-fidelity video for optimal communication between the interpreter and patient. To promote the willingness to disclose medical information through VRI among deaf patients, the interpreter must be highly skilled in both expressive and receptive communication and have the requisite background in medicine and rehabilitation.

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KEYWORDS

video remote interpreting; deaf; sign language; assistive technology; accessibility; communication

Introduction

Around 500,000 people are deaf or hard of hearing (termed as "deaf" henceforth) in the United States and rely primarily on American sign language (ASL), which requires visual communication [1]. As such, they have much in common with members of other linguistic and cultural minority groups, due to their reliance on ASL over English for daily communication. For this reason, among others, ASL users continue to report difficulties accessing health care many years after passage of the Americans with Disabilities Act of 1990. Many rely on in-person ASL interpreters for effective communication with

health care or rehabilitation professionals, but still report difficulties accessing health care due to geographical, time, and financial constraints in booking ASL interpreters. A solution to these constraints is the advent of video remote interpreting (VRI) technology, which is a specialized translation service that relies on a high-speed internet connection and a camera-equipped device to connect a remote interpreter with a health provider and a patient to facilitate their communication [2,3]. VRI technology is not subject to geographical and time constraints, since the interpreter can provide services from anywhere and does not have to spend time commuting to and from the appointment.

VRI is often used for sessions, one-on-one visits, and patient walk-ins when an interpreter is needed immediately. The equipment for VRI typically consists of a tablet that is sometimes mounted on a rolling stand that can be moved around, with an adjustable position and location. The medical provider is responsible for providing the tablet with the interpreter, which is brought in when the deaf patient is present. The medical provider then presses a button on the tablet to connect to an interpreter stationed elsewhere. This video connection depends on the internet and is usually wireless. The interpreter is portrayed on the whole screen, and the video of the patient is shown in a smaller box in the corner of the screen.

However, in practice, VRI equipment has significant limitations compared to on-site interpreting service for the health care provider, patient, and interpreter in terms of interaction and visibility. For example, while an on-site interpreter can independently move and focus on either the deaf person or health care provider, the tablet video is usually focused on the deaf patient, and consequently, the VRI interpreter cannot see the body language and gestures of the health care provider when they are talking. Similarly, on-site interpreters are in a better position to filter background audio or focus on multiple speakers, while VRI interpreters experience more challenges in filtering noises and attending to key messages. Finally, VRI services are prone to more technical and logistical barriers due to the lack of familiarity regarding their use by health care providers and deaf users.

Because VRI technology is new, empirical research is still emerging and, to date, only one published qualitative study was performed outside the United States. Much of the relevant literature has focused on lawsuits and complaints, which are outside the scope of this paper. In a qualitative study of 58 interpreters, about half of the sample had a positive experience with VRI, primarily because they could work from home and immediately provide accessibility when called [4]. The negative experiences reported by the other half were due to the poor quality of video technology, low bandwidth, and issues arising from the limited range of visual cues in the environment. This study did not include experiences or perspectives of deaf patients who used VRI. Although there has been a rapid growth in the use of VRI by health care and rehabilitation providers, current data are needed to understand deaf patients' experiences with VRI technology. This study investigates the trends of deaf patients' use of and satisfaction with the quality of VRI technology service in health settings.

Methods

Materials and Data Source

With approval from the institution's human subjects review board and informed consent from the participants, data related to deaf adults' experiences of using VRI service in a medical setting were obtained from the Health Information National Trends Survey in ASL, which was administered to a US sample of deaf adults between 2016 and 2018 [5]. The VRI items were drafted and revised by a team of deaf experts with extensive experience using this technology in health care. These items were translated and back translated by deaf bilingual professionals. The translated items were then tested for clarity and understanding through cognitive interviews with deaf people who had a high school or less education [5]. The final translated items were then filmed and uploaded to an online survey platform prior to administration. All items had ASL videos with English text.

Responses

This paper focuses on the responses to the following three questions directly related to patients' opinions and experiences with VRI.

Interpreter Choice

Participants were asked, "If you had to choose one, how do you prefer to use an interpreter in health settings?" with three response options provided: "On-site," "Through video remote interpreting," and "Doesn't matter."

Quality Rating of the Video Remote Interpreting Service

Participants were asked, "How would you rate the quality of VRI services you received in healthcare settings in the past 12 months?" with six response options provided: "Excellent," "Very good," "Good," "Fair," "Poor," and "Did not use VRI." In the analysis, responses of "Excellent" to "Good" were recoded as *Satisfactory* and "Fair" to "Poor" were recoded as *Unsatisfactory*.

Disclosure of Health Information in Front of a Video Remote Interpreting Interpreter

Participants were asked, "Do you feel having a VRI will interfere with your disclosure of health information with the doctor?" with two response options provided: "Yes" and "No."

Participant Recruitment, Consent, and Other Study Procedures

Following institutional review board approval, the research staff began recruitment through national channels, focusing on ASL-using deaf community members. Given the nature of this low-incidence, hard-to-reach population, a purposive strategic respondent-driven sampling method was used to ensure adequate inclusion of deaf signers across the United States. Recruitment methods included snowball and respondent-driven samplings that were found to be effective for deaf and hidden populations [6,7], flyers, and advertisements on deaf-centered organizations' websites and electronic newsletters. Bias associated with snowball sampling was overcome with a large sample size [8]. Communication occurred through accessible channels, including

mail, email, social media, and videoconference programs. Prospective participants were informed that the survey included questions about health status, health communication, and health behaviors.

Inclusion criteria were use of ASL as a primary language, age of 18 years or above, and presence of bilateral hearing loss. Each participant received a gift card for participating in the study. The survey took approximately 1 hour to complete. No names or identifying information was included in the online survey, and a unique identifier was used to avoid storing personal information in the same online survey dataset. The identifying information was stored in a separate database that was accessible only to the principal investigator.

Statistical Analyses

Descriptive statistics were used to summarize the sociodemographic and health care accessibility sample characteristics of deaf individuals who used VRI in health care settings within the past 12 months. Unweighted descriptive statistics, such as cross-tabulation and percentage procedures, were used to describe the sample. Binary logistic analysis was used to predict the odds of reporting satisfaction with the quality of VRI services, after controlling for sociodemographic covariates.

Results

Sample Characteristics of Video Remote Interpreting Service Users

Of the 968 deaf adults who answered questions related to the use of VRI in health care, 413 never used VRI within the past 12 months and were excluded from analyses. The focus of this study was on participants who have actually used VRI in the past year and were able to provide their perspectives on the direct firsthand experience of using VRI. The final VRI user sample (N=555; mean age 45 years, SD 18 years) included 37% persons of color and 30% respondents who self-identified as sexual/gender minority. Although just over half of the sample had a job, 46% percent had a college degree and 43% fell in the middle-income category. Over 90% had insurance, including Medicare/Medicaid and private insurance, and about 88% rated their health as good, very good, or excellent. When asked how much one could understand (listening, speechreading, or both) a hearing person in a quiet room, about 25% of the sample could not understand at all and another 25% self-rated their listening or speech-reading ability as high.

Quality of the Video Remote Interpreting Service According to Video Remote Interpreting Users

Users' satisfaction with the VRI service quality according to the sociodemographic variables is presented in Table 1. About 41% (n=228) of the deaf patient sample rated the quality of VRI as satisfactory. The rest (n=327, 59%) rated their VRI experience as unsatisfactory. Results suggest that male gender or high school education has a greater influence on satisfaction of VRI service quality than of dissatisfaction.

With regard to health care accessibility indicators (Table 2), respondents who had a health care provider that they saw regularly were significantly more likely to be dissatisfied with the quality of VRI service compared to respondents who did not have a regular provider (X^2=7.0; P=.011). Deaf patients who reported that VRI interfered with disclosure of health information to their health care provider were less likely to be satisfied with the quality of VRI service (X^2=47.2; P<.001).

A model-building approach was used to determine the best fit. In the first model, all sociodemographic and health indicators were included in the analysis. Significant (P<.05) and nominally significant (P<.10) variables from the first model were retained for evaluation in the next model. Noncontributing variables that were not significant were removed, and the model was evaluated for significance. This procedure was repeated for the third model. The model that had the largest likelihood value was the final chosen model, with VRI service quality as an outcome (X^2=32.3, P<.001). This model with six variables explained 12% (Nagelkerke R^2) of the variation in VRI service quality rating and correctly classified 64% of cases. Presence of a regular provider and VRI interference (with health information disclosure) were significantly associated with deaf patients' ratings of the VRI service quality (Table 3). Respondents who did not have a health care provider that they saw regularly were 1.5 times more likely to rate the VRI service quality as satisfactory as compared to respondents who had a regular provider. Moreover, those who felt that VRI did not interfere with disclosure of health information were three times more likely to report satisfaction with VRI service quality.

Table 1. Sociodemographic characteristics of users with regard to satisfaction with the video remote interpreting service quality in health care settings (N=555). Frequencies that do not add up to the total sample size reflect missing responses.

Characteristics	Satisfied with VRI[a] service quality (n=228)	Not satisfied with VRI service quality (n=327)	Chi-square value
Age (years), mean (SD)	46 (19)	44 (17)	0.8[b,c]
Gender, n (%)			5.0[c]
Male	114 (50.2)	129 (40.6)	
Female	113 (49.8)	189 (59.4)	
Race/ethnicity, n (%)			2.4
White	134 (59.0)	214 (65.4)	
Non-white	93 (41.0)	113 (34.6)	
Education, n (%)			7.4[c]
High school	77 (34.5)	80 (24.7)	
Some college	52 (23.3)	74 (22.8)	
College	94 (42.2)	170 (52.5)	
Occupation, n (%)			2.7
Employed	117 (51.3)	182 (56.0)	
Student	25 (11.0)	36 (11.1)	
Retired	48 (21.1)	51 (15.7)	
Unemployed	38 (16.7)	56 (17.2)	
Income , n (%)			0.6
Lower	98 (44.1)	152 (47.4)	
Middle	100 (45.0)	138 (43.0)	
Upper	24 (10.8)	31 (9.7)	
Region, n (%)			2.5
Northeast	18 (7.9)	34 (10.4)	
South	95 (41.7)	123 (37.6)	
Midwest	44 (19.3)	75 (22.9)	
West	71 (31.1)	95 (29.1)	
Health insurance, n (%)			1.1
Yes	212 (96.4)	302 (94.4)	
No/not sure	8 (3.6)	18 (5.6)	
General health, n (%)			3.9
Excellent/very good	125 (55.1)	153 (46.9)	
Good	80 (35.2)	130 (39.9)	
Fair/poor	22 (9.7)	43 (13.2)	

[a]VRI: video remote interpreting.

[b]*t* value.

[c]*P*<.05.

Table 2. Health care access characteristics with regard to satisfaction with video remote interpreting quality in health care settings within the past year (N=555). Percentages are determined by the total number of responses to each question.

Characteristics	Satisfied with VRI[a] quality (n=228), n (%)	Not satisfied with VRI quality (n=327), n (%)	Chi-square value
Regular provider			7.0[c]
Yes	113 (50.4)	201 (61.8)	
No	111 (49.6)	124 (38.2)	
Frequency of visits to regular provider			5.3
Never	36 (16.7)	30 (10.0)	
A few times	133 (61.9)	208 (68.1)	
Many times	46 (21.4)	66 (21.9)	
Hospital admission			0.01
Yes	32 (26.2)	46 (26.4)	
No	90 (73.8)	128 (73.6)	
Emergency room visit			0.2
Yes	47 (38.5)	72 (41.1)	
No	75 (61.5)	103 (58.9)	
VRI interpreter presence interfering with disclosure of health information to the doctor			32.7[d]
Yes	171 (75.0)	166 (50.9)	
No	57 (25.0)	160 (49.1)	

[a]VRI: video remote interpreting.

[c]*P*=.011.

[d]*P*<.001.

Table 3. Logistic regression results for satisfaction with the quality of the video remote interpreting service (reference group: patients not satisfied).

Variable	Adjusted odds ratio (95% CI)	*P* value
Age	1.01 (0.99-1.02)	.19
Education[a]	1.36 (0.94-1.96)	.10
Gender[b]	0.73 (0.51-1.05)	.09
Race[c]	1.30 (0.88-1.91)	.16
Regular provider[d]	1.50 (1.04-2.17)	.03
Interpreter interference[e]	2.90 (1.97-4.27)	<.001

[a]Reference group: Patients with a college degree.

[b]Reference group: Male patients.

[c]Reference group: White patients.

[d]Reference group: Patients responding “Yes.”

[e]Reference group: Patients responding “Yes.”

Discussion

Overview

Our study of patient-reported outcomes is the first to report US findings related to deaf patients’ experience with VRI technology. Rigorous data-collection approaches were used to ensure that the sample was inclusive of diverse members in the deaf community that use ASL. Our study results suggest that over half of the participants do not find the quality of VRI services to be satisfactory, despite regulations that specify minimum quality of standards for both technology and interpreter qualifications. Our study also showed that VRI interference with health information disclosure is a crucial variable for satisfaction with the quality of VRI service among deaf patients. Further research is needed to clarify whether VRI interference is affected by the use of an interpreter or video technology itself.

Advantages and Disadvantages of Video Remote Interpreting Technology

Below, we discuss the advantages and disadvantages of VRI that might have affected deaf patients' responses in our study and conclude with recommendations to rectify the VRI interference with deaf patients' disclosure of health information and to increase their satisfaction with the quality of VRI service.

Advantages

There has been a rapid adoption and use of VRI as the first choice to support accessible and effective physician-provider communication in health care. Health care and rehabilitation providers may choose to provide VRI over traditional in-person interpreters due to the former's cost and flexibility.

VRI tends to be cost effective, as VRI interpreters are reimbursed only for the short amount of time that they are required for (eg, 15 minutes), and there is no need to preschedule, which means no cancellation fees. There is usually a minimum time cost for in-person interpreters [9]. For a 20-minute appointment with a deaf patient, the provider is billed 2 hours for an in-person interpreter. In addition, in emergency room or patient situations, in-person interpreters would often be present throughout the entire stay, while the VRI can be connected and disconnected on an as-needed basis when communication needs arise.

VRI offers more flexibility in terms of scheduling, as it takes a variable amount of time for an in-person interpreter to travel to the meeting site. In emergency situations, VRI can quickly assist with communication, while an in-person interpeter would need to travel to the site to provide communication access [10]. VRI has a wider geographical reach and offers access to a larger pool of interpreters including interpreters who have experience in medical settings and specialized training in medical interpreting [11]. The use of qualified interpreters can reduce the possibility of miscommunication between the medical care provider and the patient.

Disadvantages and Recommended Improvements

In most health care settings, VRI is usually an add-on on-call service and considered to be an alternative to the in-person interpreting service. Such an assumption can lead to the emergence of technical problems such as slow connections or limited bandwidth, which impedes effective communication. For example, VRI needs to be free of blurriness, freezing, and connectivity issues. Since VRI usually relies on wireless connections, which are subject to interference, the quality of video can be suboptimal. Effective sign language communication requires both clear and uninterrupted video and qualified interpreters. When the video quality is not optimal, the quality of patient-provider communication is impacted and affects the accuracy of the translation and relay of the deaf patient's health information to the health care provider. When the message is misunderstood or gets lost in the translation, it impacts the deaf patient's satisfaction with VRI services. Conversely, when the video quality is clear, the interpreter's expressive and receptive language skills must be highly proficient in order to support effective communication that takes place between the deaf patient and health care provider.

The combination of effective VRI technology and highly qualified interpreters allows patient-centered care to take place. When a deaf patient experiences positive patient-centered care, it increases patient-provider trust and patient outcomes [12,13]. These have strong potentials to reduce health disparities among medically underserved groups of deaf patients, including reduction of mortality from life-threatening diseases, improved management of chronic diseases, better understanding of treatment plans, and higher self-efficacy of adherence to medications.

The set-up time can also impact deaf patients' satisfaction with the VRI service. When the VRI system is quickly set up and connected to a call center that employs interpreters with strong receptive and expressive skills, the wait time will be shorter [14]. If the patient is seen quickly and provided with a fully functioning VRI system with qualified interpreters, this system can potentially reduce the number of emergency visits and unnecessary diagnostic tests, all of which are associated with cost burden.

Future Research: Evaluation of Certified Deaf Interpreters to Improve Communication Through the Video Remote Interpreting Service

VRI interferes with the health information disclosure possibly through communication difficulties between the deaf patient and interpreter, which needs to be evaluated in a future study. Selecting a certified deaf interpreter via VRI, who is usually listed as a "deaf interpreter" instead of an "ASL interpreter" on the list of languages on the VRI, can potentially resolve the communication problems and decrease the feelings of VRI interference with disclosing health information. Certified deaf interpreters are deaf people who work as professional interpreters, often acting as an intermediary between the interpreter who can hear (hearing ASL interpreters) and the deaf client.

Certified deaf interpreters are in a unique position to help improve the quality of the patient-physician interaction even when VRI is used. For example, they are very perceptive to body language and subtle changes in facial expressions and sensitive to cultural issues that may impede communication between the medical provider and the deaf patient [15]. They can also reduce the impact of technical issues that modify language use [16]. Examples of technical problems that modify sign language use include the limited viewing angle of the tablet with VRI and limited ability to follow focus of the conversation. When this occurs, interpreters and deaf patients may have the tendency to simplify their signs to deal with these constraints, which can affect the quality of the patient-physician interaction.

A small-scale study on spoken-language VRI services found that spoken-language interpreters were adapting to the new VRI technology used by foreign patient speakers [17]. Therefore, it is possible that CDIs have more experience with adapting to the constraints associated with VRI technology angles and are able to fill in missing contexts that were affected by the modification in sign-language use. Future research should consider assessing the role of CDI in reducing the constraints associated with VRI technology angles, increasing the efficiency

of communication between the medical provider and the deaf patient, and ultimately increasing the deaf patient's trust in the provider.

Limitations

Although we asked for deaf respondents' preference between on-site interpreter and VRI, we did not inquire whether they chose to experience VRI or were forced to do so due to various reasons. Deaf patients are often presented with VRI technology or an in-person interpreter when they show up at an appointment, and it is difficult to switch to a preferred method of communication at the last minute. If a majority of participants were forced to use VRI, it might have contributed to the low preference scores in this study.

Conclusions

To increase satisfaction with VRI technology and service in health care and rehabilitation settings, special attention needs to be given to the video quality and customer control of VRI, as sign-language communication requires high-fidelity video for the patient be able to understand the interpreter and vice versa. To promote the deaf person's willingness to disclose medical information to the provider and increase trust in patient-physician communication, the interpreter must be highly skilled in both expressive and receptive communication and have the requisite background in medicine and rehabilitation.

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Conflicts of Interest

None declared.

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Abbreviations

VRI: video remote interpreting
ASL: American Sign Language

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Original Paper

Medium-Term Outcomes of Digital Versus Conventional Home-Based Rehabilitation After Total Knee Arthroplasty: Prospective, Parallel-Group Feasibility Study

Fernando Dias Correia[1,2], MD; André Nogueira[1], MPhysio, MBA; Ivo Magalhães[1], MPhysio; Joana Guimarães[1], MPhysio; Maria Moreira[1], MPhysio; Isabel Barradas[1], MPhysio; Maria Molinos[1], PhD; Laetitia Teixeira[3,4,5], PhD; José Tulha[6], MD; Rosmaninho Seabra[6], MD; Jorge Lains[7], MD; Virgílio Bento[1,8], PhD

[1]SWORD Health, Porto, Portugal

[2]Neurology Department, Hospital de Santo António, Centro Hospitalar do Porto, Porto, Portugal

[3]Department of Population Studies, Abel Salazar Institute of Biomedical Sciences, Porto, Portugal

[4]Centro de Investigação em Tecnologias e Serviços de Saúde (CINTESIS), Abel Salazar Institute of Biomedical Sciences, University of Porto, Porto, Portugal

[5]Epidemiology Research Unit, Instituto de Saúde Pública, Universidade do Porto, Porto, Portugal

[6]Orthopaedics Department, Hospital da Prelada - Dr. Domingos Braga da Cruz, Porto, Portugal

[7]Physical Rehabilitation Medicine Department, Rovisco Pais Medical and Rehabilitation Centre, Tocha, Portugal

[8]Engineering Department, University Institute of Maia - ISMAI, Maia, Portugal

Corresponding Author:
Fernando Dias Correia, MD
SWORD Health
Rua de Sá da Bandeira 651, 1ºDTO
Porto, 4000-437
Portugal
Phone: 351 966 557 789
Email: fanacorreia@gmail.com

Abstract

Background: Physical rehabilitation is recommended after total knee arthroplasty (TKA). With the expected increase in TKA over the next few decades, it is important to find new ways of delivering cost-effective interventions. Technological interventions have been developed with this intent, but only preliminary evidence exists regarding their validity, with short follow-up times.

Objective: This study aimed to present the follow-up results of a feasibility study comparing two different home-based programs after TKA: conventional face-to-face sessions and a digital intervention performed through the use of an artificial intelligence-powered biofeedback system under remote clinical monitoring.

Methods: The digital intervention uses a motion tracker allowing 3D movement quantification, a mobile app and a Web portal. This study presents the results of the previous single-center, prospective, parallel-group, feasibility study including an 8-week active treatment stage and further assessments at 3 and 6 months post-TKA. Primary outcome was the Timed Up and Go score, and secondary outcomes were the Knee Osteoarthritis Outcome Scale (KOOS) score and knee range of motion.

Results: A total of 59 patients completed the study (30 in the digital intervention group and 29 in the conventional rehabilitation group) and follow-up assessments. During the active treatment stage, patients in the digital intervention group demonstrated high engagement and satisfaction levels, with an 82% retention rate. Both groups attained clinically relevant improvements from baseline to 6 months post-TKA. At the end of the 8-week program, clinical outcomes were superior in the digital intervention group. At the 3- and 6-month assessments, the outcomes remained superior for the Timed Up and Go score (P<.001) and all KOOS subscale scores (at 3 months, P<.001 overall; at 6 months, KOOS Symptoms: P=.006, Pain: P=.002, Activities of Daily Living: P=.001, Sports: P=.003, and Quality of Life: P=.001). There was progressive convergence between both groups in terms of the knee range of motion, which remained higher for standing flexion in the digital intervention group than the conventional group at 6 months (P=.01). For the primary outcome, at 6 months, the median difference between groups was 4.87 seconds (95% CI 1.85-7.47), in favor of the digital intervention group.

Conclusions: The present study demonstrates that this novel digital intervention for independent home-based rehabilitation after TKA is feasible, engaging, and capable of maximizing clinical outcomes in comparison to conventional rehabilitation in the short and medium term; in addition, this intervention is far less demanding in terms of human resources.

Trial Registration: ClinicalTrials.gov NCT03047252; https://clinicaltrials.gov/ct2/show/NCT03047252

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KEYWORDS

knee; TKA; home-based telerehabilitation; digital physiotherapist; artificial intelligence; eHealth

Introduction

Total knee arthroplasty (TKA) is the third most commonly performed surgery in the United States, with over 700,000 procedures performed annually [1]. According to the Centers for Medicare & Medicaid Services, the average Medicare expenditure for surgery, hospitalization, and recovery after TKA ranges from US $16,500 to $33,000 [2]. As a consequence of population aging, the incidence of TKA is expected to increase, leading to an exponential growth in costs [3]. Reducing costs of care is thus a priority, with several initiatives already in place, such as the implementation of Bundled Payment options and the Comprehensive Care for Joint Replacement models [4,5]. These are examples of a broader trend favoring discharge from hospital to home, as opposed to more costly facility-based care [6].

Physical rehabilitation, the evidence-based [7] standard of care immediately following TKA, is being increasingly delivered to TKA recipients at home. Indeed, current evidence indicates that home-based care is a viable, more cost-effective alternative to conventional outpatient rehabilitation [8-12].

In the in-home setting, telerehabilitation, involving continuous monitoring from physical therapists, has shown to be very well accepted by patients [13,14], with results comparable to conventional outpatient physical therapy [13,15,16] or face-to-face home rehabilitation [17]. Besides reducing health costs, telerehabilitation enhances therapy uptake while allowing professionals to remotely adjust rehabilitation programs. In recent years, more advanced technological solutions have emerged, which further enhance patient's autonomy and minimize real-time human supervision. These solutions incorporate biofeedback systems with the intent of increasing both patient performance and adherence [18].

Although there is preliminary evidence of the benefits of such technologies [18], they are generally poorly interactive, include complex machinery, and still show a low evidence level, with no long-term validation available yet [18]. Alternatively, smart portable biofeedback systems coupled with motion-tracking sensors are appealing sophisticated solutions that hold great promise in the upcoming age of artificial intelligence-guided therapies [19]. Promising as these may be, we found only one randomized controlled trial (n=142) testing an interactive telerehabilitation solution based on inertial motion trackers after TKA [16]; however, in that study, the intervention was too short (2 weeks) to draw definitive conclusions, and the outcomes were similar in both groups (system against conventional rehabilitation) [16].

In a previous study, we tested an artificial intelligence-powered digital system for home-based physical rehabilitation that uses inertial motion trackers in order to digitize patient motion and provide real-time feedback on performance through a mobile app. This system also includes a Web-based platform that allows the clinical team to monitor each patient's progress and adapt the programs remotely, with the help of machine-learning algorithms. In this single-center, parallel-group, feasibility study (Trial registration: Clinicaltrial.gov NCT03047252; n=59), we compared the digital intervention to conventional face-to-face home-based rehabilitation after TKA, over an 8-week program, to test patient acceptance, engagement, and compliance and assess its clinical impact. The digital intervention was generally very well accepted, with high compliance and satisfaction levels, and the clinical outcomes were superior to those of the conventional rehabilitation group, in terms of change between the baseline and the end of the program [20]. In the present study, we assessed the medium-term results (3 and 6 months post-TKA) of both rehabilitation programs.

Methods

A complete description of the methods can be found in the previously paper published by Correia et al [20]. An abridged version is presented here.

Sample Size Estimation

Sample size estimation was performed considering the primary outcome measure Timed Up and Go (TUG) test score, based on the study by Mizner et al [21] (baseline TUG SD 2.4 seconds), where patients performed a rehabilitation protocol broadly comparable to the one used in the present study. A minimal clinically important difference (MCID) change of 2.27 seconds was considered, based on the study published by Yuksel et al [22]. Considering a power of 90%, a two-sided significance level of .05, and a dropout rate of 15%, 55 patients would be needed to detect a 2.27-second difference between the two groups. Given the wide variation in the SD of the TUG reported by different authors—from 0.5 seconds [23] to 6.3 seconds [16]—we decided to increase the sample size to 70 patients in order to account for a greater variation than the one reported by Mizner et al .

Eligibility Criteria

All consecutive patients admitted to Hospital da Prelada, Porto, Portugal, for primary TKA, between December 19, 2016, and January 16, 2018, were screened for eligibility. Subjects were included if they were ≥18 years old and had clinical and imaging evidence of hip or knee osteoarthritis, indication for TKA

according to the patient's orthopedic surgeon, the ability to walk (unaided or with assistive device), and a caregiver available to assist the patient after surgery.

Exclusion Criteria

The exclusion criteria were as follows: admitted for revision TKA; contralateral knee osteoarthritis severely limiting patient mobility and ability to comply with a rehabilitation program; aphasia, dementia, or psychiatric comorbidity interfering with communication or compliance to the rehabilitation process; respiratory, cardiac, metabolic, or other conditions incompatible with at least 30 minutes of light-to-moderate physical activity; major medical complications occurring after surgery, which prevented discharge of the patient within 10 days after the surgery; other medical or surgical complications that prevent the patient from complying with a rehabilitation program; and presence of blindness or illiteracy.

Allocation

Patients were assessed preoperatively and subsequently scheduled for elective TKA. On discharge, patients were allocated to one of two groups, using patient address as criterion. Subjects residing in areas outside the administrative limits of the city of Oporto were allocated to the digital intervention group. Conversely, patients residing within the administrative limits of the city were allocated to the conventional rehabilitation group.

Blinding

The nature of the study did not allow blinding of patients. Patient assessment was performed by one trained investigator (JT) who was blinded to the study groups. Statistical analysis was performed by a blinded statistician (LT).

Intervention

Both groups received an 8-week rehabilitation program starting on the day after discharge (7-10 days after surgery). The conventional rehabilitation group received a home-based supervised program provided by a physiotherapist, 3 times a week, for 1 hour (total of 24 hours of active treatment time).

The digital intervention group received an initial onboarding visit from the assigned physical therapist, who trained the patient or caregiver to use the system and then performed a supervised session with the patient, ensuring that the patient was able to interact with the system independently or with assistance from a caregiver. From then onward, patients performed the rehabilitation program solely through the use of the biofeedback system, under remote monitoring from the physical therapist. Patients were asked to perform independent sessions at least 5 times per week with a minimum duration of 30 minutes (ideally, total of 20 hours of active treatment time), but were not excluded in case of lower intensity.

Ethics Approval of Research

The study was approved by the National Data Protection Commission (authorization number 1476/2017) and the local ethics committee at Hospital da Prelada. The methods were conducted in accordance with the approved guidelines. All patients and caregivers were informed about the purpose and procedures of the study; they provided written informed consent before inclusion. All patient data were anonymized and linked to the patient by a unique study number that did not contain any personal identifiers.

Outcome Assessments

In our previous report, outcomes were measured 4 weeks into the rehabilitation program and at the end of the rehabilitation program (week 8) [20]. For this study, patients were reassessed at 3 and 6 months postsurgery (± 10 work days) through face-to-face visits.

Several studies suggest that the outcomes should be measured not only in terms of range of motion (ROM) [24-27], but also using patient-reported outcomes and a performance-based test [28,29].

The primary outcome was the TUG score [30], which measures the time that a person takes to rise from a chair, walk 3 meters, turn around, walk back to the chair, and sit down. This test was chosen because it is simple and practical, has high interrater reliability [31], and has been demonstrated to predict both short- [32] and long-term [33] function following knee arthroplasty.

The secondary outcomes were patient-reported outcomes, measured by the Knee Osteoarthritis Outcome Scale (KOOS) and knee ROM in degrees. The KOOS scale [34] was validated by Alviar et al for patients undergoing TKA [35]. The KOOS consists of 5 subscales: (1) pain, (2) other symptoms, (3) function in daily living (activities of daily living [ADL]), (4) function in sport and recreation, and (5) knee-related quality of life (QoL). Standardized options were given (5 Likert boxes), and each question was assigned a score from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) was calculated for each subscale.

Regarding knee ROM, since the system used in this study was a validated medical device for joint angle measurement, with a reported root mean square error of 3.5º in comparison to standard goniometry in the technical file, knee ROM was measured automatically by the system. Active ROM was measured in the following movements: lying, sitting, standing knee flexion, and sitting knee extension. For each exercise, the patient was asked to perform three repetitions, and the best value of the three was recorded.

Individual patient data that underlie the results reported in this article were submitted as supplementary information (Multimedia Appendix 1), which can be accessed through the online version of this paper.

Statistical Analysis

Outcome analysis was performed using a per-protocol analysis. The impact of the interventions on the primary and secondary outcomes was evaluated while considering the change between the baseline and 3 and 6 months. Differences between the two study groups were performed using the independent samples *t* test or Mann-Whitney *U* test. The 95% CIs were determined using Hodges-Lehman estimator. Since outcomes were measured at three different time points (baseline, 3 months, and 6 months), a repeated measures of analysis was performed using a 3 × 2 analysis of variance with group as an independent factor and

time as a within-subject factor. When necessary, logarithm or square root transformations were performed to obtain normally distributed variables. In all analysis, a significance level of 0.05 was considered.

System Technical Specifications

The system is composed of the following components (Figure 1).

Inertial Motion Trackers

Each tracker comprises gyroscopes, accelerometers, and magnetometers, allowing 3D movement quantification. The trackers communicate via Bluetooth low energy with a tablet computer. The trackers are placed on body segments using Velcro straps in specific positions.

Mobile App

Before each exercise, a video demonstration is presented to the patient (Figure 1) along with an audio explanation. During execution, the patient is given real-time visual and audio biofeedback through a dedicated interface (Figure 1). In each repetition, the patient is asked to fill a progress bar, earning a maximum of three stars if he/she surpasses the target range of motion. To do so, the patient must keep within prespecified movement and posture constraints (eg, excessive abduction in a straight leg raise is not allowed). If the patient performs a movement error or assumes an incorrect posture, an error message is displayed, with audio and video information on the specific error performed, thus allowing correction in the following attempts.

Web-Based Portal

The portal allows clinical teams to prescribe exercises, monitor results, and edit prescriptions (Figure 1).

Figure 1. System components. (A) Motion tracker setup. (I) Red tracker: over the sternal manubrium. (II) Green tracker: anterior surface of the hip. (III) Blue tracker: over the anterior tibial crest. (B) Mobile App: preparation screen. This screen is shown before each exercise and displays a video of the exercise as well as audio instructions. (C) Mobile App: execution screen. (D) Web Portal - prescription screen. This screen displays the available exercises on the left and the layout of the exercise session on the right. (E) Web Portal - results screen. In this screen, the following information is presented: date and time of the session; session duration; pain and fatigue reported by the patient through the app; and one card per exercise, showing baseline and target joint angles, wrong and incomplete repetitions, and posture errors.

Figure 1A

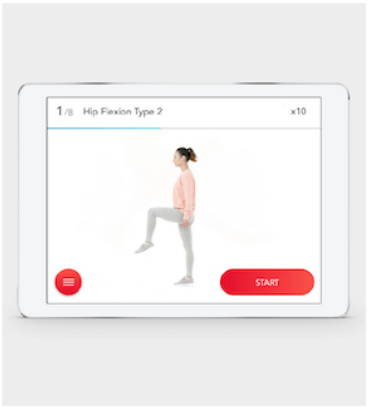


Figure 1B

Figure 1C

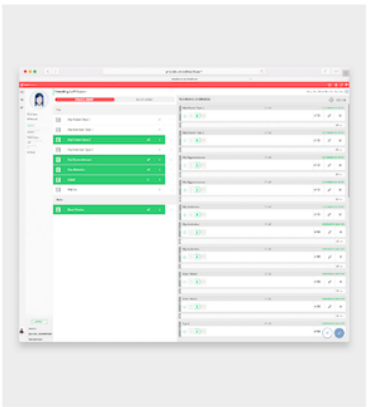


Figure 1D

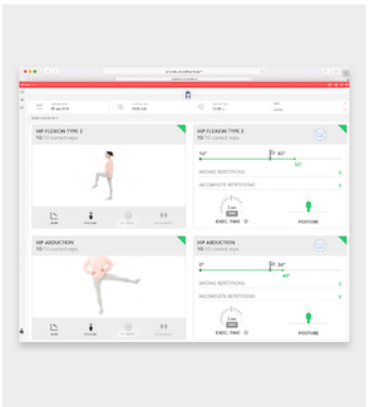


Figure 1E

Results

In total, 59 patients completed the previous 8-week intervention study [20] (30 patients in the digital intervention group and 29 in the conventional rehabilitation group), and there was no loss to follow-up in this study. The CONSORT (Consolidated Standards of Reporting Trials) diagram is presented in Figure 2.

Baseline Sample Characterization

Baseline characteristics of the study participants regarding demographics, comorbidities, and risk factors for adverse events as well as data on hospitalization and surgery are presented in Table 1. There were no differences between the two study groups regarding the abovementioned characteristics. In terms of primary and secondary outcomes, there were no differences between the two study groups regarding TUG and knee ROM (Tables 1 and 2). Regarding the KOOS, the digital intervention group had lower scores in every subscale [20] (Table 3).

Figure 2. Study CONSORT diagram. CONSORT: Consolidated Standards of Reporting Trials; TKA: total knee arthroplasty.

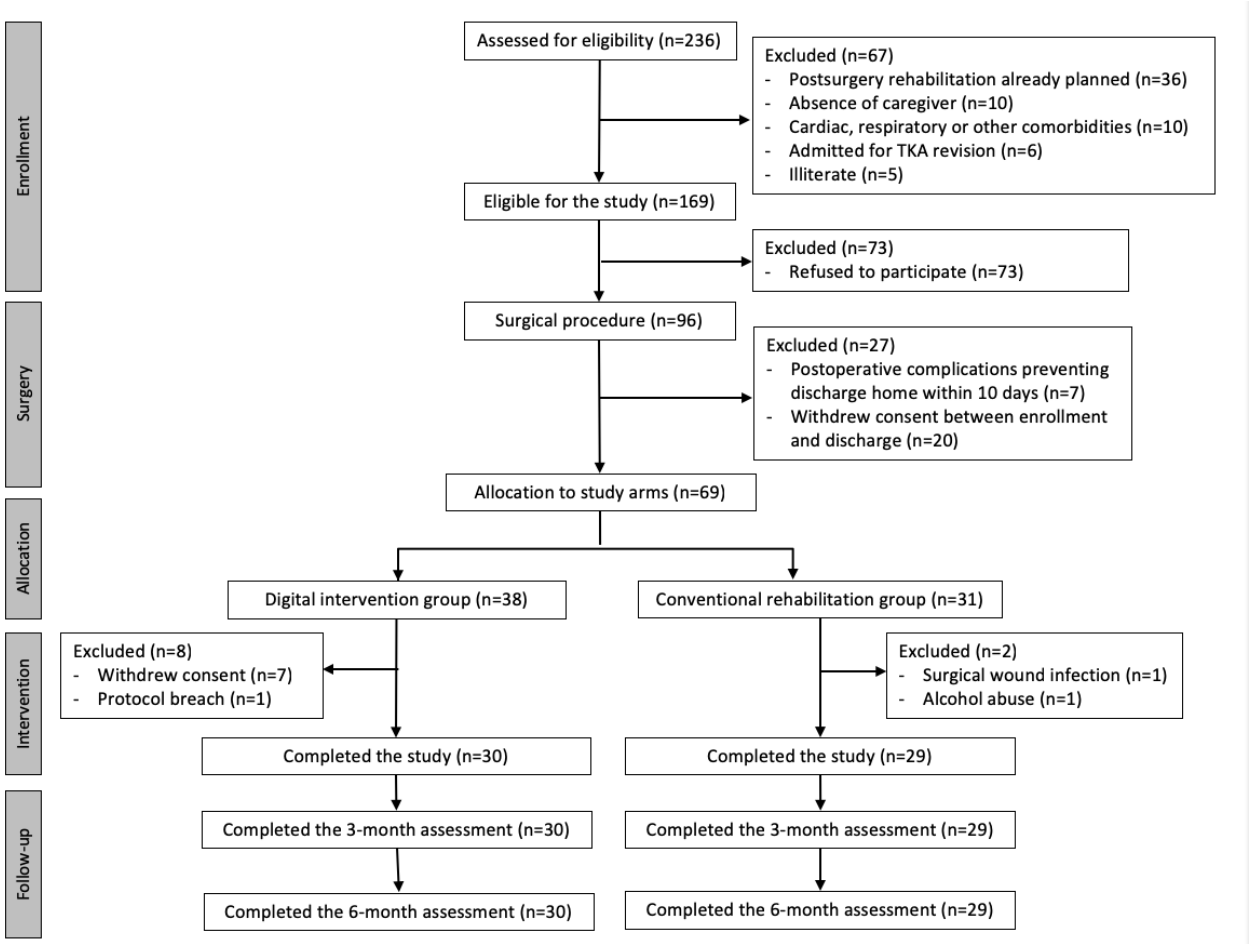


Table 1. Baseline characteristics of the study participants.

Characteristics	Total (N=69)	Digital intervention group (N=38)	Conventional rehabilitation group (N=31)	*P* value[a]
Demographics				
Age (years), mean (SD)	68.5 (7.0)	67.3 (6.8)	70.0 (7.2)	0.12[b]
Gender, female, n (%)	54 (78.3)	32 (84.2)	22 (71.0)	0.30[c]
Operated knee - right, n (%)	38 (55.1)	23 (63.2)	14 (45.2)	0.21[c]
Comorbidities and known risk factors for adverse events				
Body mass index, mean (SD)	30.9 (4.9)	31.0 (4.5)	30.8 (5.4)	0.84[b]
Smoking, n (%)	8 (11.6)	4 (10.5)	4 (12.9)	1.00[d]
Hypertension, n (%)	48 (69.6)	25 (65.8)	23 (74.2)	0.62[c]
Diabetes, n (%)	11 (15.9)	7 (18.4)	4 (12.9)	0.74[d]
Pulmonary disease, n (%)	9 (13.0)	3 (7.9)	6 (19.4)	0.28[d]
Cardiac disease, n (%)	4 (5.8)	2 (5.3)	2 (6.5)	1.00[d]
Stroke, n (%)	0 (0)	0 (0)	0 (0)	N/A[e]
Renal disease, n (%)	2 (1.4)	0 (0)	1 (3.2)	0.45[d]
Bleeding disorders, n (%)	0 (0)	0 (0)	0 (0)	N/A
ASA[f] class 3 or 4[g], n (%)	10 (14.5)	5 (13.2)	5 (16.1)	0.74[d]
Steroids for chronic condition, n (%)	0 (0)	0 (0)	0 (0)	N/A
Previous contralateral knee replacement, n (%)	17 (24.6)	7 (18.4)	10 (32.3)	0.30[c]
Previous hip replacement, n (%)	3 (4.3)	3 (7.9)	0 (0)	0.25[d]
Hospital admission and surgical procedure				
Time between admission and surgery (hours)	<24	<24	<24	N/A
Operative time (min), mean (SD)	62.6 (11.3)	62.4 (9.87)	62.8 (13.0)	0.89[b]
Minor adverse events before discharge, n (%)	1 (1.4)	0 (0)	1 (3.2)	0.45[d]
Hospital length of stay (days), median (interquartile range)	6 (1.0)	6 (1.0)	6 (2.0)	0.83[c]

[a]Mann-Whitney *U* test.

[b]Independent samples *t* test.

[c]Chi square test.

[d]Fisher exact test.

[e]N/A: not applicable.

[f]ASA: American Society of Anesthesiology.

[g]American Society of Anesthesiology physical status classification system.

Table 2. Results of the secondary outcome measure (Knee Osteoarthritis Outcome Score).

Outcome variables	Digital intervention group, median (IQR[a])	Control group, median (IQR)	*P* value[b]	Estimate difference between groups[c]	95% CI[c]
Baseline					
Symptoms	34.0 (20.0)	50.0 (29.0)	<.001	–18.0	–25.0 to –17.0
Pain	33.0 (12.0)	47.0 (24.0)	<.001	–11.0	–19.0 to –6.0
ADL[d]	34.0 (18.0)	41.0 (18.0)	.005	–9.0	–15.0 to –3.0
Sports	0.0 (0.0)	5.0 (8.0)	.006	0.0	–5.0 to 0
Quality of life	13.0 (19.0)	25.0 (19.0)	.007	–12.0	–18.0 to 0
At 3 months					
Symptoms	87.5 (11.8)	82.0 (19.5)	.01	9.0	0-15.0
Pain	95.5 (11.8)	86.0 (22.5)	<.001	11.0	5.0-17.0
ADL	93.0 (8.0)	87.0 (22.5)	.001	7.0	3.0-15.0
Sports	30.0 (11.3)	20.0 (7.5)	.001	10.0	5.0-15.0
Quality of life	81.0.0 (14.5)	56.0 (25.0)	<.001	19.0	12.0-25.0
Change from baseline to 3 months					
Symptoms	51.5 (24.25)	25.0 (27.0)	<.001	25.0	15.0-35.0
Pain	58.0 (12.0)	31.0 (23.5)	<.001	23.0	15.0-31.0
ADL	57.5 (17.8)	35.0 (16.5)	<.001	20.0	13.0-27.0
Sports	30.0 (11.3)	15.0 (10.0)	<.001	10.0	10.9-15.0
Quality of life	65.0 (22.0)	44.0 (21.0)	<.001	25.0	18.0-37.0
At 6 months					
Symptoms	96.0 (15.0)	86.0 (22.0)	.006	7.0	3.0-14.0
Pain	100.0 (8.0)	86.0 (23.5)	.002	11.0	3.0-16.0
ADL	97.0 (6.0)	87.0 (14.5)	.001	7.0	4.0-13.0
Sports	42.5 (36.3)	20.0 (22.5)	.003	15.0	5.0-30.0
Quality of life	94.0 (12.0)	63.0 (37.5)	.001	25.0	12.0-32.0
Change from baseline to 6 months					
Symptoms	60.5 (25.8)	29.0 (33.5)	<.001	25.0	15.0-36.0
Pain	61.0 (11.8)	39.0 (24.0)	<.001	20.0	14.0-28.0
ADL	58.0 (17.5)	43.0 (23.0)	<.001	19.0	11.0-26.0
Sports	40.0 (35.0)	15.0 (27.5)	<.001	20.0	10.0-30.0
Quality of life	81.0 (20.0)	43.0 (40.5)	<.001	36.5	24.0-49.0

[a]IQR: interquartile range.

[b]Mann-Whitney *U* test.

[c]Hodges-Lehman estimator.

[d]ADL: activities of daily living.

Table 3. Results of the primary outcome measure (Timed Up and Go score).

Time point	Digital intervention group, median (IQR[a])	Control group, median (IQR)	*P* value[b]	Estimated difference between groups[c]	95% CI[c]
Baseline	18.19 (6.2)	15.27 (8.5)	.13	2.02	–0.78 to 4.44
3 months	7.83 (2.4)	10.3 (3.5)	<.001	–2.50	–1.43 to –3.80
Change from baseline to 3 months	–10.28 (5.9)	–5.23 (8.5)	.004	–4.48	–1.64 to –7.37
6 months	6.86 (1.6)	8.74 (4.0)	<.001	–1.95	–1.24 to –2.90
Change from baseline to 6 months	–10.47 (7.2)	–5.08 (9.3)	.003	–4.87	–1.85 to –7.47

[a]IQR: interquartile range.

[b]Mann-Whitney *U* test.

[c]Hodges-Lehman estimator.

Usability, Satisfaction, and Compliance Analysis in the Digital Intervention Group

Seven patients withdrew consent in the first week of the study, due to the inability to interact with the system. Of the remaining 30 patients, 18 (60%) required assistance of a caregiver for motion tracker placement or interacting with the app. There was no age difference between autonomous patients or those needing assistance (*P*=.19).

Only 4 patients (13%) did not comply with the recommended session frequency of 5 times per week.

Total active treatment time was superior in the digital intervention group (*P*=.005), with a median of 31.5 hours (interquartile range 18.0 hours; range 10.8-69.1 hours).

Patients had three face-to-face contacts with the therapist (one deployment session, one contact at 4 weeks, and one contact at the end of the 8-week program) and, on average, 0.4 (SD 0.7; range 0-2) additional face-to-face contacts as well as a median of 2.5 extra calls (interquartile range 3.0; range 1-12) for technical assistance.

Twenty-seven patients rated their satisfaction as 10/10, one with 9/10, and two with 8/10.

Clinical Outcomes

The TUG scores were better (*P*<.001) in the digital intervention group (Table 3) in both 3- and 6-month assessments.

Concerning KOOS, the scores in the digital intervention group were higher than those in the conventional rehabilitation group for all subscales at both 3 and 6 months after TKA (Table 2).

Knee ROM was higher for sitting knee flexion (*P*=.046), sitting knee extension (*P*=.002), and standing knee flexion (*P*<.001) in the digital intervention group than in the conventional group at 3 months. At the 6-month assessment, only the standing knee flexion ROM remained significantly high (*P*=.01; Table 4).

Change Between Baseline and the 3- and 6-Month Assessments

At 3 months, the change in all outcome measures was superior in the digital intervention group and at the 6 months, this was true for the primary outcome (TUG), the KOOS score, and knee flexion while standing (Tables 2-4).

Based on the MCID reported in the literature for TUG (2.27 seconds) [22], clinically significant improvements were noted in both groups at 3 and 6 months, with participants taking 58% and 33% less time to complete the test in the digital intervention and control groups, respectively, at 6 months after surgery.

The difference between the median changes in the two groups was clinically significant, more than doubling the MCID (4.48 seconds at 3 months and 4.87 seconds at 6 months) in favor of the digital intervention group.

Regarding KOOS scores, the improvement noted in both groups was superior to the minimal important changes reported for the KOOS scores in subjects undergoing rehabilitation after TKA [36] (Symptoms: 10.7 points; Pain: 16.7 points; ADL: 18.4 points; Sports: 12.5 points; QoL: 15.6 points) in all subscales, denoting clinically relevant changes from baseline, 3 months, and 6 months after TKA (Table 2). The difference between the median changes in the two groups was also statistically and clinically significant in all subscales, again favoring the digital intervention group, except for the Sports subscale at the 3-month assessment, where the difference between the groups was lower than the minimal important change for this subscale (10.0 points; 95% CI 10.9-15.0).

Table 4. Results of the secondary outcome measures (knee range of motion).

Outcome variables	Digital intervention group, mean (SD)	Control group, mean (SD)	*P* value[a]	Estimate difference between groups	95% CI
Baseline					
Lying flexion	80.7 (12.4)	84.7 (18.7)	.34	4.0	–12.2 to 4.3
Sitting flexion	85.3 (16.0)	90.4 (13.1)	.19	5.1	–12.8 to 2.5
Standing flexion	71.6 (20.3)	78.8 (16.6)	.15	7.2	–16.8 to 2.6
Sitting extension	26.5 (8.4)	24.8 (7.8)	.43	1.7	–2.5 to 6.0
At 3 months					
Lying flexion	100.1 (12.6)	93.3 (13.6)	.052	6.8	–0.04 to 13.62
Sitting flexion	102.5 (13.1)	96 (11.3)	.046	6.5	0.10-12.89
Standing flexion	95.6 (10.2)	84.9 (10.4)	<.001	10.7	5.22-16.08
Sitting extension	11.8 (8.3)	19 (8.8)	.002	–7.2	2.73-11.65
Change from baseline to 3 months					
Lying flexion	19.4 (15.5)	8.7 (15.1)	.009	10.7	2.8-18.7
Sitting flexion	17.3 (20.1)	5.7 (14.7)	.01	11.6	2.4-20.8
Standing flexion	23.9 (17.6)	6.1 (14.1)	<.001	17.8	9.5-26.2
Sitting extension	–14.8 (9.0)	–5.9 (11.6)	.002	-8.9	–3.5 to –14.3
At 6 months					
Lying flexion	103.4 (10.6)	101.5 (13.3)	.55	1.9	–4.38 to 8.15
Sitting flexion	102.5 (10.8)	102.2 (12.3)	.93	0.3	–5.77 to 6.29
Standing flexion	97.4 (9.9)	89.9 (11.7)	.01	7.5	1.78-13.08
Sitting extension	7.1 (6.6)	9.7 (5.8)	.12	–2.6	–5.83 to 0.64
Change from baseline to 6 months					
Lying flexion	22.7 (12.9)	16.8 (17.4)	.15	5.8	–2.1 to 13.8
Sitting flexion	17.2 (19.1)	11.9 (13.9)	.22	5.4	–3.4 to 14.1
Standing flexion	25.7 (20.1)	11.2 (14.0)	.002	14.6	5.5-23.6
Sitting extension	–19.4 (8.4)	–15.1 (8.7)	.06	–4.3	–8.8 to 0.2

[a]Independent samples *t* test.

For knee ROM in patients undergoing TKA, there are no minimal important changes validated so far. The only comparable metric was reported in a study by Stratford and collaborators [37], which reported a minimal detectable change at a 90% CI of 9.6º for knee flexion and 6.3º for knee extension in patients after TKA. Hence, at 3 months, only the digital intervention group showed clinically relevant improvements in the knee ROM as compared to baseline assessment; however, this was true for both groups 6 months after TKA (Table 4). The difference in median changes revealed the superiority of the digital intervention over conventional rehabilitation at 3 months. At 6 months, only the mean change in the standing flexion knee ROM was significantly higher and clinically meaningful in the digital intervention group (14.6º; 95% CI: 5.5-23.6).

Repeated Measures Analysis

This analysis was performed only for the normally distributed variables TUG and ROM after transformation. The results are summarized in Table 5.

For TUG, the repeated measures analysis revealed a main effect of time ($F_{2.2,124.5}$=76.406, P<.001), a main effect of group ($F_{1,57}$=9.346, P=.003), and an interaction between time and group ($F_{2.2,124.5}$=7.807, P<.001) in favor of the digital intervention group (Table 5, Figure 3).

Regarding knee ROM, the repeated measures analysis revealed a main effect of time and an interaction between time and group in the four knee ROMs measured, again in favor of the digital intervention group (Table 5, Figure 3).

Adverse Events

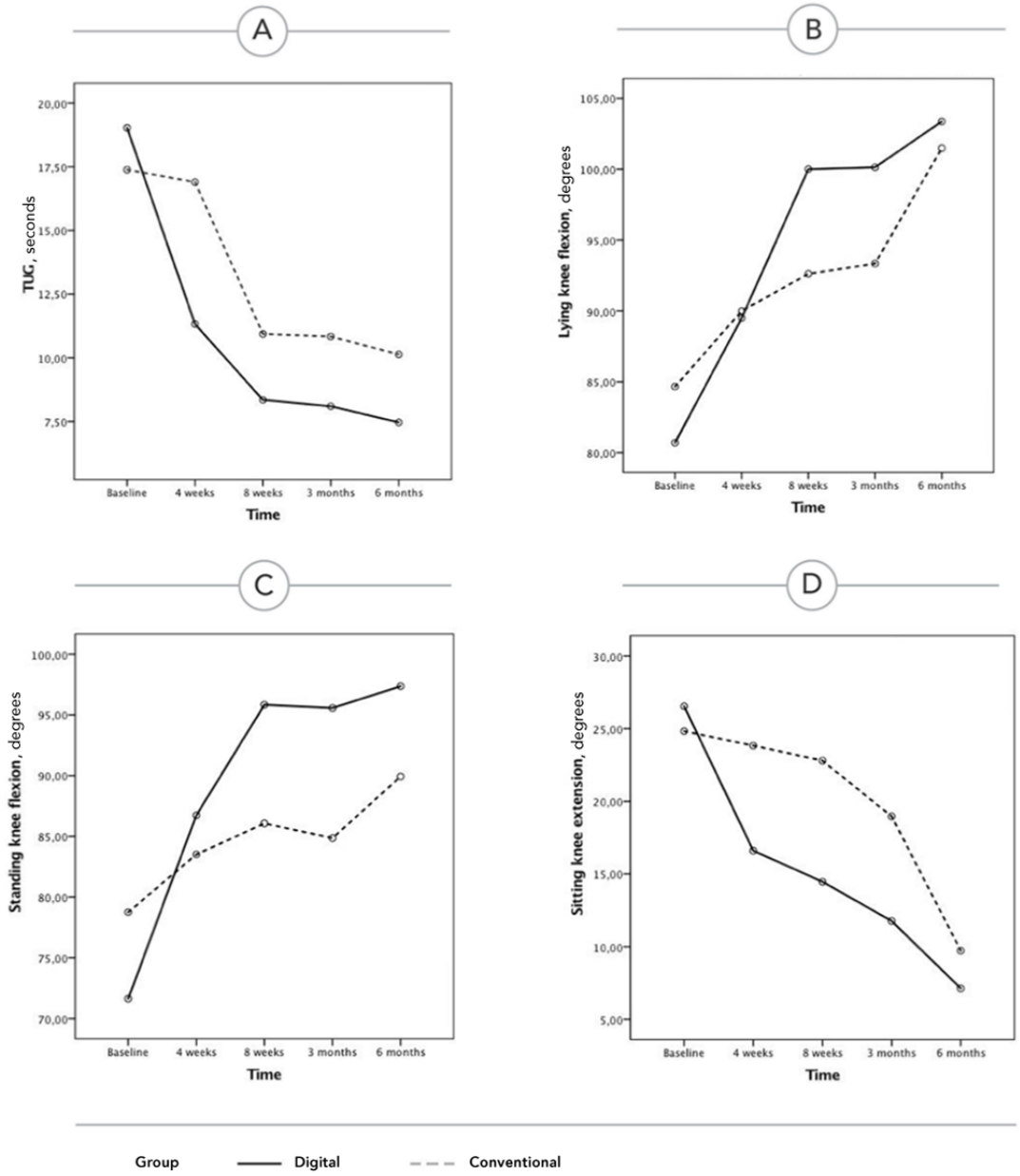
No adverse events were reported in any of the study groups in the period between the end of the active treatment stage and the 6-month assessment. In particular, there were no falls in any of the groups, readmissions to hospital for any reason, or TKA revision.

Table 5. Repeated measures analysis. Greenhouse-Geisser correction was used for all variables.

Outcome variables	Time			Group			Time*Group		
	$F_{df1,df2}$	*F* value	*P* value	$F_{df1,df2}$	*F* value	*P* value	$F_{df1,df2}$	*F* value	*P* value
Patient performance									
Timed Up and Go[a]	$F_{2.2,124.5}$	76.406	<.001	$F_{1,57}$	9.346	0.003	$F_{2.2,124.5}$	7.801	<.001
Knee range of motion									
Lying flexion	$F_{2.6,150.9}$	42.3	<.001	$F_{1,57}$	0.8	0.375	$F_{2.6,150.9}$	4.29	0.008
Sitting flexion	$F_{2.2,126.2}$	24.8	<.001	$F_{1,57}$	0.27	0.604	$F_{2.2,126.2}$	3.98	0.02
Sitting extension	$F_{3.0,169.4}$	50.9	<.001	$F_{1,57}$	11.4	0.001	$F_{3.2,169.4}$	5.6	0.001
Standing flexion	$F_{2.0,116.2}$	37	<.001	$F_{1,57}$	3.88	0.054	$F_{2.2,116.2}$	9.17	<.001

[a]Logarithmic transformation.

Figure 3. Evolution of the outcomes over time in both groups, based on the repeated measures analysis (estimated marginal means of transformed variables are presented). (A) Timed Up and Go score. (B) Lying knee flexion. (C) Standing knee flexion. (D) Sitting knee extension. TUG: Timed Up and Go.



Discussion

The feasibility study was designed to assess both patient acceptance, engagement, and satisfaction with a novel digital intervention for rehabilitation after TKA and to estimate the clinical impact of the intervention in comparison to conventional face-to-face rehabilitation.

In terms of patient acceptance, the enrollment rate of this study was very low (29%), with patient refusal or consent withdrawal corresponding to more than half the screening failures. This was expected, given the relatively high mean age of the study participants (68.5 years; SD 7.0 years) and is a common issue in this field [16], likely representing patients' skepticism toward new technological solutions as well as suspicion of possible hidden costs. This limitation can be overcome by ensuring better training and broader involvement of clinical teams (both doctors and nurses) that approach the patient upon admission.

From the patients initially allocated to the digital intervention, there was an 18% dropout rate in the first week, and 60% of the remaining patients needed assistance from a caregiver. Even if the number of additional face-to-face contacts for technical assistance was low, the number of extra calls for this reason was relatively high. This represents important usability issues faced by these new technologies in an older population and shows that there is room for improvement, namely, in facilitating tracker setup and removing physical interactions with the tablet. Nonetheless, in the patients who completed the 8-week program, user compliance with the program was very high, with only 4 patients using the system less than 5 days per week. Patient satisfaction was also very high. These are very promising results in terms of engagement, and they validate the gamification strategies in use.

Regarding clinical outcomes, the present study demonstrates clinically relevant improvements of all outcome measures in both groups at 3 and 6 months after TKA. We speculate that the good results obtained in both groups may be related to an early and intensive rehabilitation program.

When comparing the results obtained in the two groups, it is important to note that the study was sufficiently powered to detect clinically meaningful changes between the two groups, with posthoc analysis showing a statistical power of 95%.

Overall, this study demonstrates that the greater benefits observed in the digital intervention group for all outcome measures at the end of the 8-week assessment period were maintained at 3 and 6 months for the primary outcome (TUG) and KOOS score, with a convergence in terms of knee ROM (except for standing knee flexion). We speculate that maximizing short-term outcomes may also maximize medium-term (and possibly, long-term) outcomes. In addition, we speculate that one particular factor—patient empowerment regarding the rehabilitation journey—is maximized with an independent home-based program, possibly leading to a more active lifestyle and maintenance of some of the exercises included in the program. This may have, in turn, maximized the results. These aspects warrant further investigation in upcoming studies.

Regarding TUG, participants in the digital intervention group experienced a median change of 10.47 seconds (58% change from baseline) in the TUG test 6 months after surgery, while the control group experienced a median change of 5.08 seconds (33% change from baseline).

However, it must be noted that baseline TUG values in the present study were much higher than those reported by other authors, with preoperative values between 8 and 12 seconds, which in turn yield poor changes from baseline to the intervention time (approximately 8%-30% improvement) [21,38-40]. We could only find one randomized controlled trial (n=142) [16] with comparable baseline values for TUG (control: 22.8 seconds; SD 11.33 seconds and experimental: 18.9 seconds; SD 7.34 seconds). This study also compared an interactive virtual rehabilitation system for rehabilitation after TKA with conventional rehabilitation. However, in this study, the difference from baseline to 3 months was greater for the conventional rehabilitation group (10.86 seconds, SD 8.72 seconds; approximately 48% change) than for the digital intervention group (7 seconds, SD 6.31 seconds; approximately 37% change).

It is also important to note that the mean value reported for TUG at the 6-month follow-up assessment in the digital intervention group (6.9 seconds, SD 1.6 seconds) is similar to the value reported for healthy older individuals (50-85 years of age) by Bade et al (5.6 seconds, SD 1.0 seconds) and much lower than the value reported by the same authors for patients treated with conventional physiotherapy 6 months after TKA (9.1 seconds, SD 2.4 seconds) [41]. In the conventional group, the results at the 6-month assessment are in line with those reported by Bade et al [41].

Overall, the TUG analysis shows that important benefits were attained in both study groups; the results of the conventional group were in line with those reported by other authors, and those of the digital intervention group were superior to the results reported in the literature.

Concerning KOOS, Stevens-Lapsley et al [23] published a retrospective cohort evaluation on the self-reported and performance-based assessments of knee recovery following TKA. The scores obtained in this study for both groups surpassed those reported by these authors for KOOS subscales Symptoms, Pain, and ADL at all time points, but not for the KOOS subscale Sports. This could be explained by the fact that, in this study, baseline scores in the Sports subscale were much lower. Regarding the QoL subscale, the scores for the Sports subscale in the conventional rehabilitation group were slightly lower than those reported by Stevens-Lapsley et al [23] (3 months: 56.0 [SD 25] vs 63.3 [SD 2.98]; 6 months: 63.0 [SD 37.5] vs 66.96 [SD 3.01]), whereas the digital intervention group achieved much higher scores (3 months: 81 [SD 14.5]; 6 months: 94.0 [12.0]).

Overall, the results of the KOOS subscale scores demonstrate that for the comparison group, the clinical improvements were in line with those published by other authors, and results in the digital intervention group were much higher than those reported by other authors.

Regarding knee ROM outcomes, the results of knee flexion at 6 months in both groups were comparable to those reported in other studies (97º to 116º) [37], while active knee extension values were much lower than those found in the literature [37,41,42]. This latter difference could be a result of the more demanding position used to measure knee extension—sitting as compared to lying supine—which ultimately hampered direct comparison of the results.

Overall, differences between the intervention groups were not so evident, with results from all exercises converging at the 6-month assessment and entering a typical plateau phase, except for standing flexion, which showed higher amplitudes in the digital intervention group. However, importantly, short-term assessments (8 weeks and 3 months) revealed a much quicker improvement in the digital intervention group, potentially minimizing the time spent in rehabilitation after TKA surgery.

This study has several limitations that need to be acknowledged. First, it was a quasi-randomized study, where patient allocation was performed using a geographical criterion. Therefore, a number of factors (namely, socioeconomic) that were not controlled or addressed may have influenced the results. Nonetheless, both groups were similar in terms of baseline characteristics, except for KOOS scores, which were lower in the digital intervention group. It could be argued that the difference may be related to different health perceptions between the two groups, but the reason is not clear. Future studies should consider that pure randomization allows for a better control of these aspects.

Second, this was a single-center study performed in a low-volume orthopedic hospital, and all patients were admitted for elective surgery, which may not reflect the reality of other hospitals. In addition, the average length of stay (ie, 6 days) is higher than that reported in other studies [43], probably due to the inexistence of a fast-track protocol for TKA. The results reported here therefore need to be confirmed in multicentric trials in larger hospitals before generalization.

Third, the low inclusion rate may have represented a selection bias toward more technologically prone patients/caregivers, which needs to be properly addressed in future trials.

Fourth, treatment intensity was higher in the digital intervention group, which may have potentiated clinical results in this group. Nonetheless, even if this is the case, it is noteworthy that the superiority was maintained at the 3- and 6-month assessments.

Fifth, even though no serious adverse events were reported until the 6-month assessment, the absence of minor adverse events is more difficult to explain and was most likely due to an underreporting of these events. In future studies, besides direct telephone contact and specific questioning of adverse events in assessment appointments, event logs should be delivered to the patients to avoid underreporting.

In conclusion, the present study demonstrates that this novel digital intervention for rehabilitation after TKA is feasible and associated with high patient compliance and satisfaction. Like other novel technological approaches, it is still met with some skepticism by older patients, and usability still needs to be improved to ensure greater independence by users. This study also demonstrates that the digital intervention can maximize both short- and medium-term outcomes in comparison to conventional rehabilitation. As this approach is far less demanding in terms of human resources, this might be the first step toward a paradigm shift to artificial intelligence-assisted personalized electronic rehabilitation. These promising results warrant larger multicentric randomized controlled studies that address the study limitations to ensure widespread validation of this novel approach.

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Authors' Contributions

Study concept and design: FDC, VB, JT, RS, AN, and LT. Data acquisition: IM, JG, M Moreira, and IB. Direct supervision of the rehabilitation program: IM, JG, M Moreira, and IB. Outcome assessment: JT. Analysis and interpretation of data: FDC, LT, M Molinos, and AN. Critical revision of the manuscript for important intellectual content: All authors. Obtained funding: FDC and VB. Administrative, technical, and material support: IM, JG, M Moreira, M Molinos, and IB. Study supervision: FDC, VB, JT, RS, and AN.

Conflicts of Interest

FDC and VB have a shareholder position at SWORD Health, a company that develops and commercializes SWORD-related products. AN, IM, JG, M Moreira, M Molinos, and IB are employees of SWORD Health but do not have shareholder positions. LT and JL receive honoraria from SWORD Health. JT and RS have no conflicts of interest to report.

Multimedia Appendix 1

Raw data for outcome measures.

[XLSX File (Microsoft Excel File), 71KB - rehab_v6i1e13111_app1.xlsx]

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Abbreviations

ASA: American Society of Anesthesiology
ADL: activities of daily living
CONSORT: Consolidated Standards of Reporting Trials
IQR: interquartile range
KOOS: Knee Osteoarthritis Outcome Scale
MCID: minimal clinically important difference
QoL: quality of life
ROM: range of motion
TKA: total knee arthroplasty
TUG: Timed Up and Go

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Original Paper

Therapist-Guided Tablet-Based Telerehabilitation for Patients With Aphasia: Proof-of-Concept and Usability Study

Stephan Moreno Gerber[1], MSc; Narayan Schütz[1], MSc; Arif Sinan Uslu[1], MSc; Nadine Schmidt[1], BSc; Carina Röthlisberger[1], BSc; Patric Wyss[1], MSc; Sandra Perny[2], MSc; Corina Wyss[2], MSc; Monica Koenig-Bruhin[3], MSc; Prabitha Urwyler[1], PhD; Thomas Nyffeler[3], Prof Dr, MD; Laura Marchal-Crespo[1,4], Prof Dr; Urs Peter Mosimann[1], Prof Dr, MD; René Martin Müri[2], Prof Dr, MD; Tobias Nef[1,4], Prof Dr

[1]Gerontechnology & Rehabilitation Group, University of Bern, Bern, Switzerland

[2]Department of Neurology, University Neurorehabilitation, University Hospital Bern (Inselspital), University of Bern, Bern, Switzerland

[3]Neurocenter, Luzerner Kantonsspital, Luzern, Switzerland

[4]ARTORG Center for Biomedical Engineering Research, University of Bern, Bern, Switzerland

Corresponding Author:
Tobias Nef, Prof Dr
ARTORG Center for Biomedical Engineering Research
University of Bern
Murtenstrasse 50
Bern, 3008
Switzerland
Phone: 41 31 632 75 79
Email: tobias.nef@artorg.unibe.ch

Abstract

Background: Aphasia is the loss or impairment of language functions and affects everyday social life. The disorder leads to the inability to understand and be understood in both written and verbal communication and affects the linguistic modalities of auditory comprehension, verbal expression, reading, and writing. Due to heterogeneity of the impairment, therapy must be adapted individually and dynamically to patient needs. An important factor for successful aphasia therapy is dose and intensity of therapy. Tablet computer–based apps are a promising treatment method that allows patients to train independently at home, is well accepted, and is known to be beneficial for patients. In addition, it has been shown to ease the burden of therapists.

Objective: The aim of this project was to develop an adaptive multimodal system that enables aphasic patients to train at home using language-related tasks autonomously, allows therapists to remotely assign individualized tasks in an easy and time-efficient manner, and tracks the patient's progress as well as creation of new individual exercises.

Methods: The system consists of two main parts: (1) the patient's interface, which allows the patient to exercise, and (2) the therapist's interface, which allows the therapist to assign new exercises to the patient and supervise the patient's progress. The pool of exercises is based on a hierarchical language structure. Using questionnaires, therapists and patients evaluated the system in terms of usability (ie, System Usability Scale) and motivation (ie, adapted Intrinsic Motivation Inventory).

Results: A total of 11 speech and language therapists (age: mean 28, SD 7 years) and 15 patients (age: mean 53, SD 10 years) diagnosed with aphasia participated in this study. Patients rated the Bern Aphasia App in terms of usability (scale 0-100) as excellent (score >70; Z=–1.90; P=.03) and therapists rated the app as good (score >85; Z=–1.75; P=.04). Furthermore, patients enjoyed (scale 0-6) solving the exercises (score>3; mean 3.5, SD 0.40; Z=–1.66; P=.049).

Conclusions: Based on the questionnaire scores, the system is well accepted and simple to use for patients and therapists. Furthermore, the new tablet computer–based app and the hierarchical language exercise structure allow patients with different types of aphasia to train with different doses and intensities independently at home. Thus, the novel system has potential for treatment of patients with aphasia as a supplement to face-to-face therapy.

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KEYWORDS

aphasia; high-intensity training; telerehabilitation; multiplatform system

Introduction

Language and speech are crucial to communication and play a central role in everyday social life. Aphasia is an acquired language impairment that follows brain injury. It affects the linguistic modalities of auditory comprehension, verbal expression, reading, and writing and must be distinguished from other cognitive communication problems [1]. Aphasia is common in patients with stroke and traumatic brain injury. In acute stroke, it affects about one-third of the patients [2,3]. The recovery depends mainly on the type of aphasia and severity of the initial insult. The recovery rate is highest during the first 3 months [4]. Patients with aphasia not only differ in the degree of language impairment but also in cognitive functioning and communication capabilities [5].

The most common treatment of aphasia is direct retraining of the linguistic deficits. Alternative therapy forms include pharmaceutical drugs or treatment of neurobehavioral functions [6]. A study conducted by Grechuta et al suggested that silent visual cues facilitate word retrieval and verbal execution and thus improve language functions [7]. Another effective strategy to improve word retrieval and auditory comprehension is intensive language-action therapy, combining speaking and writing with nonlinguistic actions [8,9].

However, there is a lack of consensus between the relationship of dose and intensity of the therapy [10]. Dignam et al showed that distributed therapy over 8 weeks showed higher improvement in language functions than intense therapy over 3 weeks [11], but there is evidence that intensive face-to-face therapy time improves later outcome [12-15]. Furthermore, therapy should commence as early as possible after stroke incidence [16].

The feasibility of intense face-to-face therapy in clinics is limited, since it requires a sufficient number of qualified therapists and is quite expensive. Therefore, the advent of computer-aided therapy is increasing, since it reduces the load of therapists while maintaining and augmenting established therapy [17]. Evidence has shown that computer-based training, in addition to established therapy, is feasible and improves later outcomes [18-20]. For example, Lee et al developed a computer-based system where patients have to mimic the observed action to improve speech after stroke [21].

In particular, the use of tablet computers with touch screen manipulation has opened new opportunities for therapeutic purposes. Compared to paper-pencil exercises, they are more intuitive to use and highly portable [17]. Moreover, telerehabilitation apps allow therapists to treat and provide remote support and feedback through telerehabilitation technology.

The state-of-the-art telerehabilitation apps for aphasic patients mostly focus on disorder-oriented treatment to restore the linguistic processing ability, whereas fewer apps focus on functional treatment to develop strategies to compensate for the deficit [22,23]. Evidence has shown that remotely delivered computer aphasia training is acceptable [24-27] and beneficial for patients [28-33].

To be practical, telerehabilitation apps should focus on multiple linguistic modalities. There are several validated systems on the market (eg, Constant Therapy, Tactus Therapy, and StepByStep Aphasia Therapy), which have shown evidence that tablet computer-based aphasia therapy focusing on multiple linguistic modalities is beneficial and improves later outcome [18,26,34].

Due to the heterogeneity of the aphasic population, the speech and language therapy, and thus intensity and dose, must be adapted dynamically to the individual patient's needs. Until now, speech and language therapists had to create exercises based on recommendations and heuristics, which is very time consuming, as the therapists must develop a number of tasks to supplement the patients with enough training materials to avoid repetition.

Additionally, the ageing demographic and increase in the number of aphasic patients create a significant need for new adaptive multimodal telerehabilitation methods to improve the later outcome, quality of life, and probability of returning to work.

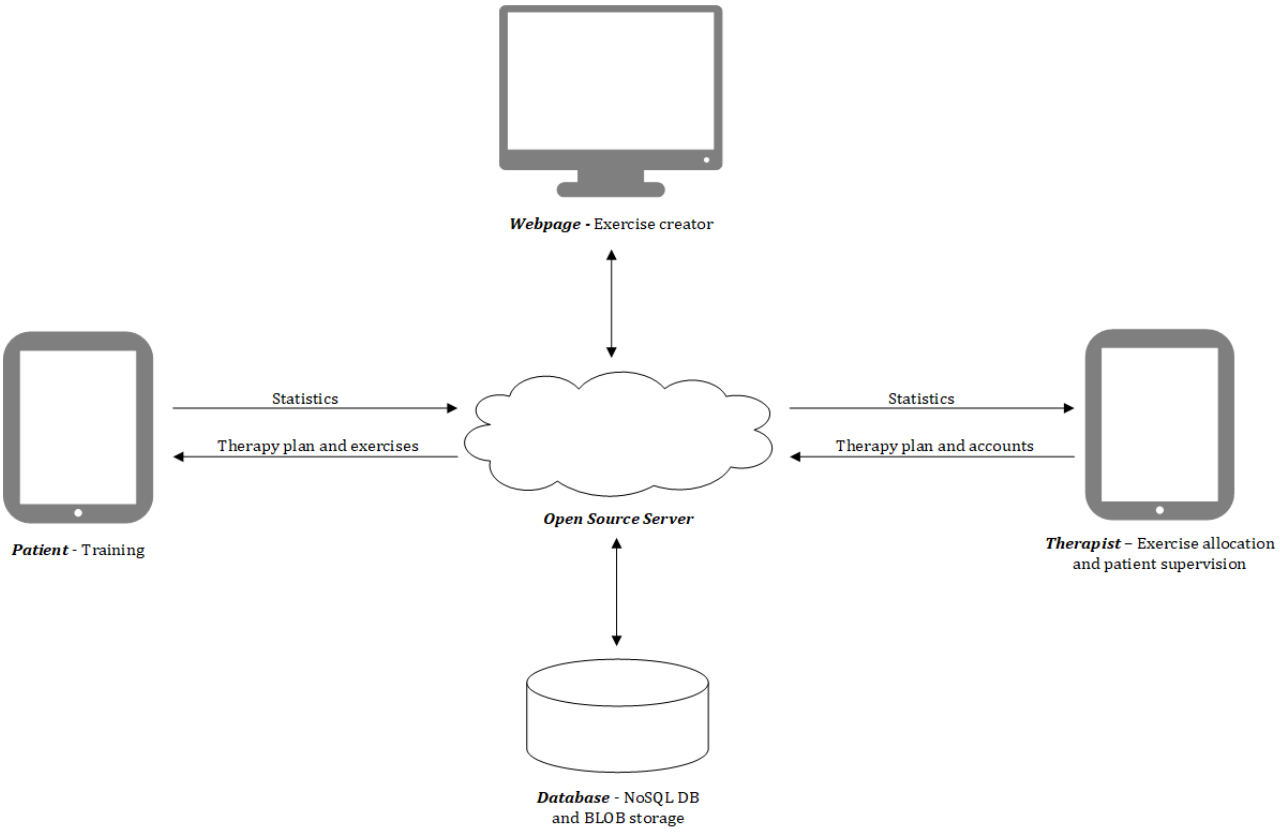
Therefore, in this study, we propose a new adaptive multimodal telerehabilitation system for patients with aphasia, which allows control of the dose and frequency of speech and language therapy remotely. We hypothesize that the developed system is simple and intuitive to use for both therapists and patients. This includes the ability for therapists to assign new exercises easily and efficiently based on an adaptive hierarchical language exercise structure, create new exercises for all linguistic modalities, give progress feedback to the patient, and access the system from different locations.

Methods

General Concept of the Bern Aphasia App

The system was developed by the University of Bern along with the speech and language therapist of the University Hospital of Bern (Inselspital). The system contains five main parts (Figure 1): (1) The patient interface that allows the patient to train according to the therapy plan. (2) The therapist interface that allows the therapist to assign new exercises to the patient, create new patient accounts, and supervise the progress of the patient. The patient and therapist interfaces run on tablet computers (iPad) programmed in Object-C. (3) The Web page to create new exercises independent of the app. (4) The NoSQL (Not Only Structured Query Language) database to store patient and exercise data, and the Binary Large Objects storage to store all images and videos of the exercises. The database is located behind a secure firewall on a managed server and can only be accessed by authorized personnel (ie, administrator of the system). (5) The open-source server served as a backend service.

Figure 1. The general concept of the Bern Aphasia App with the five main parts and related data flow (ie, webpage to create exercises, NoSQL database and BLOB storage to store patient and exercise data, tablet computer interfaces [patient and therapist, iPad], and the open source server as backend service). NoSQL: Not Only Structured Query Language; DB: database.



Multimodal Exercises

In collaboration with speech and language therapists, 10 different exercise types were defined to meet all linguistic modalities (Table 1). More than 30,000 exercises in German were implemented, and new exercises can be added online by the exercise creator. The exercises are split into training units (deck), consisting of about 25 tasks.

The exercises consist of three main elements (ie, fixed, response, and supportive elements). Fixed elements build the structure of exercises and cannot be moved. Response elements are needed to complete the task and can be moved to fulfill the task. The number of fixed and response elements can be varied and are either videos, images, written language, placeholders, or audio tracks. Supportive elements (ie, videos, images, and audio tracks) act as an aid to solve the tasks and can thus be used to fine tune task difficulty. For example, in the sentence completion task in Figure 2, “kalt” (cold) and “brandheiss” (boiling) are response elements, whereas “Der” (The), “Winter” (winter), “ist” (is), and “.” are fixed elements. The video of a speech and language therapist spelling the correct word acts as a supportive element.

Based on the broad spectrum of impaired language functions, the difficulty of an exercise differs in patients, and thus, categorization into one difficulty measure is not possible and must be adapted individually. Therefore, a hierarchical system that is structured according to characteristics (ie, based on linguist rules) and difficulty within an exercise type (eg, phonology, morphology, syntax, semantics, and pragmatics) was implemented. Detailed information of each exercise type and the hierarchical structure can be found in the Multimedia Appendices 1 and 2.

Workflow

The therapist has to first create an account for the patient. Depending on the type and severity of the language impairment, the therapist assigns tasks and the corresponding decks to the patient. The tasks and decks are downloaded automatically onto the patient’s tablet computer. Each time the patient trains using the tablet computer, results are sent to the patient’s database. Feedback about the correctness of response is given automatically after the exercise is completed. In parallel, the therapist is able to change the exercise types and decks remotely, according to the needs of the patient. Furthermore, the therapist can monitor the patient’s progress in real time. The workflow is presented in Figure 3.

Table 1. Exercise categories.

Category and level	Exercise type	First level of the hierarchical language structure	Description	Supportive Media
Assigning				
Phonology	Single picture-word matching	Adjective, substantive, verb	Selecting the correct word from phonematically respective semantically related distractors	Audio, video
Phonology	Single word-picture matching	Adjective, substantive, verb	Selecting the correct picture from phonematically respective semantically related distractors	Audio, video
Semantic	Multiple Matching	Homonym, antonym	Matching all objects (word-picture, picture-picture, word-word)	—[a]
Insertion				
Phonology	Word completion	Number of phonemes	Selecting the correct letter(s) (from distractors) and inserting them into the correct position(s)	Audio, image, video
Phonology	Sentence completion	Grammatical syntactic and semantic processing	Selecting the correct words(s) (from phonematically respective semantically related distractors) and inserting them into the correct position(s)	Audio, image, video
Sort				
Phonology	Anagram	Phonematic and semantic criteria	Bringing the letters into the correct order	Audio, image, video
Grammar	Sentence ordering	3-6 words	Bringing the words into the correct order	Audio, image, video
Mimic				
Phonology	Word repetition	Number of syllables, hierarchic, mixed, consonant clusters	Repeating the audio-visually recorded spoken word by a speech and language therapist	—
Writing				
Phonology	Copy and recall	Low- and high- frequency words	Copying and recalling presented words by typing or writing	—
Comprehension				
Auditory	—	—	Selecting the correct answer to a question about the auditory-based information	—
Audio-visual	—	—	Selecting the correct answer to a question about the audio-visual based information	—
Reading	—	Narrative and procedural	Selecting the correct answer to a question about the text-based information	—
Visual	—	—	Selecting the correct answer to a question about the image-based information	—

[a]Not available.

Figure 2. Set of possible exercise types and tasks.

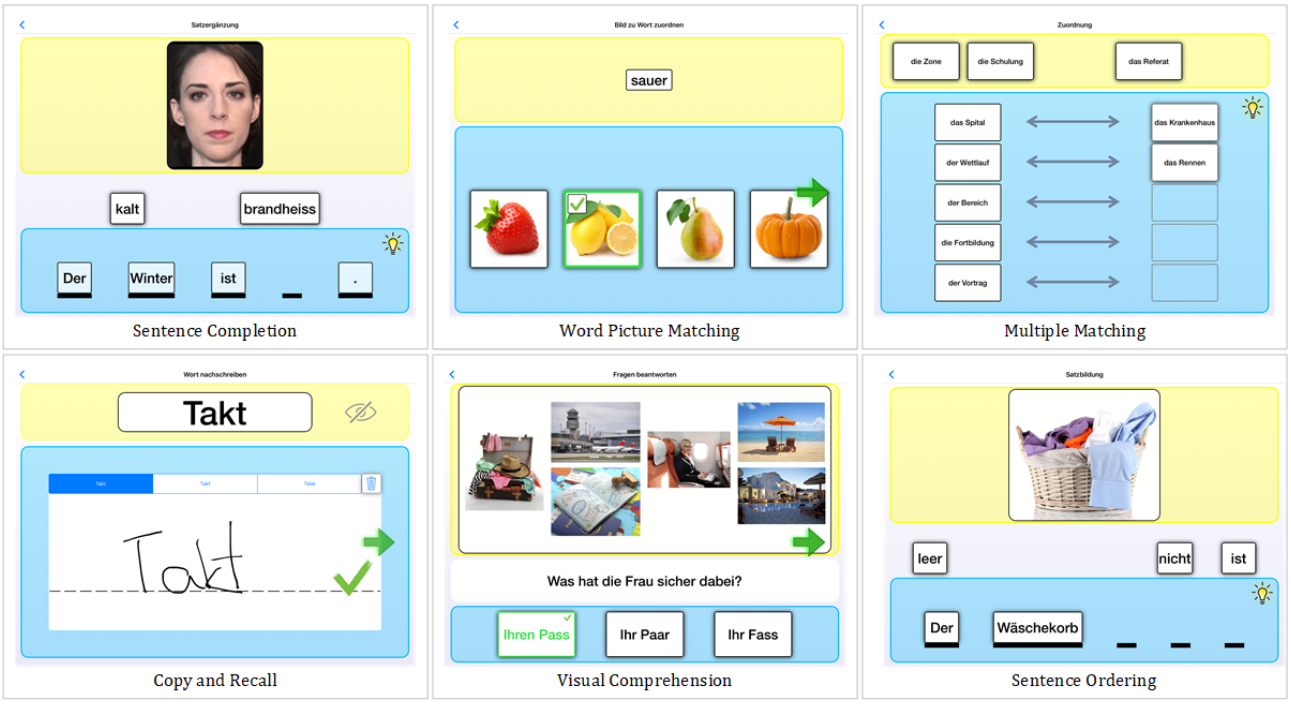
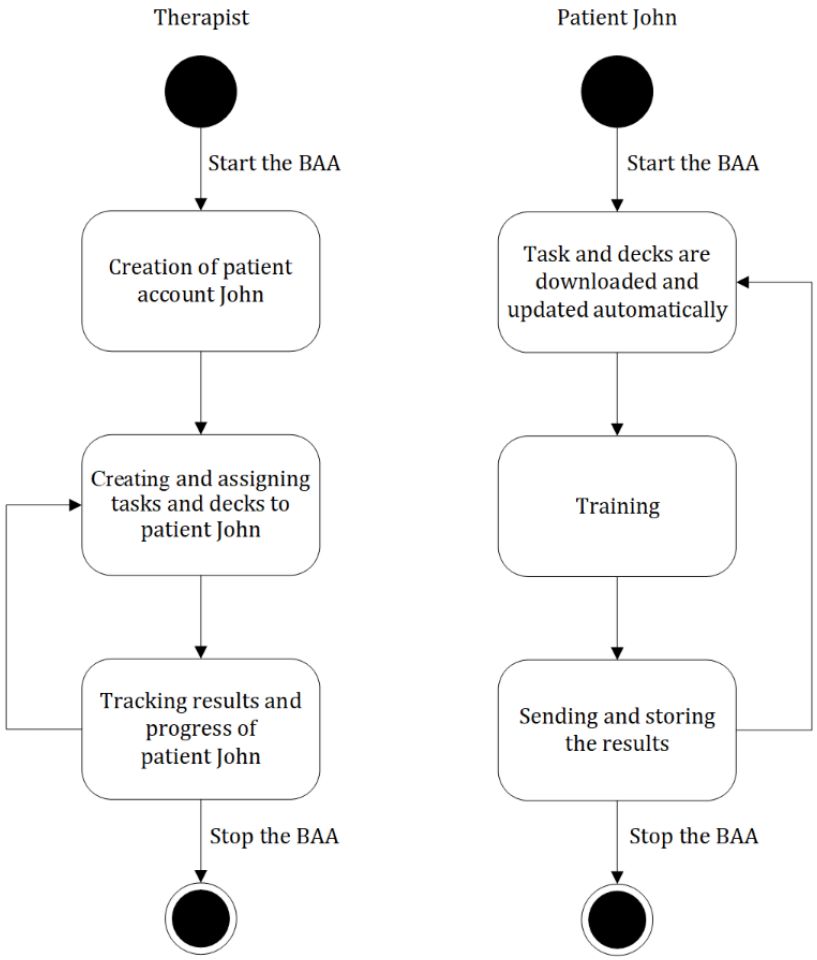


Figure 3. The general workflow of the Bern Aphasia App (BAA).



Textbox 1. Adapted intrinsic motivation inventory questionnaire scale showing the subscales and items within each subscale.

- **Feasibility:**
  - The training sequences were too long.
  - The training was too difficult for me.
- **Interest/Enjoyment:**
  - This activity was fun to do.
  - I thought the training was boring.
  - I thought the training was frustrating.
  - I liked to exercise.
  - I thought the training was arduous.
  - I thought the training was enjoyable.
  - I thought the training was very interesting.
- **Value/Usefulness:**
  - I thought the training helped me to feel better.
  - I would like to continue the training in the future.
- **Pressure/Tension:**
  - I felt pressured during the training.
  - I felt very tense while doing this activity.
  - I was worried about getting the training right.

Procedure, Subject Recruitment, and Demographics

The study was divided into two phases: the development phase followed by evaluation of the system by patients and therapists. The study was carried out in accordance with the current version of the Declaration of Helsinki and approved by the Ethics Committee of the Canton of Bern, Switzerland. The participants (patients and therapists) were recruited via the University Hospital of Bern. Prior to participation, written informed consent was obtained, and procedures related to the study were explained to the participants. The main inclusion criteria for patients were age >18 years, diagnosis of aphasia, and a minimal level of cognitive function to handle a tablet computer and to understand the task and questionnaire. Patients with hemiparesis were not excluded from the study. For therapists, neither inclusion nor exclusion criteria were set. The study was conducted in the general ward (ie, neurorehabilitation) at the University Hospital Bern, and questionnaires were completed during the patient's stay.

Evaluation of the System

To assess patients' and therapists' opinion, attitude, and perception of the system, the well-established usability scale (System Usability Scale) [35] was used. The System Usability Scale is based on 10 questions and has a 5-point scale (1=strongly disagree, 5=strongly agree). To measure the patient's subjective experience, enjoyment, and stress experienced, an adapted selection of 14 items of the intrinsic motivation inventory questionnaire was used (Textbox 1) [36]. The adapted Intrinsic Motivation Inventory questionnaire encompassed the dimensions of Feasibility, Interest/Enjoyment, Value/Usefulness, and Tension/Pressure based on a 7-point scale (0=strongly disagree, 6=strongly agree). For patients' understanding, the questionnaires were explained and filled out with the therapists. The assignment of exercises based on diagnostic tests and the assessment of the system was performed by the same therapist. The intrinsic motivation inventory questionnaire was added later to the study and was therefore not assessed in all patients.

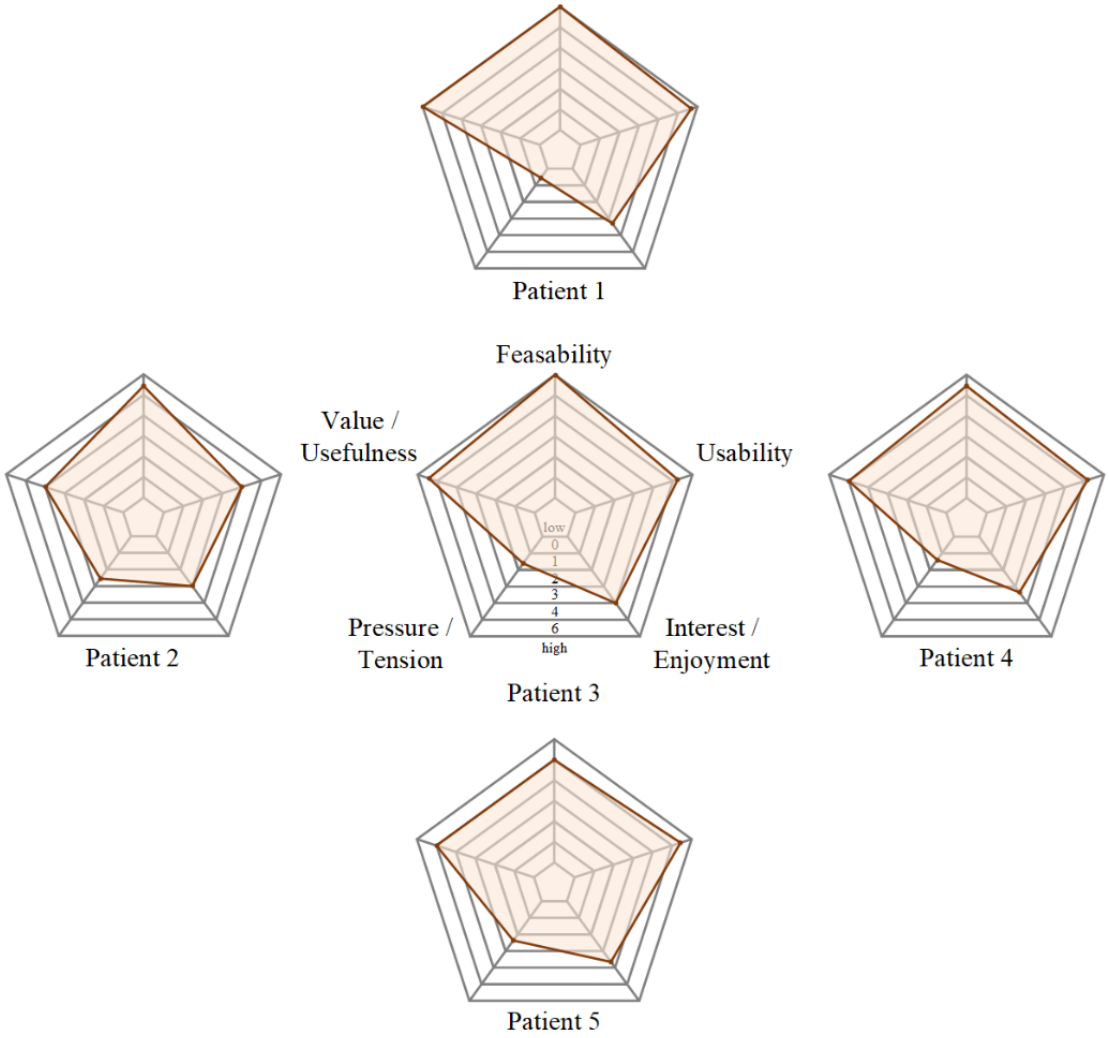
Statistical Analysis

Analysis was conducted using R (R Foundation for Statistical Computing, Vienna, Austria), whereas for the intrinsic motivation inventory, a nonparametric Wilcoxon signed rank test was used, which accounts for a small sample size. For the subscale Interest/Enjoyment, Value/Usefulness, and Feasibility, a score>3 (ie, mean of the score scale) and for Pressure/Tension, a score<3 was regarded as positive and significant. To analyze the System Usability Scale, a nonparametric Wilcoxon signed rank test was used if the score was significantly above 70 (Good) or 85 (Excellent) [37].

Results

Overall, the Bern Aphasia App was used by 166 patients who solved 82,891 cards (64,144 cards solved correctly) and exercised for a mean of 3.96 (SD 21.88) hours. Furthermore, while in use (required internet connection), the Bern Aphasia App ran stably without any technical issues.

Figure 4. Patients' answers to the intrinsic motivation inventory questionnaire (ie, Interest/Enjoyment, Pressure/Tension, Value/Usefulness, and Feasibility) and the System Usability Scale (ie, Usability).



A total of 11 (10 female and one male) experienced speech and language therapists (age: mean 28, SD 7 years), and 15 of all patients using the Bern Aphasia App (12 male and 3 female patients) diagnosed with aphasia (age: mean 53, SD 10 years) participated for an average of 444 days after the incident (SD 427.61 days) in the study. Based on the therapist's diagnosis, patients had moderate to severe aphasia due to stroke or traumatic brain injury.

The usability, scored between 0 and 100, revealed that both patients (mean 90.0, SD 8.9) and therapists (mean 75.5, SD 8.2) scored the Bern Aphasia App above the mean of the score scale. Patients rated the Bern Aphasia App in terms of usability as excellent (Z=–1.90, *P*=.03) and therapists rated the app as good (Z=–1.75, *P*=.04).

Five of the 15 patients also filled out the intrinsic motivation inventory questionnaire (Figure 4). On an average, the Feasibility (mean 5.6, SD 0.42; *Z*=–0.91; *P*=.03), Interest/Enjoyment (mean 3.5, SD 0.40; *Z*=–1.66; *P*=.049), and Value/Usefulness (mean 5.1, SD 0.74; *Z*=–1.90; *P*=.03) of the training were rated significantly higher than the mean of the score scale (range of the score scale =0-6), whereas Pressure/Tension was rated significantly lower, close to the minimum of the score scale (mean 1.7, SD 0.80, *Z*=–1.86, *P*=.03; Figure 2).

Discussion

Principal Results

In this study, we developed a multimodal telerehabilitation system to train the linguistic modalities in patients with aphasia. In line with our hypothesis, the system is simple to use, highly adaptable to the patient's need, and highly accepted. It ran stably and was appreciated by patients as well as therapists.

Patient Interface

The first main finding is that the questionnaire response in terms of usability was rated as excellent, and thus, the developed system is well accepted by patients.

Training with the Bern Aphasia App was rated as enjoyable, which confirms that the personalized content and difficulty of exercises could be adapted by therapists to the needs of patients. The slight increased pressure and tension to train indicate that the exercises were challenging but not frustrating. Overall, the usability and motivation indicate that the design for the patient interface is clear and consistent and thus offers the possibility

of training independently. The intrinsic motivation score was consistent with that in the literature, whereas the usability score was higher [38,39].

Therapist Interface

The second main finding was that the new system allows therapists to adapt and monitor the training of the patient remotely. The usability for the therapist interface was rated lower than that for the patients' interface but still considered good. One reason for the lower usability score might be the need for more functionality in the therapist interface compared to the patient interface and thus the need for more time for familiarization. Another reason for the lower usability score in the therapist interface could be that the patient interface was better designed and thus more adapted to their needs.

Limitations and Outlook

Due to the study design of a feasibility study, it remains unclear whether this result can be generalized to all patients with aphasia and therapists and whether evaluation can be transferred from a clinical to a home setting. An additional limitation of this study is the small sample size of patients and therapists and that the therapist who assigned exercises and conducted the study was the same person.

Furthermore, when using the app, patients must be connected to the internet. In rare cases, the internet connection was too slow, or patients lost internet connection and had trouble reconnecting. Therefore, it is crucial that future telerehabilitation apps can be used offline while exercising and that internet connection is only needed to synchronize the app (ie, loading new exercises and sending statistical reports to the therapist).

In the next step, we will investigate the effect of the Bern Aphasia App in a randomized multicenter clinical trial at patients' homes. Positive results in clinical trials could have a great socioeconomic impact in addition to increased quality of life of the affected patients. With tablet-based apps like the Bern Aphasia App, both patients and therapists can benefit from an intuitive, cost-efficient, touch-based reliable product that fits well with the current trend of moving health treatment from hospital to home. We suggest standard linguistic tests (eg, Boston naming [40], Token test [41], and Amsterdam-Nijmegen everyday language [42]) prior to and after the intervention as a primary outcome and follow-up measurement as well as questionnaires about motivation and quality of life as secondary outcomes to determine the actual improvement caused by the therapy exercises.

The exercises in the hierarchical language structure are usually created by recommendations and heuristics, which is highly time consuming. Therefore, future research should focus on automated exercise creation based on artificial intelligent algorithms to ease the burden of therapists.

Conclusions

Based on the questionnaire scores, the developed system is well accepted and simple to use for patients and therapists. The tablet computer–based app and the hierarchical language exercise structure offer patients with different forms of aphasia a possible chance to train with different doses and intensities independently at home. Overall, the novel system has potential for treatment of patients with aphasia as a supplement to face-to-face therapy.

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Authors' Contributions

SG, SU, N Schmidt, CR, PU, T Nyffeler, LMC, UM, RM, and T Nef designed the study. SG and N Schütz developed the Bern Aphasia App. SG, SP, CW, SU, N Schmidt, and CR created the structure and exercises. SG, SP, CW, and MB validated the Bern Aphasia App, and SG and PW analyzed the data. PW, SG, N Schütz, SU, N Schmidt, CR, SP, CW, MB, PU, T Nyffeler, LMC, UM, RM, and T Nef wrote the manuscript. All authors approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Exercises in the Bern Aphasia App.

[PDF File (Adobe PDF File), 607KB - rehab_v6i1e13163_app1.pdf]

Multimedia Appendix 2

Bern Aphasia App video.

[MP4 File (MP4 Video), 21MB - rehab_v6i1e13163_app2.mp4]

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Abbreviations

NoSQL: Not Only Structured Query Language

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Original Paper

Global Consensus From Clinicians Regarding Low Back Pain Outcome Indicators for Older Adults: Pairwise Wiki Survey Using Crowdsourcing

Arnold YL Wong[1*], PT, MPhil, PhD; Henrik H Lauridsen[2*], DC, MSc, PhD; Dino Samartzis[3*], MSc, DSc; Luciana Macedo[4*], PT, MSc, PhD; Paulo H Ferreira[5], PT, MSc, PhD; Manuela L Ferreira[6], PT, MSc, PhD

[1]Department of Rehabilitation Sciences, Hong Kong Polytechnic University, Hong Kong, China (Hong Kong)

[2]Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark

[3]Rush University Medical Center, Chicago, IL, United States

[4]Population Health Research Institute, Hamilton, ON, Canada

[5]Department of Physiotherapy, University of Sydney, Sydney, Australia

[6]Institute of Bone and Joint Research, University of Sydney, Sydney, Australia

[*]these authors contributed equally

Corresponding Author:
Arnold YL Wong, PT, MPhil, PhD
Department of Rehabilitation Sciences
Hong Kong Polytechnic University
Room ST512, 5/F, Ng Wing Hong Building
11 Yuk Choi Road
Hong Kong,
China (Hong Kong)
Phone: 852 2766 6741
Fax: 852 2330 8656
Email: arnold.wong@polyu.edu.hk

Abstract

Background: Low back pain (LBP) is one of the most debilitating conditions among older adults. Unfortunately, existing LBP outcome questionnaires are not adapted for specific circumstances related to old age, which may make these measures less than ideal for evaluating LBP in older adults.

Objective: To explore the necessity of developing age-specific outcome measures, crowdsourcing was conducted to solicit opinions from clinicians globally.

Methods: Clinicians around the world voted and/or prioritized various LBP outcome indicators for older adults on a pairwise wiki survey website. Seven seed outcome indicators were posted for voting while respondents were encouraged to suggest new indicators for others to vote/prioritize. The website was promoted on the social media of various health care professional organizations. An established algorithm calculated the mean scores of all ideas. A score >50 points means that the idea has >50% probability of beating another randomly presented indicator.

Results: Within 42 days, 128 respondents from 6 continents cast 2466 votes and proposed 14 ideas. Indicators pertinent to improvements of physical functioning and age-related social functioning scored >50 while self-perceived reduction of LBP scored 32.

Conclusions: This is the first crowdsourcing study to address LBP outcome indicators for older adults. The study noted that age-specific outcome indicators should be integrated into future LBP outcome measures for older adults. Future research should solicit opinions from older patients with LBP to develop age-specific back pain outcome measures that suit clinicians and patients alike.

(JMIR Rehabil Assist Technol 2019;6(1):e11127) doi:10.2196/11127

KEYWORDS

crowdsourcing; wiki survey; low back pain; older people; outcome indicators

Introduction

Low back pain (LBP) is a debilitating condition [1,2] that causes functional decline in older adults [3]. The predicted percentage of adults aged 60 years and over will triple by 2050 [4], which may inevitably increase incidences of noncommunicable conditions (including musculoskeletal disorders) [5]. It has been estimated that 30% of seniors aged 65 years and over in the United States live with LBP [6].

Since the sequelae of LBP has larger impacts on physical function and quality of life of older adults than younger individuals [7,8], it is essential to effectively treat the affected older adults. Unfortunately, the efficacy of different LBP interventions in older adults remains uncertain because many clinical trials on LBP interventions exclude older patients [9], and existing LBP outcome measures do not consider age-related physical and psychosocial changes in older adults and may not comprehensively evaluate the impact of LBP on those older adults [3,10]. Although more studies have evaluated the efficacy of various LBP interventions on older adults [11,12], there is no consensus regarding the necessity of developing age-specific outcome measures for older adults with LBP. Some clinicians believe that LBP outcome indicators for older adults should not differ from those for young adults, whereas others argue that older adults need another set of LBP outcome indicators given their comorbidities and altered psychosocial conditions [13,14]. Given the controversy, it is important to broadly solicit clinicians' opinions on the importance of various key LBP outcome indicators to determine the necessity of developing new or adapting existing LBP outcome measures for older adults.

Crowdsourcing is a research approach collating information and solutions from a group of people or experts using the internet in a controlled manner. Specifically, an organization presents a complex problem to a specific group of internet users who will provide solutions to the challenge or problem on a voluntary or employee-paid basis. The organizer then analyzes the findings for further applications [15]. Crowdsourced results are highly applicable to the target audience and end users because they are involved in deriving the solutions [15]. Multiple health disciplines have adopted crowdsourcing to monitor disease outbreaks, analyze gene expression data, interpret medical images, or record drug responses [16-18]. Collectively, crowdsourcing can facilitate knowledge translation and inform biomedical research [19].

Our study aimed to use a crowdsourcing approach to identify global clinicians' opinions regarding the relative importance of various LBP outcome questionnaire indicators for older adults.

Methods

Creation of a Pairwise Wiki Survey

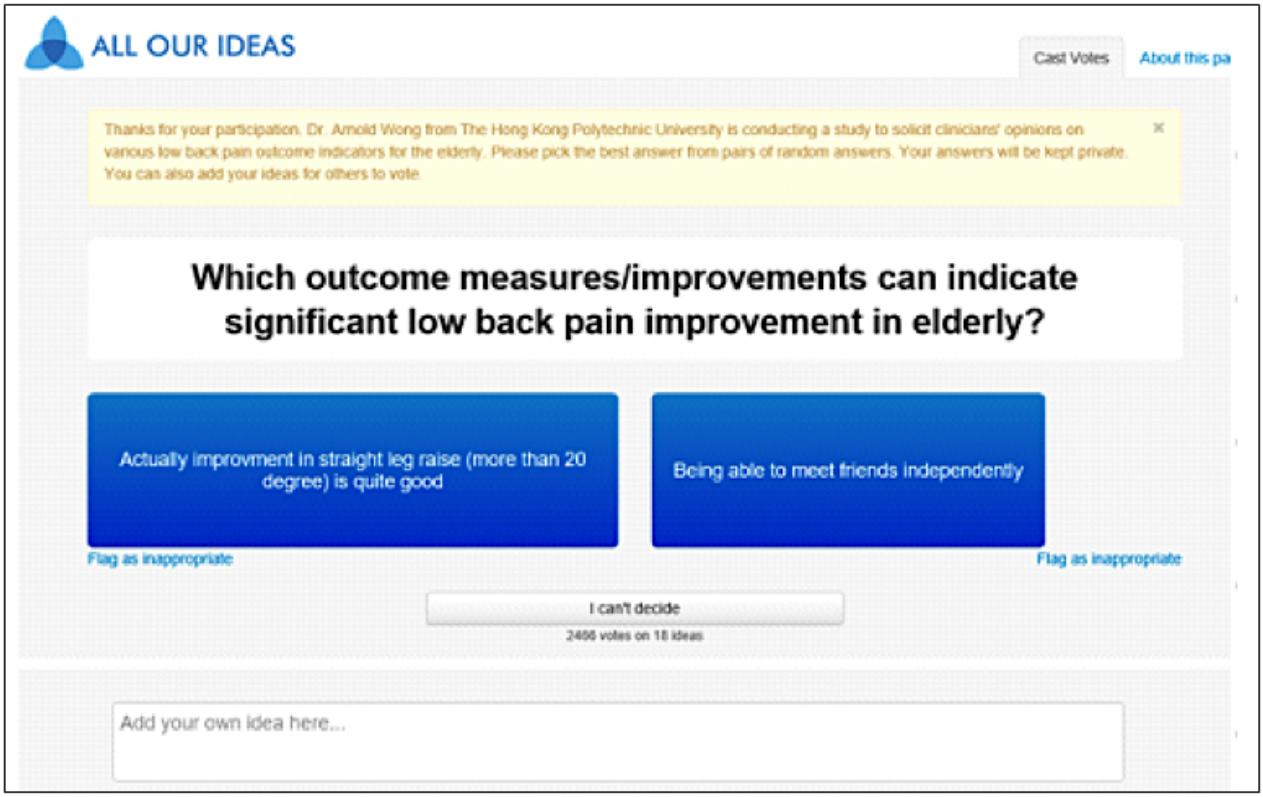
Our study adopted a pairwise wiki survey approach via a crowdsourcing method, which allows prioritization of ideas [20]. Briefly, a pairwise wiki survey involves a single question with multiple potential answers. Respondents contribute to the survey by (1) making pairwise comparisons between two randomly presented answers (ie, voting between two ideas) and/or (2) adding new ideas for future respondents to vote. This approach quantifies responses based on the relative priority of different answers from all respondents and integrates respondents' new ideas for prioritization (vote up or down) using an established algorithm [20]. Unlike traditional surveys, respondents do not confine their responses to the choices offered by the researchers [21]. Therefore, influences of researchers' preexisting knowledge or biases are minimized during data collection [20].

A pairwise wiki survey was created on a free open-source website, All Our Ideas (www.allourideas.org), to let respondents vote on ideas about "Which outcome measures/improvements can indicate significant low back pain improvement in elderly?" [22]. A brief description of the research objective along with the research question (Figure 1) and 7 seed answer items were posted on the website for voting on June 12, 2016. The 7 seed answers were determined by a panel of clinicians with 7 to 22 years of relevant clinical experience and are as follows:

- Able to walk independently with or without walking aids
- Able to do grocery shopping without significant increase in pain
- No longer requires support from caregivers
- Able to take care of grandkids
- Able to meet friends independently
- Doesn't need to see physicians/clinicians because of low back pain
- At least a 2-point decrease in pain on visual analogue scale

The panel comprised a physiotherapist specializing in spinal pain management, a physiotherapist specializing in geriatric rehabilitation, an orthopedic surgeon, and a geriatrician. These seed answers were aligned with the core set of outcome domains (physical functioning, pain intensity, and health-related quality of life) derived from a Delphi study for measuring and reporting nonspecific LBP in clinical trials [23]. To evaluate the relevance of age-related outcome indicators in assessing LBP improvements of older adults, an age-specific outcome indicator (ie, being able to take care of grandkids) was added as one of the 7 seed answers. Only 7 clinically relevant seed answers were included because they were used as catalysts to stimulate constructive contributions from respondents and minimize biases from the panel. Respondents were encouraged to contribute their new ideas about potential LBP outcome indicators for older adults on the website (Figure 1). The primary investigator determined the appropriateness of the ideas submitted by respondents. Respondent-contributed answers were deactivated for voting if they were duplicates of existing answers/ideas, irrelevant to the question of interest (ie, LBP outcome indicators for older adults), or comments/questions about the appropriateness of the study design, website, answers, or research objectives. This study was approved by an ethics board committee and conducted according to the Declaration of Helsinki.

Figure 1. Research objective and research question.



To advertise the survey to targeted clinicians (ie, physiotherapists, occupational therapists, chiropractors, osteopaths, physicians, nurses, physicians, gerontologists, and general practitioners), 3 strategies were adopted. First, standardized messages with the survey hyperlink were posted on the Facebook accounts of multiple health care professional organizations (Multimedia Appendix 1) identified using various key words: chiropractic, chiropractors, general practice, general practitioners, geriatric, geriatricians, gerontological, gerontology, manual therapists, manual therapy, medical, medicine, nurses, nursing, orthopaedics, orthopedics, physical therapists, physical therapy, physiotherapists, physiotherapy, osteopathic, osteopathy, occupational therapists, or occupational therapy. Briefly, the Facebook message explained that a group of researchers was conducting a survey to solicit clinicians' opinions regarding various LBP outcome indicators for older adults with LBP and that respondents could contribute to the online survey by selecting their preferred outcome indicators or suggesting new outcome indicators (Textbox 1). Second, similar key words were used to identify various target groups (Multimedia Appendix 1) and a standardized Tweet message alongside the hashtag of these groups was used to advertise the survey (Textbox 1). A second round of the advertisement was sent to the same social media sites on July 3, 2016. Third, the primary investigator sent personal messages through Facebook messenger to invite 15 lead clinicians and clinician-scientists (orthopedic specialists, physiotherapists, chiropractors, and nurses) in Australia, Canada, Hong Kong, Denmark, Norway, and the United States to cast their votes and share the survey hyperlink on their personal Facebook pages or the Facebook pages of their respective local professional organizations. Only a small number of personal messages were sent because this pilot study mainly aimed to use social media to promote the survey.

Textbox 1. Standardized Facebook and Twitter messages that were posted or linked to various physiotherapy, chiropractic, osteopathic, occupational therapy, medical, and gerontology professional groups.

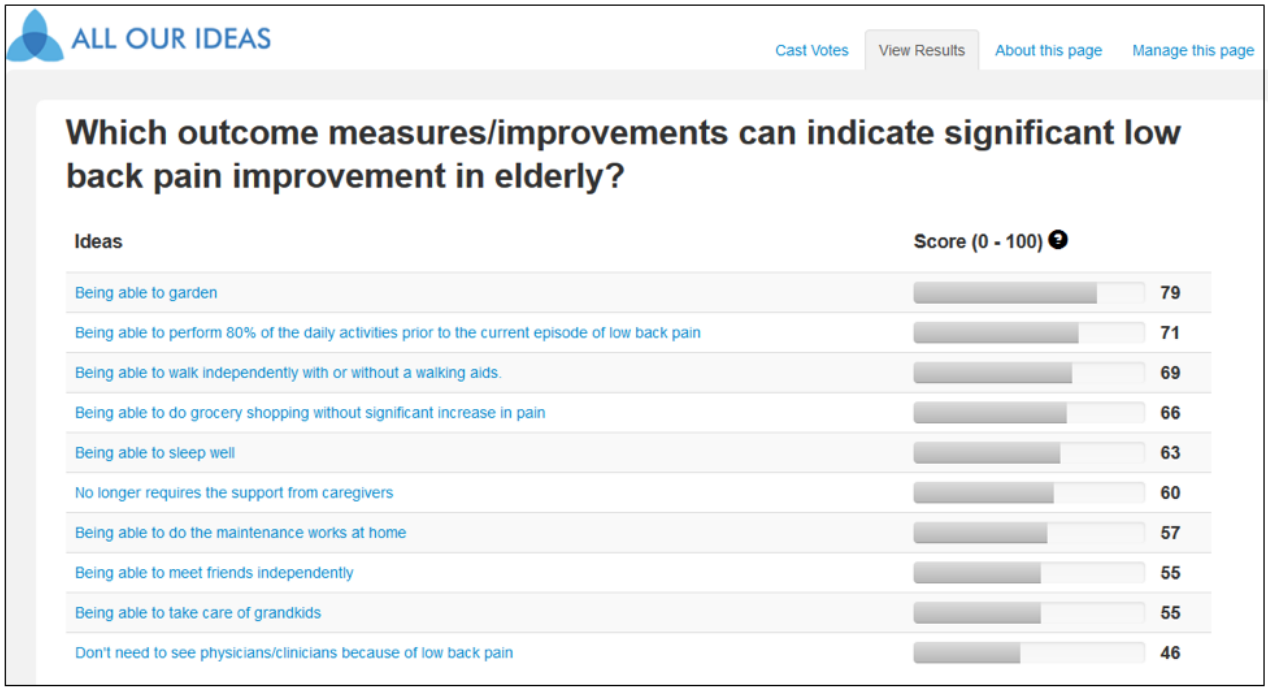
Facebook

- A group of researchers is conducting a crowdsourcing research project to understand clinicians' opinions regarding the key outcome indicators that represent low back pain improvements in older adults aged 65 years and over. The results can help develop tailored outcome measures for older adults. If you are willing to help, please click on the link and cast your votes. Your participation is voluntary. When you click on the link, you will see two potential answers that indicate significant improvements of low back pain in older adults. You are requested to pick the best answer from the two options. Once you submit your answer, another two random outcome options will be shown for comparison. The procedure will be repeated until you quit. Your answers will be kept strictly confidential. You can also add new ideas of outcome indicators for others to vote. Please feel free to share the link with your colleagues. Thanks in advance for your help. allourideas.org/olderpeoplewithlowbackpain

Twitter

- Please cast your vote to help develop new low back pain outcome measures for the elderly allourideas.org/olderpeoplewithlowbackpain

Figure 2. Resulting scores of all the answer items displayed on the website.



Data Analysis

The website uses a published algorithm to estimate the chance of a given answer item in beating another randomly presented item for a randomly chosen respondent [20]. Briefly, a binomial model was chosen to estimate the probability of a win for each answer item. Assuming a uniform prior probability for a binomial variable, the resulting posterior probability to a win follows a beta distribution [24]. By multiplying the expected value of that beta distribution by 100, the resulting estimated score (ranging from 0 to 100) would represent the winning percentage of a given item. If a given item scores 0, it is expected to lose for all pairwise comparisons. Conversely, if an item scores 100, it is anticipated to always win. The resulting scores of all the answer items are displayed on the website (Figure 2).

Additionally, raw data (ie, the number of responses of each respondent, actual responses of each respondent, time spent on each comparison, number of new ideas from each participant, and response time of each respondent) were downloaded from the website for descriptive analysis using SPSS Statistics version 20.0 (IBM Corp). The binomial confidence interval of the mean score of each answer was also calculated [25].

Results

Number of Respondents and Responses

Over 42 days, 128 respondents contributed 2466 responses. During the same period, 179 visitors visited the website without casting any vote (a response rate of 41.7%). Respondents came from 60 cities in 22 countries on 6 continents (Table 1). The United States, China (Hong Kong), Australia, Canada, and Great Britain were the top 5 countries with the highest number of responses (range 239-541) and respondents (range 10-31).

The median number of responses per respondent was 17 (range 1-142) (Figure 3). The median time spent on each comparison by the respondent was 4.7 seconds (range 0.4-314.9 seconds). Fourteen new ideas were proposed by the respondents (Table 2). Six respondents suggested 1 new idea each, 1 proposed 2, and 1 proposed 6. Nine out of 14 new ideas were proposed within the first 3 days of the survey, but the last active idea (If trunk flexion is indicated as a significant factor increasing low back pain in the first assessment, then straight leg raise would be one of the indicators) was proposed on the day 35. Three contributed ideas were not activated for voting because they were deemed to be inappropriate or duplicate. Given the respondent-contributed ideas, the number of active ideas in the survey increased from 7 to 18. Sixteen activated ideas were self-reported outcome indicators and 2 were related to physical examinations. The median number of times each activated idea was presented to respondents for comparison was 585 (range 55-686).

Prioritization of Answers

Nine out of 18 activated answer items scored more than 50, implying that these answers had a more than 50% chance of beating other answers in pairwise comparisons. The top 3 high-scoring ideas (able to perform 80% of the daily activities prior to the current episode of LBP, able to walk independently with or without walking aids, and able to do grocery shopping without significant increase in pain) had mean scores of 72, 69, and 66, respectively. Two of the top 5 high-scoring ideas were suggested by respondents (Figure 4). As hypothesized, outcome indicators related to pain and physical impairments yield only low scores. Specifically, the items “at least a 2-point decrease in visual analogue scale” and “actually improvement in straight leg raise (more than 20 degrees) is quite good” scored only 32 and 18, respectively.

Table 1. Number of responses and respondents by country.

Country	Responses (N)	Respondents (N)
United States	541	31
China and Hong Kong	433	21
Australia	420	19
Canada	320	15
Great Britain	239	10
Japan	98	4
Singapore	51	2
Netherlands	50	3
Rwanda	44	3
New Zealand	43	3
Brazil	37	2
Norway	34	2
Romania	31	2
Greece	28	2
Denmark	26	2
Colombia	25	1
Belgium	17	1
India	17	2
Switzerland	8	1
Trinidad and Tobago	3	1
Portugal	1	1

Figure 3. Distribution of responses per participant.

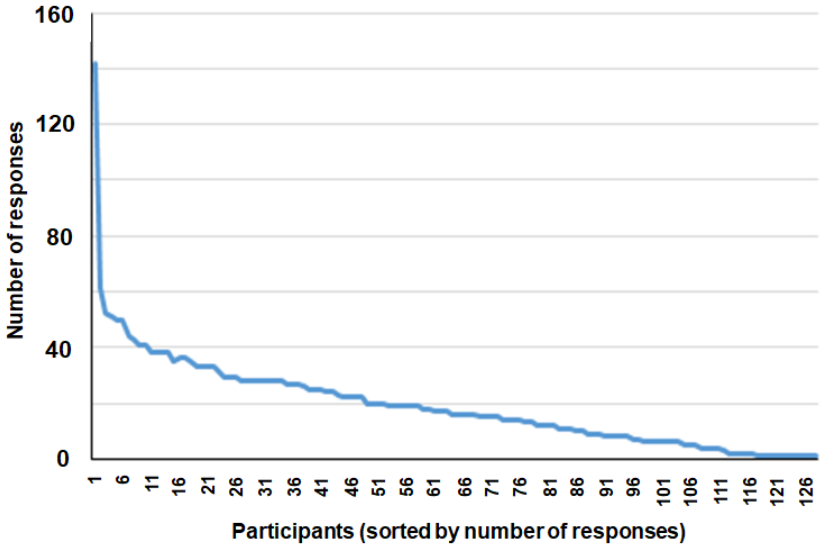
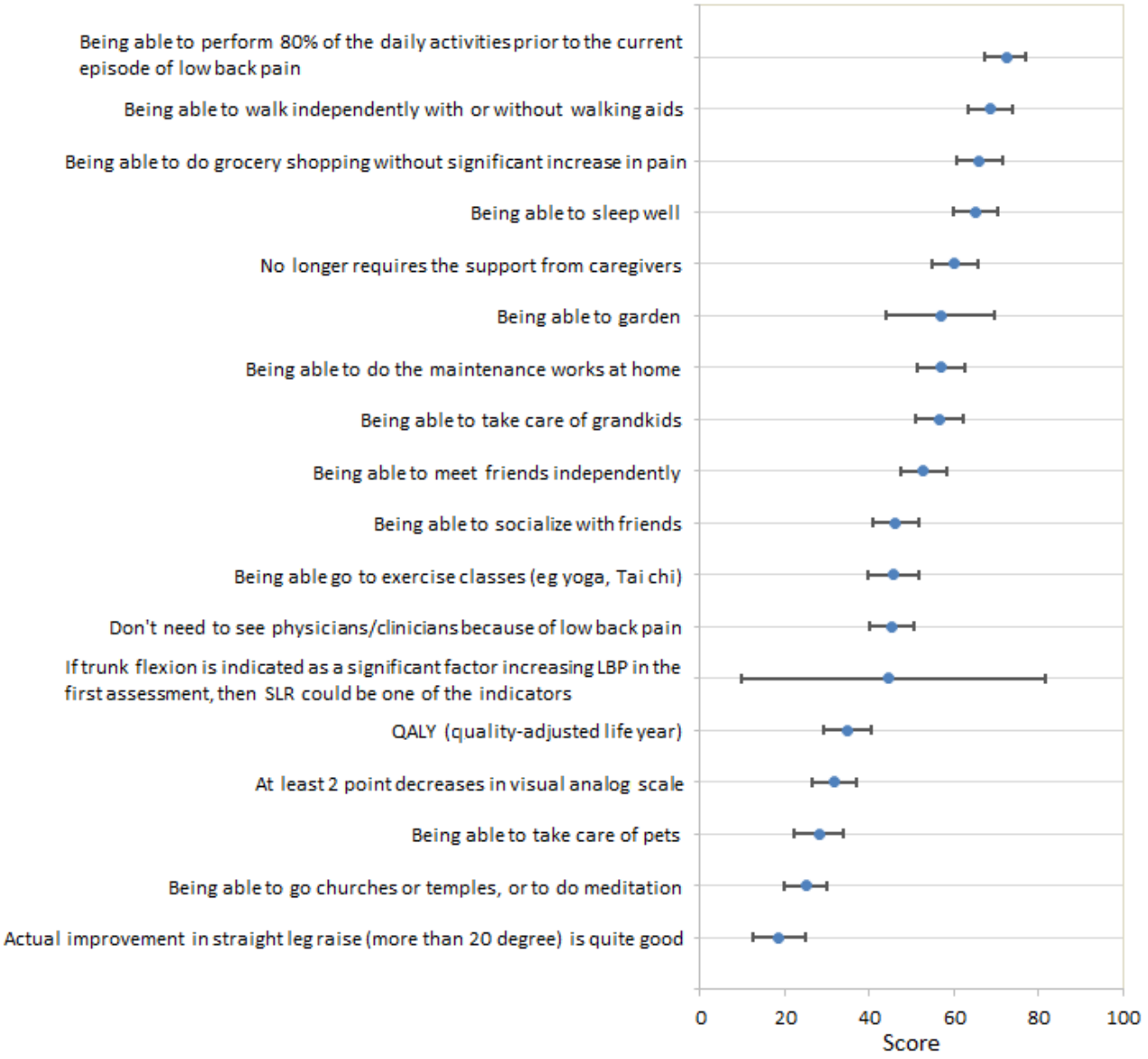


Table 2. Answer items created by the researchers and respondents/users.

Answer or idea items	Source	Status	Score
Able to walk independently with or without walking aids	Seed	Activated	69
Able to do grocery shopping without significant increase in pain	Seed	Activated	66
No longer requires support from caregivers	Seed	Activated	60
Able to take care of grandkids	Seed	Activated	57
Able to meet friends independently	Seed	Activated	53
Doesn't need to see physicians/clinicians because of low back pain	Seed	Activated	44
At least a 2-point decrease in pain on visual analogue scale	Seed	Activated	32
Able to perform 80% of the daily activities prior to the current episode of low back pain	Respondent	Activated	72
Able to sleep well	Respondent	Activated	65
Able to garden	Respondent	Activated	57
Able to do maintenance work at home	Respondent	Activated	57
Able to socialize with friends	Respondent	Activated	46
Able to go to exercise classes (eg, yoga, tai chi)	Respondent	Activated	46
If trunk flexion is indicated as a significant factor increasing low back pain in the first assessment, then straight leg raise would be one of the indicators	Respondent	Activated	44
Quality-adjusted life year	Respondent	Activated	35
Able to take care of pets	Respondent	Activated	28
Able to go to church or temple or do meditation	Respondent	Activated	25
Actually improvement in straight leg raise (more than 20 degrees) is quite good	Respondent	Activated	18
I get the question but the semantics aren't clear. Why should straight leg raise be an outcome measure for low back pain without mention of radiculopathy or sciatica?	Respondent	Deactivated	N/A[a]
Quality-adjusted life year	Respondent	Deactivated	N/A
The survey is overly repetitive. It will likely reduce your response rate. I have addressed the same issues more than 10 times	Respondent	Deactivated	N/A

[a]N/A: not applicable.

Figure 4. Rank scores of various potential low back pain outcome indicators for geriatric patients as estimated by the established algorithm on the website. LBP: low back pain; SLR: straight leg raise.



Twitter Versus Facebook

Of 128 respondents referred to our wiki survey website, 94 (73.4%) were from Facebook and 34 (26.6%) were from Twitter. Most of the respondents (78/128, 60.7%) used a cell phone or computer tablet to participate in the survey; the rest (50/128, 39.3%) completed their surveys on their computers.

Discussion

Principal Findings

This is the first online crowdsourcing research to collect global clinician opinions regarding the relative importance of different LBP outcome indicators for older adults. As hypothesized, the majority of the respondents (clinicians) deemed that functional improvements were more important than improvements of pain or physical examinations. While some self-reported LBP outcome indicators identified in our study (eg, able to perform 80% of the daily activities prior to the current episode of LBP) might be true for other age groups, our respondents generally agreed that the age-specific functional outcome indicator (eg, able to take care of grandkids) was an important self-reported outcome indicator for older adults with LBP. These findings highlight that age-specific LBP outcome indicators, which have been ignored in existing self-reported LBP outcome measures, should be considered in the future development of new outcome measures for older adults with LBP.

Interestingly, 5 out of 7 seed answers derived from a panel of health care experts were deemed to be important by respondents. In fact, seed answers contribute to 56% of the answers scoring more than 50 points (Table 2). These results indicate that many clinicians around the world agreed on using certain seed answers to be the key LBP outcome indicators for older patients. Since several respondent-contributed outcome indicators were also rated as important, our study substantiates the feasibility and value of using a pairwise wiki survey to identify LBP outcome indicators for older people with LBP.

Participant responses were highly related to the advertising strategy. Since our study was mainly promoted on Facebook

and Twitter accounts of various health care professional associations in the United States, Hong Kong, Australia, Canada, and Great Britain, greater response rates were attained from these regions. Interestingly, although our advertisements were posted on Facebook and Twitter accounts, 73.4% of the respondents were referred from Facebook, which indicates that Facebook was a more effective social media for recruiting clinician respondents in similar research than Twitter.

It is noteworthy that the confidence interval of one LBP outcome indicator (If trunk flexion is indicated as a significant factor increasing LBP in the first assessment, then straight leg raising test could be one of the indicators) was relatively large. This was attributed to the fact that this idea was received 7 days before the completion of data collection. Since this idea was only presented 55 times to respondents for comparison, its confidence interval was wide. Although this might affect the relative ranking of this outcome indicator, it would not affect the conclusion on the top priority outcome indicators because the most important outcome indicators should have been suggested at the early stage of the survey.

Limitations

As with any clinical-based or survey type of research, inherent study limitations exist. Since the study did not involve older patients with LBP, our findings are limited to clinicians' perspectives. Future research is warranted to solicit opinions from the target patient population during the process of developing a new LBP outcome measure for older adults.

Like many internet-based surveys, the study was limited by sample representativeness [26] because it did not collect participants' detailed demographic information (eg, age, gender, years of education and clinical experience, health care disciplines). However, our respondents were highly likely to be clinicians because the survey was (1) not searchable on common search engines (eg, Google) unless the exact survey Web address was used, (2) only openly advertised on the Facebook and Twitter accounts of relevant professional bodies, and (3) promoted by personal emails sent to clinicians and clinician-scientists. This notion was further corroborated by the fact that the respondent-contributed ideas and voting results demonstrated high face validity to the research topic from the clinicians' perspective.

The response rate of the study was 41.7%. In comparison, the response rate for Delphi studies that evaluated core outcome sets for LBP were between 45% and 52% [23]. This slight discrepancy might be attributed to the recruitment methods (open advertisements on social media vs personal invitations). Previous studies have found that response rates of internet surveys for clinicians are usually lower than traditional paper surveys [27-29]. While multiple reasons may explain the low response rate among clinicians (eg, lack of time, perceived low priority of surveys, and concerns about confidentiality) [29], response rates can be improved by sending multiple reminders or personalized letters [29,30]. Future studies should adopt multiple strategies (eg, incentives [31], personalized invitations [32], multiple reminders [30] and advertisements [33], or endorsements from professional associations [34]) to improve response rates and total number of respondents.

Since traditional surveys require researchers to determine all the details (eg, questions, orders of questions, and multiple plausible answers) prior to data collection, this top-down approach may introduce investigator biases and limit the knowledge that can be learned from respondents [20]. Conversely, our pairwise wiki survey used an ongoing collaborative approach to encourage respondents to create knowledge that was not anticipated by the researchers. Similar to a focus group that allows participants to react to others' responses [35], user-contributed ideas collected from the wiki survey were continuously evaluated by future respondents. The success of this bottom-up interactive approach is reflected from our findings that respondents from all continents (except Antarctica) contributed 2 folds of new LBP outcome indicators within a short period of time and some of the proposed indicators were ranked as highly relevant LBP outcome indicators for older adults.

Our survey collected information based on the respondents' eagerness to participate. While some respondents cast a single vote, others contributed heavily to the voting and/or new idea suggestions (Figure 3) [36]. Unlike traditional surveys that prohibit high contributors from answering extra questions and discard incomplete questionnaires from data analysis, a pairwise wiki survey collects as much or as little information as the respondent is willing to offer. Since wiki surveys value contributions from all respondents equally regardless of their time or effort spent on answering, wiki surveys may solicit more useful information from respondents than traditional surveys [20].

Conclusions

Our study reveals a novel method for soliciting opinions from clinicians around the globe during the process of developing a new clinical outcome measure. Traditionally, the development of a new self-administered clinical outcome questionnaire involves a process of literature review, conduction of multiple focus groups or meetings among content experts (eg, clinicians, patients, scholars) to determine relevant items and/or domains in a questionnaire, and further modifications of items after pilot testing on target populations [37]. A pairwise wiki survey can be implemented as a low-cost adjunct survey tool to solicit ideas from a large population of clinicians or patients globally following the initial draft of items pooled from a panel of content experts. The survey results not only can broaden the perspectives to inform further panel discussions but allow rapid preliminary feedback from target users. However, further studies are warranted to evaluate the effectiveness of such an approach in improving the psychometric properties of the resulting questionnaires (eg, whether the inclusion of crowdsourcing-identified items would improve the internal consistency or responsiveness of questionnaires).

While our approach has revealed the relative importance of different LBP outcome indicators perceived by clinicians, the respondents' rationales for choosing or prioritizing their answers remains unclear. Future qualitative research (eg, interviews or focus groups) should investigate clinician reasons for prioritizing various LBP outcome indicators and solicit information from older adults regarding their perceived important LBP outcome

indicators. Collectively, our findings can be incorporated with patient and expert opinions obtained from qualitative and/or Delphi research to develop a new outcome measure for geriatric patients with LBP. This study has laid the foundation for developing better outcome measures for older patients with LBP. Such knowledge has the potential to ultimately contribute to better clinical management or treatment algorithms for older adults with LBP.

Overall, this is the first global crowdsourcing study to address LBP outcome questionnaire indicators for older adults. The study found that clinicians deemed functional improvements more important LBP outcome indicators for older adults with LBP than pain reduction or improvements of physical examinations. Clinicians generally perceive age-specific social functioning as an important outcome assessment domain for older adults with LBP. While further studies are warranted to compare our findings with the opinions obtained from older adults with LBP and/or leading spine experts, our study has laid the foundation for developing better outcome measures for older adults with LBP. In addition, this proof-of-concept study has also provided a framework to illustrate that global crowdsourcing approaches in spine research are viable and achievable, hopefully providing impetus for other investigators to adopt such an approach for future spine research.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

List of professional organizations on Facebook and Twitter selected to advertise the project.

[PDF File (Adobe PDF File), 34KB - rehab_v6i1e11127_app1.pdf]

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Abbreviations

LBP: low back pain

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