JMIR Rehabilitation and Assistive Technologies

Development and Evaluation of Rehabilitation, Physiotherapy and Assistive Technologies, Robotics, Prosthetics and Implants, Mobility and Communication Tools, Home Automation and Telerehabilitation
Volume 7 (2020), Issue 2 ISSN 2369-2529 Editor in Chief: Sarah Munce, MS, PhD

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Original Paper

Virtual Reality in Pain Rehabilitation for Youth With Chronic Pain: Pilot Feasibility Study

Anya Griffin[1], PhD; Luke Wilson[2], BSc; Amanda B Feinstein[1], PhD; Adeline Bortz[3], MSc; Marissa S Heirich[1], BSc; Rachel Gilkerson[4], PT, DPT; Jenny FM Wagner[4], MS, OTR/L; Maria Menendez[4], MD; Thomas J Caruso[1], MD, MEd; Samuel Rodriguez[1], MD; Srinivas Naidu[1], MD; Brenda Golianu[1], MD; Laura E Simons[1], PhD

[1]Department of Anesthesiology, Perioperative, and Pain Medicine, Stanford University School of Medicine, Stanford, CA, United States

[2]Mighty Immersion, Inc., New York, NY, United States

[3]PGSP-Stanford University Psy.D. Consortium, Stanford, CA, United States

[4]Lucile Packard Children's Hospital, Stanford, CA, United States

Corresponding Author:
Anya Griffin, PhD
Department of Anesthesiology, Perioperative, and Pain Medicine
Stanford University School of Medicine
300 N Pasteur Dr
Stanford, CA, 94305
United States
Phone: 1 650 736 3656
Email: anyag@stanford.edu

Abstract

Background: In the field of pain, virtual reality (VR) technology has been increasingly common in the context of procedural pain management. As an interactive technology tool, VR has the potential to be extended beyond acute pain management to chronic pain rehabilitation with a focus on increasing engagement with painful or avoided movements.

Objective: We outline the development and initial implementation of a VR program in pain rehabilitation intervention to enhance function in youth with chronic pain.

Methods: We present the development, acceptability, feasibility, and utility of an innovative VR program (Fruity Feet) for pediatric pain rehabilitation to facilitate increased upper and lower extremity engagement. The development team was an interdisciplinary group of pediatric experts, including physical therapists, occupational therapists, pain psychologists, anesthesiologists, pain researchers, and a VR software developer. We used a 4-phase iterative development process that engaged clinicians, parents, and patients via interviews and standardized questionnaires.

Results: This study included 17 pediatric patients (13 female, 4 male) enrolled in an intensive interdisciplinary pain treatment (IIPT) program, with mean age of 13.24 (range 7-17) years, completing a total of 63 VR sessions. Overall reports of presence were high (mean 28.98; max 40; SD 4.02), suggestive of a high level of immersion. Among those with multisession data (n=8), reports of pain (P<.001), fear (P=.003), avoidance (P=.004), and functional limitations (P=.01) significantly decreased. Qualitative analysis revealed (1) a positive experience with VR (eg, enjoyed VR, would like to utilize the VR program again, felt VR was a helpful tool); (2) feeling distracted from pain while engaged in VR; (3) greater perceived mobility; and (4) fewer clinician-observed pain behaviors during VR. Movement data support the targeted impact of the Fruity Feet compared to other available VR programs.

Conclusions: The iterative development process yielded a highly engaging and feasible VR program based on qualitative feedback, questionnaires, and movement data. We discuss next steps for the refinement, implementation, and assessment of impact of VR on chronic pain rehabilitation. VR holds great promise as a tool to facilitate therapeutic gains in chronic pain rehabilitation in a manner that is highly reinforcing and fun.

(JMIR Rehabil Assist Technol 2020;7(2):e22620) doi:10.2196/22620

KEYWORDS

digital health care; virtual reality; immersive technology; chronic pain management; adolescents

Introduction

Background

Virtual reality (VR) is a newly emerging and promising intervention tool for chronic pain treatment to both distract individuals from their pain and facilitate otherwise painful or feared movements [1,2]. For adults exhibiting a variety of chronic pain conditions—including spine, shoulder, abdominal, hip, musculoskeletal, and neuropathic pain—research has demonstrated the efficacy of VR tools, finding significant reductions in subjective reports of pain both during and after VR sessions [3-7]. VR treatments have also been shown to significantly reduce pain, prompt physiological reactions of relaxation, improve physical functioning, and improve social role functioning for adults with chronic low back pain [8,9]. When compared to telephone and internet-based interventions, VR programs are one of the most effective electronic health care modalities for delivering interventions and potentially reducing pain interference within the context of chronic pain [10]. However, most applications of VR for chronic pain remain focused on distraction and pain alleviation, rather than on functional gains through motor and behavioral physical engagement [11].

Moreover, few studies have applied VR tools for pediatric chronic pain [12]. In a recent review of VR studies in pediatric pain (PubMed 2000-2017), there were only 4 that focused on VR for chronic pain, compared to 94 that focused on VR for coping with medical procedures and acute pain [13]. Each of these 4 preliminary studies found VR treatment to be feasible, safe, and potentially efficacious in children with chronic pain conditions. Two pilot studies conducted by Won and colleagues [14] demonstrated a VR program to be feasible and safe for children with complex regional pain syndrome (CRPS). The pilot studies noted qualitative observations of increased relaxation, minimal complaints of pain, and program engagement during the VR sessions. Another pilot study conducted by Shiri and colleagues [15] implemented a 10-session VR and biofeedback regimen over 3 months in youth with chronic headaches. Patients reported significant decreases in headache severity and improved functional outcomes. Despite sparse research on VR interventions for pediatric chronic pain, new work examining specific design factors of VR programs that can enhance youth experience within medical settings sets the context for the development of creative and well-tolerated programming [16].

Beyond pain treatment, VR programs that target physical rehabilitation in children are emerging. Meyns and colleagues [17] developed a VR program, ICT4Rehab, which uses a Wii Balance Board (Nintendo) as a treatment for children with cerebral palsy following lower extremity surgery in inpatient rehabilitation. The study found that patients in both ICT4Rehab and the control group had improvements in sitting balance, with greater improvements noted in the ICT4Rehab group. In another VR system, patients undergoing ankle rehabilitation respond to various VR simulations through interaction with a “Rutgers Ankle” system applying mechanical force to the ankle [18]. The VR simulations seek to improve range of motion, motor coordination, and broad lower extremity function [18]. Taken together, there are considerable opportunities to develop and implement VR programs that target physical rehabilitation in the treatment of pediatric chronic pain.

Objectives

The goal of this project was to develop a VR intervention to enhance mobility in the presence of chronic pain. Fruity Feet is a VR program created with input from a multidisciplinary team of pediatric pain rehabilitation clinicians, pediatric pain researchers, and VR technology developers. Fruity Feet responds to the growing need for VR applications that specifically target pediatric chronic pain populations who experience limited mobility due to fear and activity avoidance. In this paper, we first describe the development, acceptability, feasibility, and utility of Fruity Feet using a 4-phase iterative development process to facilitate increased upper and lower extremity engagement. We then discuss next steps for the refinement, implementation, and impact assessment of Fruity Feet.

Methods

Participants and Setting

Youth admitted to an intensive interdisciplinary pain treatment (IIPT) program were specifically targeted as these individuals typically present with fear of movement and significant physical limitations due to pain. IIPT teams include physical therapists (PTs), occupational therapists (OTs), pain psychologists, pain medicine physicians, and pain medicine nurse practitioners [19,20]. Treatment includes aquatic therapy, individual and group PT/OT/psychology therapy, family therapy, caregiver support, and weekly team care conferences. Many patients admitted to IIPT programs rely on assistive devices to ambulate (ie, walkers, wheelchairs), have limited mobility, and struggle with deconditioning. The goal of the Fruity Feet program was to provide an enhanced, immersive IIPT experience that increased engagement with physical exercises and improved functional outcomes within a difficult-to-treat population.

Eligibility criteria for enrollment in the VR in pain rehabilitation pilot feasibility study included the following: (1) English speaking, (2) aged 7-21 with (3) a diagnosis of chronic pain and the need for physical rehabilitation, and (4) on stable medication/therapy for 2 weeks prior to the initial session. Patients were deemed ineligible if they had (1) diagnoses of neurological conditions (seizures, cerebral palsy, developmental delay) or (2) severe psychiatric symptoms (severe depression/anxiety).

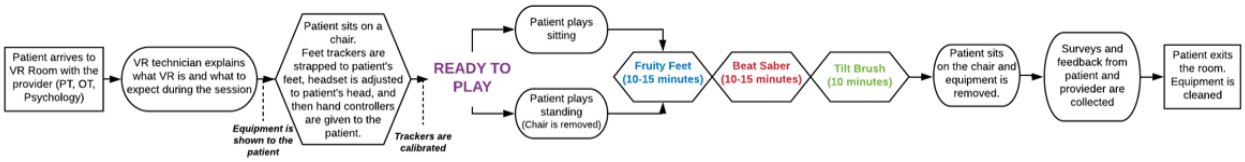
Development and Prototyping

The IIPT pediatric pain rehabilitation team worked collaboratively with the CHARIOT technology software design team and Mighty Immersion, Inc. to develop Fruity Feet, a unique VR experience for youth undergoing chronic pain treatment and rehabilitation. This team incorporated an iterative process to develop this VR intervention, building upon patient and clinician feedback to improve acceptability and utility. The development of Fruity Feet consisted of 4 phases: Needs Assessment, Prototyping, Iteration and Refinement, and Feasibility and Acceptability. The Needs Assessment phase

involved gathering information from the IIPT team to determine the scope of clinical needs and establish parameters for the VR intervention, hardware, and space. The Prototyping phase involved designing the initial functionality for lower extremity movement. The Iteration and Refinement phase involved a cyclical process of (1) testing the program with clinicians and test case patients, (2) gathering feedback, and (3) adjusting the software design, space, and hardware needs accordingly.

The Feasibility and Acceptability phase ran in parallel to the Iteration and Refinement phase. Following Institutional Review Board approval, eligible patients that were enrolled in the IIPT at Stanford Children's Health were invited to participate in feasibility testing. After consent from parent and assent from child were obtained, VR sessions were incorporated into the patient's IIPT schedule. VR sessions occurred once weekly for approximately 30 minutes. Figure 1 describes a typical VR session. Parents were not present during VR sessions, but were given the opportunity to observe the session either live behind a one-way mirror or via recorded video footage after the session. After the session, the child, parent, and clinician present completed measures or interview questions. A technician was also present to manage the session flow and administer the measures and questions at the end. The primary developer (LW) also attended multiple sessions to inform the iterative development of Fruity Feet.

Figure 1. VR session flowchart. Patient arrives to session with clinician who orients patient to the use of VR equipment safely. While seated, foot and hand trackers are placed, and VR headset adjusted on patient. Clinician has patient begin while seated initially to orient to VR system and then eventually standing, as deemed appropriate. Three VR programs were utilized for approximately 10 minutes each (Fruity Feet, Beat Saber, and Tilt Brush). After the VR session, patient once again is seated to remove trackers and headset. Patient completes survey and both patient and clinician give feedback after each session. Equipment is thoroughly cleaned and sanitized following each session. VR: virtual reality.



Outcome Measures

After each session, patients were asked to complete the following questionnaires related to their experience while in VR.

Presence Questionnaire

Patients were asked to provide a rating, ranging from 0 (not at all) to 4 (very strongly) to 10 questions, assessing the patient's perception of how real the virtual world seemed and whether they felt their virtual body (avatar) was an extension of their own. Higher scores are suggestive of greater presence in the virtual environment [21].

Child Daily Questionnaire

The Child Daily Questionnaire was developed for repeated administration in the context of pediatric pain clinical trials [22]. The Child Daily Questionnaire consists of 13 items assessing pain and functioning in the last 24 hours. Eleven of the daily items were pain related: worry/fear (2 items), avoidance (2 items), functional limitations (3 items), activity engagement/acceptance (2 items), and reactivity (2 items). These items and domains are derived from validated full-version measures. These 11 items are rated on a 100-point visual analog scale ranging from strongly disagree to strongly agree. Item 12 assesses current pain (ie, pain felt in the last 24 hours) on a numeric rating scale from 0 (no pain) to 10 (worst possible pain). Item 13 includes an open text box for the patient to describe anything exciting or stressful from the past 24 hours.

After each VR session, patients, parents, and clinicians were also asked to provide feedback in an open-ended interview format (Textbox 1).

Statistical Analysis

Descriptive statistics for all questionnaires were run and repeated measures mixed models were run for the multisession Child Daily Questionnaire data using SPSS 25 (IBM). For interview data, NVivo qualitative statistical software was utilized to analyze participant (patient, clinician, parent) responses provided following VR sessions. Interview responses were imported into NVivo and case nodes were set up for each participant. The material was explored and emerging themes were coded. Text was searched and word frequency queries were placed into those coded themes. Themes from interview feedback responses with the most frequency were summarized into visual charts for patients and clinicians.

Textbox 1. Post-VR interview questions. VR: virtual reality.

Patient questions

- What was it like to be in VR?
- How did it feel to be in VR?
- Tell me about any of the feelings you are experiencing now after being in VR.
- Tell me about what happened when you were in VR. Tell me about the parts that you expected? Tell me about the parts that you did NOT expect?
- Now that you have tried VR, how do you think VR can help other kids?
- How do you think we could improve the VR experience for other kids?
- If you could change anything about this, how would you make it better?
- Questions about the process of learning to use the avatar: eg, "How did you learn to use the VR character?" "Which bits were easy to learn?" "Which bits were hard to learn?"
- Feelings of ownership and control of the avatar: eg, "How did you feel you could control your virtual character?" "How was it difficult to control? How was it easy to control?"
- Feelings of presence or immersion: eg, "How 'real' did it feel to you?" "When you were in the virtual world, what did you notice was happening around you in the real world?" "What else did you think about?" "Where did you have your attention focused?"
- What they consider to be the biggest benefits and failures of VR therapy eg, "What are the best things about the virtual reality?" "What are the things you don't like about it?" "What would you do differently?"
- Would they consider doing VR therapy often as a more intensive treatment program? eg, "How often would you be willing to come back to the clinic to do more VR?" "How much do you think doing VR regularly would help with your pain?" "How would you compare VR to other treatments for pain?"

Parent questions

- What do you think or how do you feel about your child's VR session today?
- Is there anything that could be improved in the VR sessions?

Clinician questions

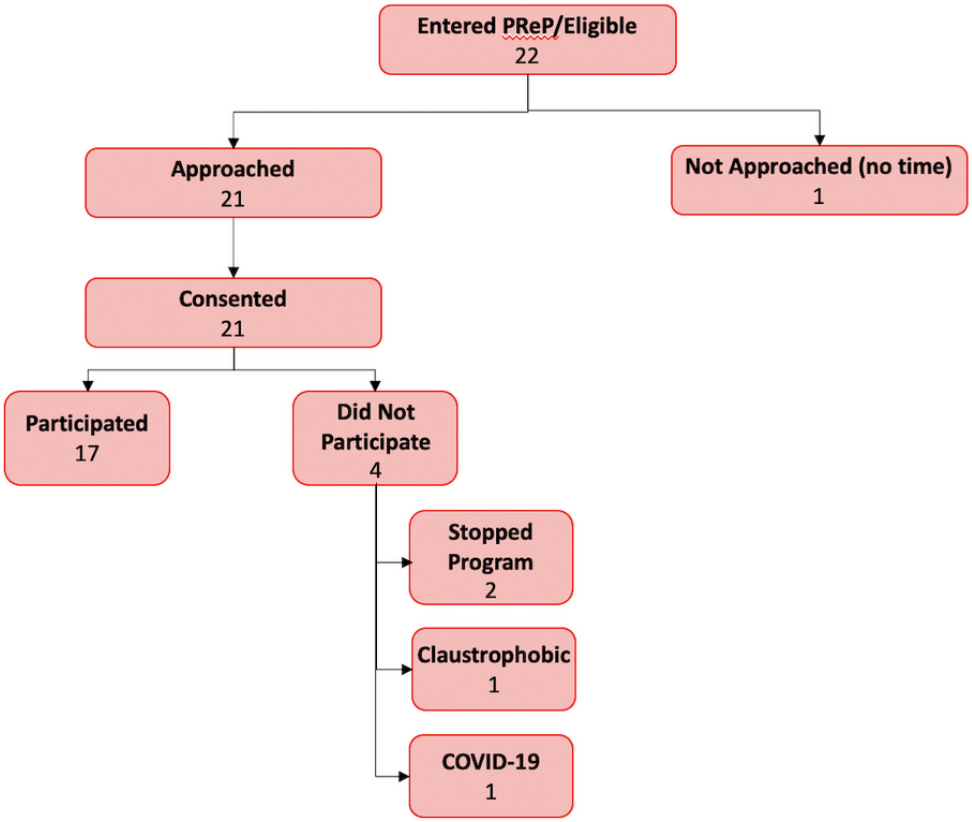
- How did the VR session go today?
- Is there anything that could be improved in the VR sessions?

Results

Participants and Setting

Seventeen, predominantly female (13 female, 4 male) youth with a mean age of 13.24 (ranging from 7 to 17 years) being treated in an IIPT from January 2019 to March 2020 participated in this feasibility pilot (Figure 2). Patients had a variety of chronic pain conditions (ie, lower extremity CRPS=9, primary musculoskeletal pain [diffuse/widespread and localized]=6, Ehlers–Danlos syndrome=1, irritable bowel syndrome=1). Patients presented having experienced pain for an average of 17 months (range 1-60 months). Patients were in IIPT treatment for an average of 7 weeks (range 4-12 weeks). Patients participated in an average of 4 VR sessions (mean 3.71 sessions), with a range of 1-8 total sessions. For all but 1 patient, the number of sessions was contingent on availability of VR technician and duration of IIPT admission. One patient withdrew after her third VR session due to dizziness and photophobia. No other adverse events were reported.

Figure 2. Virtual reality CONSORT flowchart.



Across 17 patients, 63 VR sessions were completed. All sessions were conducted with a clinician (ie, PT, OT, or pain psychologist) present in a dedicated VR room with flooring for physical activity use, such as floor mats typically used in a rehabilitation gym for safety. VR sessions were typically 30 minutes in duration (mean 29.57; median 30.08; range 6.16 to 80.1). The clinician determined the appropriate treatment and chose the duration as well as the mode that was needed for each patient while engaged in VR. Clinicians ensured safety parameters within the space and considering patient ability and function.

Development and Prototyping

The first phase of the project was dedicated to program start-up, which included identifying needs for the VR intervention, obtaining Institutional Review Board approval, outfitting a permanent testing room for VR use, and training clinicians on how to administer a VR session. The team initially met to establish the parameters for the intervention, following an extensive exploration of existing VR programs for rehabilitation purposes. The team found that existing rehabilitation programs focused solely on upper extremity involvement. The team deemed these existing programs inadequate for the pediatric pain rehabilitation population, which presents with a greater need for lower extremity interventions within a more age-appropriate and engaging platform. The needs assessments with pediatric clinicians (ie, physical therapy, occupational therapy, pain psychology, and pain medicine physicians) further defined the goals and recommendations for VR interventions in pediatric pain rehabilitation. PTs requested activities targeting functional goals to strengthen muscles and increase range of motion. OTs requested movements targeting activities of daily living. Pain psychologists provided insights into fears about pain related to movement during OT and PT sessions. Pain psychologists also requested options for modifying the delivery format for youth who may be distressed by wearing a headset or too anxious to begin lower extremity VR in a standing position. Pain medicine physicians requested options for patients who were sitting, standing, or otherwise limited in their physical abilities.

Following clinician needs assessments, the software design team shadowed each clinician to observe youth with chronic pain during typical IIPT sessions. This process provided the software design team with use cases and insight into the tasks youth were attempting to master in physical therapy, occupational therapy, and pain psychology sessions (eg, functional goals for lower and upper extremities, methods to increase mobility, use of pain coping skills to manage pain symptoms during treatment, the benefits of distraction from pain). Understanding these tasks, as well as the process and protocols within each therapy session allowed the software design team to further define an optimal VR tool for IIPT—an immersive VR world that would promote engagement in gamified pain rehabilitation tasks that scale to meet treatment demands based on a patient's current ability.

Following the clinician needs assessment and initial program software design, the technical team was able make decisions about the VR hardware and room setup. The team chose to use an HTC VIVE VR System, which tracks a user's head in a 10′

× 10′ play space with 6 degrees of freedom. The VIVE VR System also includes 4 additional 6 degrees of freedom trackers, which track the position and rotation of the player's hands and feet. Using this system, users can fully immerse themselves in a virtual world, with the ability to walk around and touch virtual objects with their hands and feet. The VIVE VR System requires a VR-ready computer and 2 external trackers (lighthouses) positioned in opposite corners of the play area. In order to house this system, the program used a dedicated VR room with adequate space for the hardware setup, which included a 10′ × 10′ play area, a locked cabinet for storing the computer and other VR equipment, 2 permanently mounted VR lighthouses for quick session setup, a retractable cable management system to help keep the VR headset's cable out of the way during a session, and rubber gym flooring for safe, active VR usage.

The software design team began by focusing on a single game, Fruity Feet, to prototype and test with patients. Fruity Feet gamifies lower extremity PT, helping patients increase their range of motion and become more comfortable with moving their feet and legs. Gameplay mechanics were built around the following lower extremity PT movement goals: multiplanar stepping (ie, forward, side, back), stomping, marching, kicking, raising leg to different heights, and active ankle range of motion tasks (ie, dorsiflexion, plantarflexion, inversion, and eversion). Importantly, the module was also built to scale to a patient's mobility, ensuring that patients of all abilities could play the game and benefit from the VR intervention.

The team designed Fruity Feet to be developmentally appropriate for children and adolescents. The game is fun, light-hearted, and often silly, while employing stylized graphics, in-game feedback, and sound design to offer immersive and engaging game play. During play, users are placed on a farm and instructed to stomp and kick as many virtual fruits and vegetables as possible in order make juice and gain points before a timer runs out. Player step/stomp quality is measured by the VIVE sensors, scoring players based on how high they raise their legs and whether they land their feet in the center of the fruit. As players stomp and kick at the fruit appearing beneath their feet, virtual fruit juice splatters the world and a cartoon farmer yells encouraging phrases such as "Nice job!" and "That's some juicy fruit!" (Figure 3). Clinicians can adjust aspects of the game to tailor the VR experience to a patient's ability level and other needs using the game's control panel (Figure 4).

Figure 3. Fruity Feet Gameplay. The player embodies the avatar feet and hands, using them to squish virtual fruit. The player must stomp on as much fruit as possible before the timer runs out. Players are awarded points based on how quickly and effectively they stomp on the fruit. Their score is tracked in real-time and they can keep track of previous high scores to try and beat their old records. The virtual world is built to look as if players are on a farm to further immersion and provide an engaging game environment.

Figure 4. Fruity Feet control panel. Using the control panel, clinicians can adjust the game to better fit the needs of their patient. Intensity affects the rate at which fruit appears in the world. Left/Right Focus focuses the game activity on the left/right side of the patient, encouraging patients to use their affected side. Fruit Size changes how high players must lift their foot in order to effectively stomp a fruit. Extremity Focus focuses the game activity on the player's lower or upper extremities. Foot/Hand Mirroring enables an experimental mode that mirrors the virtual extremity, much like mirror therapy. Foot/Hand Exaggeration enables an experimental mode that affects the movement gain of the virtual avatar's feet and hands (higher exaggeration results in the virtual avatar moving farther than the patient moved in the real world, and lower exaggeration results in the virtual avatar moving less than the patient moved in the real world).

Following the initial development of Fruity Feet, the team began a cyclical process of testing the program with clinicians/patients, gathering feedback, and iterating on the software design. This feedback loop was critical in building a VR module that was easy to use, fun to play, and met the appropriate therapy goals for patients and clinicians. During this process, both Fruity Feet and commercially available VR programs were used to obtain feedback to further develop Fruity Feet and the VR environment. Providers noted the importance of including both upper and lower extremity engagement during Fruity Feet tasks. For example, an OT on the team provided feedback about neck discomfort while constantly looking downward when the task was initially solely focused on lower extremity movements. One of the first patient test cases initially presented with mobility limitations, using one crutch to ambulate. The patient was a 12-year-old Caucasian female with a diagnosis of CRPS of the lower right extremity. She struggled with tasks such as standing, walking, and other movements that required her to bear weight on her right foot. She regularly participated in VR sessions during her rehabilitation process, and as her pain and function began improving, she requested more challenges and further gamification of Fruity Feet. As an avid gamer herself, she requested a competitive element for the game, and even went so far as to suggest an "alien invasion" component when players got to a certain level. With this patient's feedback, the team developed a new game add-on in which unknown flying objects (UFOs) appeared, challenging advanced users with faster-flying fruits.

Fruity Feet was eventually expanded to include new game modes. These modes were designed as a modification to allow the use of VR for lower extremities from a seated position. This prompted the development of a graded process for increasing lower extremity active range of motion and weight bearing by transitioning from seated tasks (ie, active multiplanar ankle movements, active knee flexion and extension, and multiplanar weight shifting for increased weight bearing) to standing tasks (ie, supported standing, weight shifting, squatting, single limb weight bearing, and balancing). Game modes also included the use of upper extremities, creating an active and dynamic experience for patients pursuing both upper and lower extremity goals (ie, reaching, throwing, hitting, kicking, stomping, squatting, standing, twisting, and balancing), all at once. Beyond specific movement goals, these new game modes provided variety and choice for patients using VR, which made for a more engaging and less repetitive session.

Modifications helped to simulate activities of daily living, play, and leisure activities while downregulating the sensory system. The movements within Fruity Feet helped to promote increased function for daily living tasks. Fruity Feet engaged participants in leisure activity that required movement, balance, and endurance, which could be generalized to age-appropriate occupations including the act of raising one's arms above the

head in order to don a shirt (eg, the affordance of the sling shot task), weight shifting, and standing balance skills necessary for showering (eg, stomping on virtual fruit of various sizes and locations while standing) and functional endurance activities important for school, sports, and other active recreational tasks (eg, gamification increased length of time engaged in the VR tasks). Each change and addition to Fruity Feet went through multiple iterations and feedback sessions with clinicians and patients. As the tasks became more dynamic, clinicians continued to identify and ensure safety measures were considered through each iteration of Fruity Feet (ie, need to monitor patient's movements while in VR, need for a visual barrier within VR). Many patients in the IIPT program were able to see their suggestions and feedback come to life in VR as requests for additions, such as farm animals and aliens, were incorporated into the software.

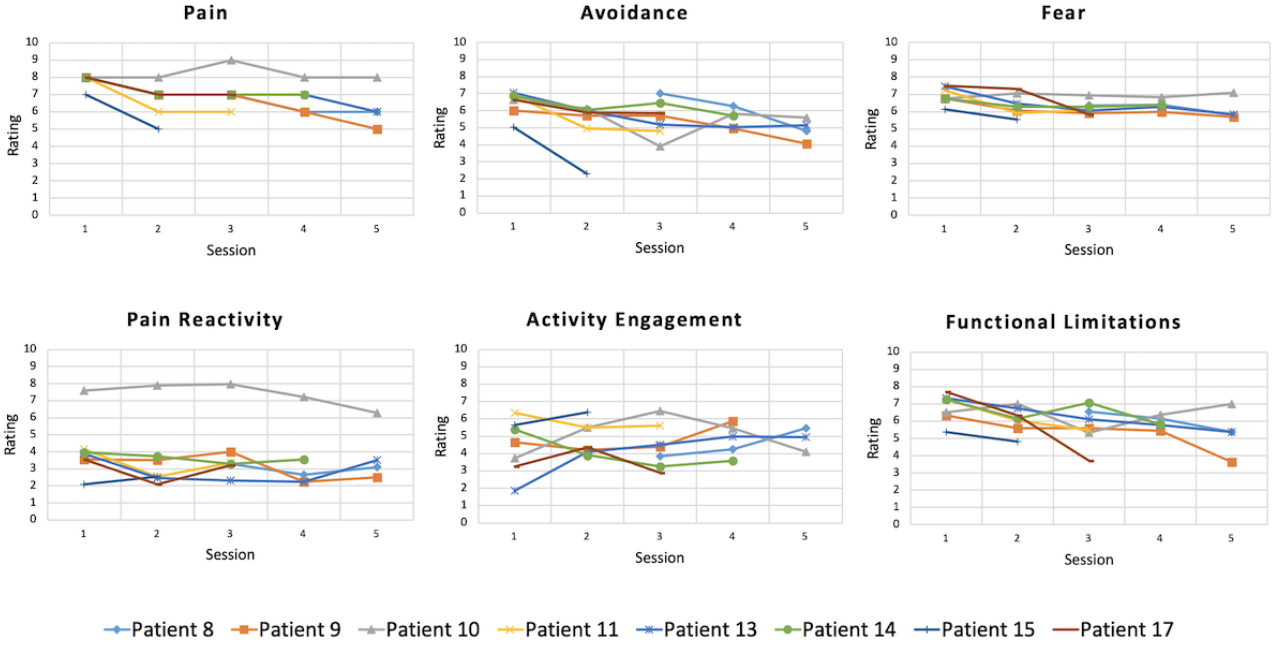
One example of how Fruity Feet was improved during the iteration and refinement phase for wheelchair-bound patients involves a 12-year-old Caucasian female patient who was nonweight bearing yet eager to participate in the VR in pain rehabilitation platform. The patient was diagnosed with CRPS in both of her lower extremities. She initially struggled with tasks of standing or stepping but seemed to benefit from active ankle range of motion tasks conducted while seated in a chair. This patient provided feedback to include rewards in addition to points, such as being able to add animals to the virtual farm in exchange for a certain amount of points earned. This addition improved motivation to remain engaged in the game for longer periods and allowed the patient to progress to more dynamic standing and stepping goals. The patient struggled to achieve these movement goals during her typical PT sessions in the IIPT program without VR in pain rehabilitation; however, once VR was added, she was able to attain such goals more effectively. The patient was able to increase use of her lower extremities, resulting in an improved ability to ambulate without assistive devices. She noted that Fruity Feet improved her motivation to engage in standing/walking IIPT goals with the PT.

Outcome Measures

Presence and Daily Questionnaire

After each VR session, patients were surveyed on their perception of the virtual character (avatar) as well as the virtual environment. Patients were asked about how real the virtual world seemed (eg, immersion), and whether they felt the avatar's body was an extension of their own body (eg, embodiment). Overall reports of presence were high (n=17; mean 28.98 [SD 4.02]), with scores ranging from 0 to 40, with higher scores suggestive of greater presence. As the child daily questionnaire began after the feasibility pilot started, we provide data on those who completed it more than once (n=8; Figure 5). The repeated measures mixed models showed a significant effect for time with decreases in pain ($F_{4,27.7}$=9.27, P<.001), fear ($F_{4,25.7}$=5.17, P=.003), avoidance ($F_{4,27.9}$=4.96, P=.004), and functional limitations ($F_{4,25.2}$=4.20, P=.01) across VR sessions. Activity engagement and pain reactivity reports did not significantly change across VR sessions.

Figure 5. Multisession ratings of pain, fear, avoidance, activity engagement, and pain reactivity. Each line represents a patient's multisession post-VR Child Daily Questionnaire ratings. As can be observed from the graphs, number of sessions/ratings ranged from 2 to 5. Repeated measures mixed model analyses revealed significant effects for time with decreases in pain, fear, avoidance, and functional limitations. No effects for time were observed for activity engagement or pain reactivity. VR: virtual reality.



Child Interviews

There were a total of 63 child interview responses from 17 patients completed after VR sessions. Feedback was obtained for the first 45 sessions (n=13), as part of the iterative process, following each VR session. These 45 responses were entered into the NVivo qualitative analysis software system. An emergent coding approach was utilized, with 2 coders (AG and AF) creating the same themes, to demonstrate accuracy, as responses could be coded in various ways. Multiple responses

informed the 4 derived themes with sample responses detailed in Table 1.

Table 1. Sample responses from participants across the 4 themes.

Participant ID	Positive response	Distraction from pain	Increased function	Decreased pain
6	*I would be willing to come to do VR for sure. It is like a more fun version of PT.* [Session 3]	*The biggest benefit is being able to do motions I wouldn't normally be able to do without thinking of the pain.* [Session 3]	*I could move my body and balance on my bad leg.* [Session 3]	*It was very distracting. It made it a lot easier to move my leg without pain.* [Session 3]
8	*Reaching my standing goals in an easy way and the time goes faster.* [Session 4]	*It distracts me from pain.* [Session 5]	*I can put more weight on my foot.* [Session 5]	*It can help you to forget about your pain.* [Session 4]
11	*VR keeps you busy and distracted from the real world, the time flies and I can be standing easily for a long time.* [Session 1]	*It can distract you and you are able to move more.* [Session 1]	*Standing for 40 minutes with no breaks and I can walk around the room for a long period of time.* [Session 1]	*I forgot about my pain.* [Session 1]

These emergent patient response themes included (1) positive experience or response to the VR session (eg, enjoyed experience, would like to utilize this VR program again, felt this was a helpful tool; 40/45 responses, 89%); (2) feeling distracted from pain while engaged in the VR task (eg, distracted from pain symptoms during VR tasks; 24/45 responses, 53%); (3) VR increased physical function/mobility (eg, achieved functional goal, able to complete more physical tasks such as standing/walking/stomping; 16/45 responses, 36%); and (4) reduced pain behaviors/symptoms (eg, decreased pain level, noted feeling painless) during VR (10/45 responses, 22%).

We highlight responses from 1 participant who demonstrated progress over 3 weekly sessions. This patient identified initially not liking the immersive experience, but agreed to continue exploring the VR platform. Over the subsequent 2 sessions, the patient's responses improved to conclude that Fruity Feet was acceptable and noted improvements in function without noticing pain with movement (Table 2). The patient also recommended this intervention for other youth with chronic pain.

Table 2. Interview responses from one patient across multiple VR[a] sessions.

Session	What was it like to be in this VR?	How did it feel to be in this VR?	Do you think VR can help other kids with chronic pain?	What are the things you like/don't like about this VR?	How often would you be willing to do more VR?
1	*Weird*	*I felt trapped. I felt I couldn't control what I was doing.*	*May be*	*I don't like to be so immersive*	*Maybe in the future*
2	*Today I liked it. It was good*	*I felt better than the last time. I could control the virtual world*	*It can help kids to stand more time and use their legs more without noticing discomfort*	*You can forget a little bit about your pain.*	*Yes, I will try it again.*
3	*Today I loved it. It was easy to reach my standing goal*	*It was good*	*Sure, VR can help me and other kids*	*I can be standing more time without any pain*	*Once a week is good for me*

[a]VR: virtual reality.

Most patients reported a positive response to the VR experience. Patients reported that it felt real, and that they felt immersed in the VR world, even while speaking with the clinician in the room during the session. Nearly all patients, in at least one of their sessions, reported feeling distracted from their pain:

> *Painless. It's ... kind of like a coping thing where you're distracted and ... you don't feel like you have pain. You're just trying to focus on whatever game you're doing* [ID 1, Session 1]

> *It was really neat! It made me forget about the pain a little because I was in a world where the pain didn't exist* [ID 6, Sessions 1 and 2]

Patients also reported experiencing ownership and control over their avatar during the VR sessions, and for some this increased over subsequent sessions. All patients responded in at least one session that VR would help other youth with chronic pain. All patients responded that they would use VR in the IIPT program, with several commenting that it was more "fun" or "distracting" than alternatives such as physical therapy sessions without VR.

Many patients also responded with increased functional gains during the VR task, reporting:

> *When I was in VR I was able to move my foot around much more in order to squash all of the fruit* [ID 6, Session 1]

Clinician Interviews

An emergent coding approach in NVivo was also utilized with clinician responses, with 2 coders (AG and AF) creating the same themes, demonstrating accuracy. Qualitative results generated frequency scores, resulting in 4 primary themes for clinicians derived from 32 responses from 5 clinicians (1 PT, 1 OT, and 3 pain psychology). Clinician response themes about observations of their patients included the following: (1) increased function/mobility (N=17 responses; 53%), (2) enjoyment of the VR experience (N=12 responses; 38%), (3) VR extended or lengthened patient's ability to engage in physical activity (N=9 responses; 28%), and (4) VR increased patient's distraction from pain symptoms during the VR sessions (N=8 responses; 25%).

Clinician feedback suggested that VR helped their patients achieve pain rehabilitation goals. Some credited VR with helping to progress patients to no longer need assistive devices.

> *He really comes to life when he's doing VR. So, it's nice to see him so active, animated ... the point where he's singing and he's dancing, and he's really blossomed with what he can do with the game* [ID 1, Session 4]

> *She didn't even mention a concern about the fact that she was standing for nearly 40 minutes ... didn't complain, didn't say anything, and she was shifting her weight onto the affected limb ... standing equally or even on the right leg, pretty frequently* [ID 2, Session 5]

Some clinicians commented that VR was a useful environment for overcoming psychological barriers.

> *It's kind of like nice to be able to tie in some of the things we're working with in psychology, with what he was doing in VR ... and (it) was sort of the perfect kind of concrete example of being able to put that into action* [ID 1, Session 5]

Parent Interviews

When available, parents were interviewed about their child's VR experience. Derived from 4 responses from 3 parents, parents remarked on the immersive quality of VR at their child's level of engagement while playing the games.

> *I love it... And the most impressive thing was that she can walk around without help and without complaining about her pain.* [ID 8, Session 1]

> *It gets her moving a lot more than she thinks she can* [ID 2, Session 7]

One parent suggested that it would benefit their child to watch footage of their own motion after the session, to "change her mind" about how much she can do [ID 2, Session 7].

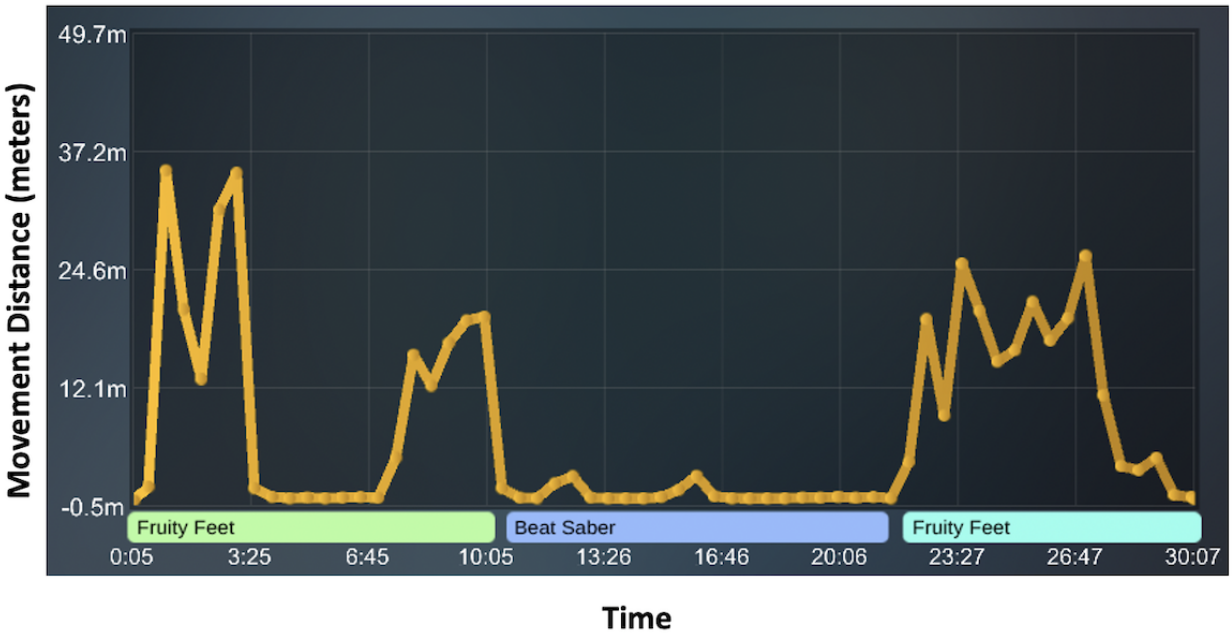
Areas for Improvement and Modification

Based on clinician observation and interviews, areas for improvement or modifications were identified to attenuate any adverse effects from VR engagement. For example, there was 1 patient (ID 5) that reported feeling "trapped" and "out of control" during her first session, which was discontinued. Rather than engaging in VR with the headset, a projector was utilized to illuminate the gaming images on the wall, because the patient was interested in finding a way to comfortably participate in the VR intervention. She returned for additional sessions with this modification, and during her third session, the patient commented that she "loved it." The patient and clinician both suggested that more games be made available in projector mode for patients who do not feel comfortable with the immersive VR experience. Furthermore, 2 patients reported feeling "dizzy" or "weird" after sessions, with 1 patient noting that it was difficult to become accustomed to light and other sensory stimuli in VR (ID 10, Session 3). This patient later reported having a headache prior to participating in the session, which may have been exacerbated by the light in VR. One patient reported that the headset was heavy (ID 9, Session 1).

Comparing Fruity Feet With Commercially Available VR Programs

Clinically, clinicians noted that patients moved their lower extremities more frequently with Fruity Feet in comparison to other VR programs. The VR team then compared Fruity Feet to other commercially available VR games and programs (eg, Beat Saber by Beat Games, Tilt Brush by Google). In order to capture differences in movement across these programs, the software developers created a novel method to compare movement while using different VR programs called the VR Clinical Comparison Research Tool. The VR Clinical Comparison Research Tool tracks the movements of each extremity simultaneously in real time with advanced analytic capabilities for range of motion across VR programs. Clinicians can create custom play lists, leveraging existing content with custom modules, while tracking progress within each session and longitudinally throughout the course of therapy. This allows for comparison across VR programs for VR in pain rehabilitation. Preliminary data for 1 sample case demonstrated that Fruity Feet tracked increased movement for a patient with CRPS in the patient's affected left lower extremity (Figure 6).

Figure 6. VR Clinical Comparison Research Tool. The screen provides a graph of the patient's progress over time during their VR session while using Fruity Feet and a commercially used program (eg, Beat Saber) and then utilizing Fruity Feet once again. The graph shows increased movement of the lower left extremity (yellow line) while engaged in Fruity Feet. The lower left extremity movement reduces with other VR programming (eg, Beat Saber). VR: virtual reality.



Discussion

Principal Findings

This paper describes the development and implementation of a novel VR intervention for youth with chronic pain participating in an intensive IIPT program. Existing game-based VR programs as well as rehabilitation-centered VR programs do not currently meet the physical rehabilitative needs of pediatric patients with pain, particularly due to the preponderance of those suffering from lower extremity pain and mobility limitations. To address this opportunity for meaningful VR engagement in rehabilitation, we implemented a multistep and iterative process of treatment development with a cohort of individuals admitted to an IIPT. The intervention described in this paper, Fruity Feet, was born out of a collaboration between pediatric pain researchers, clinicians on the front line with patients (physicians, PTs, OTs, and pain psychologists), and software developers interested in designing a VR program specifically to meet the needs of pediatric patients with chronic pain participating in functional rehabilitation. The result is a gamified VR program that has unique lower extremity capabilities and that is adaptable to each individual's mobility.

To develop Fruity Feet, a needs assessment with rehabilitation clinicians was critical to understand the unique ways that youth struggle to engage in therapies, and potential ways in which VR could not only enhance their participation in therapy, but also benefit their progress. Furthermore, understanding specific movements that are often avoided due to pain and fear provided targets for Fruity Feet optimization (eg, isolated ankle movements). After the prototyping phase, patient involvement was critical to the iteration and refinement of the Fruity Feet game developed. In this initial phase, feasibility was high, particularly with a captive audience of youth participating in an IIPT 5 days per week with multiple therapy sessions per day. Patients often preferred and even requested that their therapy session include VR, demonstrating high acceptability as well. Qualitative data from patients and parents reflected engagement in activities not previously perceived possible (eg, extended duration, increased mobility), distraction produced by VR, and therapies with VR described at times as "fun."

The Fruity Feet program yielded results consistent with prior VR therapies in the treatment of pediatric pain, as it was both tolerable and safe [14]. Moreover, subjective clinician, parent, and patient report of engagement, distraction, immersion, and enjoyment of the process were consistent with prior work [14,23,24]. The multisession daily reports indicated decreased pain, fear, avoidance, and functional impairments across VR sessions and this result is consistent with prior work [15,25-27]. Given that these changes were observed in the context of IIPT, it is possible the changes reflect general versus VR-specific effects, and thus it is necessary to conduct a more controlled pilot trial to measure the impact of VR on pain rehabilitation. Lastly, in alignment with a holistic model for VR program design developed by Ahmadpour and colleagues [28] in which autonomy, control, and empowerment are outlined as important design considerations, Fruity Feet yielded qualitative patient feedback of ownership and control over one's avatar during sessions.

Limitations

There are several limitations with regard to the implementation and generalizability of our VR program. Equipment setup for sessions using VR was typically more time-consuming than typical PT or OT sessions. A dedicated VR room with specifications for optimizing safety (eg, 10′ × 10′ play area, rubber gym flooring, mounted VR lighthouses, cable

management system) was needed for administering sessions due to space required for conducting the physically active VR sessions. Although technical issues were uncommon, our clinicians did have a dedicated technology expert available for assistance during all sessions. Expense of equipment, staffing, and space constraints may limit adoptability by other institutions. The clinical team also reported difficulty with patients generalizing their progress outside of VR sessions at times (eg, standing for 40 minutes in VR session, whereas only being able to stand for 10-20 minutes in a subsequent PT session). This suggests the importance of potentially implementing VR in pain rehabilitation over the course of several sessions to examine the cumulative impact of VR on skill generalization. In addition, it was not possible for patients to utilize the VR equipment outside of session which limited their abilities to emulate their therapy sessions when completing their home exercises. Interestingly, some families with resources to purchase VR headsets and gaming consoles requested guidance on purchasing their own; however, Fruity Feet is not yet commercially available, limiting their ability to continue with the therapy-inspired modules after participation in the IIPT. A further limitation and caution arises in terms of sanitary reuse of equipment. Although our team disinfected the headsets and controllers prior to each patient's participation, additional health and safety concerns must now be considered in a time even more focused on infectious disease prevention. Consideration should be made for also utilizing a UV sanitizing device along with the standard disinfecting process. Lastly, applying a single-case experimental design approach in future studies would allow for a more sensitive analysis of change processes as the current data collected limited the conclusions we could draw about the impact of VR in pain rehabilitation on functional outcomes.

Future Directions

Future developments of VR in this context will focus on testing with additional samples, as well as further testing of *mirror therapy* and *exaggerated movement* modules. In addition, a clinical protocol for the *exposure therapy* and *range of motion* exercises is underway. We have continued to develop tools for pain psychology interventions with the addition of a heart rate variability biofeedback component connected to VR (currently in the prototype phase). This tool will include the use of pain management coping skills with the benefits of heart rate variability to explore an immersive and interactive VR task, while fostering relaxation and self-regulation for downregulation of the nervous system. Furthermore, we have also been testing the use of VR with pedaling for increasing a variety of seated tasks. It will be critical to also assess sustained benefits from VR after active treatment across domains of function. Finally, we have begun expansion of VR in pain rehabilitation to multiple sites in the United States and Canada to examine the feasibility of dissemination and the effectiveness of this VR intervention across a large, diverse population of youth with chronic pain.

Conclusions

The VR application Fruity Feet has the potential to make a tremendous impact on the rehabilitative treatment of youth with chronic pain. The iterative process has helped to improve and refine this resource, with customized settings for a specific extremity, mirror therapy, exaggerated movement capabilities, and a VR Clinical Comparison Research Tool that tracks the movements of each extremity in real-time with advanced analytic capabilities across VR programs. Preliminary data suggest improvements in movement with decreased focus on pain symptoms while immersed in the VR world. VR in pain rehabilitation helped youth with chronic pain in an IIPT program to increase distraction from pain and helped to improve function to achieve rehabilitation goals. Furthermore, VR in pain rehabilitation successfully incorporated the use of lower extremities, in addition to upper extremities, which allowed both sitting and standing tasks for improved patient accessibility and generalizability. Youth with chronic pain found VR in pain rehabilitation to be acceptable, feasible, and engaging.

Acknowledgments

This study was supported by a grant awarded to BG, SR, and LS from the Mayday Fund.

Conflicts of Interest

LW is the CEO and Founder of Mighty Immersion, Inc., the design and development firm that was contracted by the Stanford team to help create Fruity Feet and the VR in pain rehabilitation platform.

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Abbreviations

IIPT: interdisciplinary pain treatment
VR: virtual reality

Edited by G Eysenbach; submitted 17.07.20; peer-reviewed by B Thompson, T Jones; comments to author 05.08.20; revised version received 02.09.20; accepted 29.10.20; published 23.11.20.

Please cite as:
Griffin A, Wilson L, Feinstein AB, Bortz A, Heirich MS, Gilkerson R, Wagner JFM, Menendez M, Caruso TJ, Rodriguez S, Naidu S, Golianu B, Simons LE
Virtual Reality in Pain Rehabilitation for Youth With Chronic Pain: Pilot Feasibility Study
JMIR Rehabil Assist Technol 2020;7(2):e22620
URL: http://rehab.jmir.org/2020/2/e22620/
doi:10.2196/22620
PMID:33226346

Original Paper

The Impact of Reducing the Number of Wearable Devices on Measuring Gait in Parkinson Disease: Noninterventional Exploratory Study

Matthew Czech[1], BSc; Charmaine Demanuele[1], PhD; Michael Kelley Erb[1], PhD; Vesper Ramos[1], MD; Hao Zhang[1], PhD; Bryan Ho[2], MD; Shyamal Patel[1], PhD

[1]Digital Medicine & Translational Imaging, Early Clinical Development, Pfizer Inc, Cambridge, MA, United States

[2]Tufts Medical Center, Boston, MA, United States

Corresponding Author:
Shyamal Patel, PhD
Digital Medicine & Translational Imaging
Early Clinical Development
Pfizer Inc
610 Main Street
Cambridge, MA, 02139
United States
Phone: 1 617 512 7885
Email: shyamal.patel@pfizer.com

Abstract

Background: Measuring free-living gait using wearable devices may offer higher granularity and temporal resolution than the current clinical assessments for patients with Parkinson disease (PD). However, increasing the number of devices worn on the body adds to the patient burden and impacts the compliance.

Objective: This study aimed to investigate the impact of reducing the number of wearable devices on the ability to assess gait impairments in patients with PD.

Methods: A total of 35 volunteers with PD and 60 healthy volunteers performed a gait task during 2 clinic visits. Participants with PD were assessed in the On and Off medication state using the Movement Disorder Society version of the Unified Parkinson Disease Rating Scale (MDS-UPDRS). Gait features derived from a single lumbar-mounted accelerometer were compared with those derived using 3 and 6 wearable devices for both participants with PD and healthy participants.

Results: A comparable performance was observed for predicting the MDS-UPDRS gait score using longitudinal mixed-effects model fit with gait features derived from a single (root mean square error [RMSE]=0.64; R2=0.53), 3 (RMSE=0.64; R2=0.54), and 6 devices (RMSE=0.54; R2=0.65). In addition, MDS-UPDRS gait scores predicted using all 3 models differed significantly between On and Off motor states (single device, *P*=.004; 3 devices, *P*=.004; 6 devices, *P*=.045).

Conclusions: We observed a marginal benefit in using multiple devices for assessing gait impairments in patients with PD when compared with gait features derived using a single lumbar-mounted accelerometer. The wearability burden associated with the use of multiple devices may offset gains in accuracy for monitoring gait under free-living conditions.

(JMIR Rehabil Assist Technol 2020;7(2):e17986) doi:10.2196/17986

KEYWORDS

gait; Parkinson disease; wearable sensors; digital medicine

Introduction

Gait is a complex sensorimotor activity involving dynamic spatial-temporal coordination of legs, trunk, and arms. Gait impairments negatively impact the functional mobility of patients with Parkinson disease (PD) [1,2]. In the early stages of PD, gait impairments manifest as reduced gait speed, shorter stride lengths, gait asymmetry with higher variability of gait measures, and reduced amplitude of arm swing. As the disease progresses, gait measures become less asymmetric, but impairments continue to increase in severity. Worsening gait impairments coupled with balance and postural control issues

lead to a significant reduction in mobility and an increased risk for falls in advanced PD [1,3,4].

Clinical assessment of gait in PD is limited to observational scales, such as the Movement Disorder Society version of the Unified Parkinson Disease Rating Scale (MDS-UPDRS), [5] and performance-based tests, such as the Timed Up and Go test [6]. While these tools have been clinically validated, assessments are influenced by the observer effect (Hawthorne effect) and quality of instructions [7]. Assessments are susceptible to rater bias; and because symptoms are rated on an ordinal scale, they lack the resolution to detect changes that occur on a continuum. In addition, since trained raters can only perform these assessments infrequently, they provide intermittent snapshots, which are inadequate for fully characterizing the day-to-day variability of symptoms [8].

Advances in wearable technology allow for the development of systems for objective measurement of gait [9-12]. Many of these systems, such as APDM Mobility Lab (APDM Inc) [13], provide a broad range of measures, quantifying various spatial and temporal aspects of gait. However, they generally require multiple sensing devices, which makes continuous, long-term monitoring difficult outside the lab or clinic. Recent research efforts to develop methods employing a single waist-mounted inertial sensing device (accelerometer and gyroscope) demonstrate the feasibility of monitoring gait in patients with mobility deficits, including PD, Huntington disease, poststroke disability, and sarcopenia [14-18]. Studies show moderate-to-good agreement between the frequency domain features (eg, dominant frequency amplitude or dominant frequency width) extracted from the accelerometer time series and subscales of the MDS-UPDRS associated with gait and balance [19,20]. However, unlike gait features like stride length and gait speed, these signal features do not have direct clinical meaning and are therefore, difficult to use for clinical decision making. Temporal (eg, swing time) and spatial (eg, stride length) gait features derived from a single accelerometer on the lower back (L5 vertebrae) have demonstrated moderate-to-excellent agreement with an instrumented walkway for 8 out of 14 gait parameters in healthy older adults and patients with PD [14]. Furthermore, gait features derived under free-living conditions had greater discriminative power than that of the laboratory-based gait assessments for differentiating between healthy older adults and patients with PD [21]. Compared to bilaterally worn ankle-mounted devices, lumbar-mounted accelerometers were satisfactory for measuring temporal gait features in young healthy adults despite their less accuracy [22].

While it is feasible to monitor gait using a single lumbar-mounted wearable device, the relationship between the number of devices used for deriving temporal and spatial gait features and their ability to detect clinically meaningful changes is not well understood. Herein, we employ a method, which relies on a single lumbar-mounted accelerometer that presents a significantly lower usability burden and affords better wearability compared to methods that rely on 3 or 6 devices [14,23-25]. However, the tradeoffs of reducing the number of devices may include lower accuracy in the estimation of gait features, measuring fewer aspects of gait, and reduced sensitivity for detection of clinically meaningful differences. Therefore, in order to objectively evaluate this tradeoff, we assessed (1) the accuracy and reliability of gait features derived using a single lumbar-mounted accelerometer relative to a reference system (APDM Mobility Lab) [13] and (2) the impact of reducing the number of sensing devices on the criterion and discriminative validity of gait features in patients with PD.

Methods

Study Participants

We recruited 35 participants with mild-to-moderate PD (Hoehn and Yahr scale score ≤3; mean age 68.3 years, SD 8.0 years; males, n=23; and females, n=12) and 60 healthy participants (mean age 44.1 years, SD 10.7 years; males, n=27; and females, n=33). Participants with PD took regular dopaminergic medication (levodopa-equivalent daily dose, mean 165.5 mg, SD 81.3 mg). Participants with PD were recruited and tested at Tufts Medical Center, Boston, Massachusetts. All procedures were approved by The Tufts Health Sciences Institutional Review Board (#12371). The protocol for the healthy cohort was approved by the Schulman Institutional Review Board (#201500837) and conducted at Pfizer, Andover, Massachusetts.

A participant with PD who self-reported as “On with dyskinesia” was excluded from the analysis since dyskinesia might interfere with gait feature measurements. Additionally, 1 healthy volunteer was removed from the analysis due to technical errors with data capture. The clinical and demographic characteristics of the participants whose data were available for analysis are listed in Table 1.

Table 1. Clinical and demographic characteristics.

Characteristics	Healthy participants (n=59)	Participants with PD[a] (n=34)
Males, n	27	23
Females, n	32	11
Age (years), mean (SD)	44.4 (10.5)	68.1 (8.1)
Height (m), mean (SD)	1.7 (0.1)	1.7 (0.1)
BMI (Kg/m^2), mean (SD)	25.3 (4.8)	28.9 (7.1)
Participants with the Hoehn and Yahr stage of PD, n		
Hoehn and Yahr stage 1	N/A[b]	2
Hoehn and Yahr stage 2	N/A	26
Hoehn and Yahr stage 3	N/A	6
Levodopa-equivalent daily dose (mg/day), mean (SD)	N/A	164.5 (81.1)
MDS-UPDRS[c] III gait score in On condition, mean (SD)		1.0 (0.9)
Hoehn and Yahr stage 1	N/A	0.0 (0.0)
Hoehn and Yahr stage 2	N/A	0.8 (0.7)
Hoehn and Yahr stage 3	N/A	2.0 (0.9)
MDS-UPDRS III gait score in Off condition, mean (SD)		1.4 (0.9)
Hoehn and Yahr stage 1	N/A	0.0 (0.0)
Hoehn and Yahr stage 2	N/A	1.2 (0.7)
Hoehn and Yahr stage 3	N/A	2.7 (0.5)

[a]PD: Parkinson disease.

[b]N/A: Not applicable.

[C]MDS-UPDRS: Movement Disorder Society version of the Unified Parkinson Disease Rating Scale.

Device Setup

As illustrated in Multimedia Appendix 1A, participants were instrumented with 6 wearable devices (Opal, APDM Inc) located bilaterally on the wrist and foot, and at the lumbar (approximately at the L5 vertebra) and sternum locations. Each device recorded raw data from 9-axis inertial sensors (triaxial accelerometer, triaxial gyroscope, and triaxial magnetometer) at a sampling rate of 128 Hz.

Experimental Protocol

Participants performed a battery of physical activities and cognitive tasks over the course of 2 visits. Both visits were identical for healthy participants but were randomized for participants with PD so that they were in the On state (about 1 hour after medication intake, confirmed with the patient self-report and clinician report) during 1 visit and in the Off state (about 3 hours after last medication intake, confirmed with the patient self-report and clinician report) during the other visit. Physical activities during each visit included scripted activities of daily living (eg, tying a shoe, opening and closing a door) and motor assessments from the MDS-UPDRS part III (eg, 2-minute gait task, finger tapping). In this paper, we present the analysis based on the data collected during the 2-minute gait task. This is to ensure uniform testing conditions for determining the agreement of postexperiment sensor data processing. During this gait task, participants were instructed to walk back and forth along a straight 10-meter track at a comfortable pace for a period of 2 minutes. Participants with PD were assigned an MDS-UPDRS gait score on an ordinal scale of 0 to 4 by a neurologist to assess the degree of gait impairment. Sample sizes (n) for MDS-UPDRS gait scores of 0, 1, 2, and 3 across both visits were 17, 27, 18, and 6, respectively.

Gait Feature Extraction

APDM Mobility Lab is a commercially available system widely used for objective assessment of gait and leverages data from 3 to 6 wireless, body-worn Opal inertial devices [13,26]. We used APDM Mobility Lab to derive a set of lower limbs, lumbar, and trunk range of motion and upper limb gait features from 6 wearable devices placed on the lower back, sternum, and bilaterally on the feet and wrists (Multimedia Appendix 2). Using 3 sensors located on the lower back and both feet, APDM Mobility Lab can only derive features related to the lower limb and lumbar range of motion. Therefore, we used only features related to lower limb and lumbar range of motion as the 3-sensor feature set (Multimedia Appendix 2). To derive gait features from a single lumbar-mounted triaxial accelerometer, we developed and implemented a previously published wavelet-based method [14] in a Python v3.6 package called GaitPy (Multimedia Appendix 1) [25]. A complete list of gait features derived from a single lumbar-mounted device and those requiring additional devices can be seen in Multimedia Appendix 2.

Statistical Methods

Statistical analysis was performed in R, version 3.4.1 (The R Project for Statistical Computing) [27], using the following packages: "psych" for intraclass correlation coefficient (ICC), "BlandAltmanLeh" for Bland-Altman plots, "nlme" for linear mixed-effects model, "car" for type 3 analysis of variance, and "MASS" for stepwise model selection.

The median value of each gait feature extracted from the data collected during the 2-minute walking task was calculated for each visit separately. Test-retest reliability of gait features was assessed by calculating the ICC on data collected from healthy volunteers during visit 1 and visit 2. ICC was also used in addition to Bland-Altman plots and 95% limits of agreement to evaluate the agreement between gait features derived using GaitPy and APDM Mobility Lab. The results are presented in Figure 1, where values are $ICC_{2,1}$ coefficient (2-way random effects, absolute agreement) with lower and upper confidence bounds, reported as ICC coefficient (lower, upper). Test-retest reliability and agreement between features were assessed according to the following benchmarks. ICC ≤ 0.4 indicates "poor," 0.4 to 0.59 "moderate," 0.6 to 0.74 "good," and 0.75 to 1 "excellent" reliability [28]. Variation of gait features with the MDS-UPDRS gait score in patients with PD was assessed using the Kruskal-Wallis test. Posthoc Conover-Iman tests were used for pairwise comparisons, and multiplicity was adjusted using false discovery rate correction.

Gait features derived using a single, 3, and 6 devices were separately used to fit 3 longitudinal mixed-effects regression models to predict the clinician's MDS-UPDRS gait score (using the *lme* function in "nlme" R package). Prior to model fitting, pairwise correlation between sensor features was computed, and highly correlated features were removed. Gait features and covariates including age, gender, visit number, BMI, and years since first symptoms were modeled as fixed effects and participant as a random effect. An unstructured correlation matrix was used. Numerical features were standardized to have 0 mean and unit variance. Stepwise model selection was performed using Akaike Information Criterion as a cost function to achieve the optimal model fit (using the *stepAIC* function in "MASS" R package). Analysis of variance findings were reported as chi-square values and corresponding *P* values using Type 3 sum of squares (statistics were derived using the "car" R package). Final models were used to predict the clinician's score using leave-1-subject-out cross-validation. We report the root mean square error (RMSE) and marginal R^2 representing the variance explained by the model of fixed effects. Paired Wilcoxon signed rank tests were used to compare predicted gait scores between On and Off states.

Figure 1. Agreement between gait features derived using the APDM Mobility Lab and GaitPy and test-retest reliability of gait features derived with GaitPy in healthy participants. Intraclass correlation coefficient values showing excellent agreement (between 0.75 and 1) are highlighted in blue. PD: Parkinson disease.

Gait feature	Agreement between gait features derived with APDM Mobility Lab and GaitPy		Test-retest reliability of gait features derived from GaitPy
	Healthy participants	Participants with PD	Healthy participants
Spatial and temporal gait features			
Stride time (s)	0.92 (0.02, 0.98)	0.86 (0.73, 0.92)	0.94 (0.84, 0.97)
Step time (s)	0.92 (0.09, 0.98)	0.90 (0.71, 0.95)	0.91 (0.83, 0.95)
Double support (s)	0.20 (-0.07, 0.52)	0.46 (0.16, 0.66)	0.90 (0.84, 0.94)
Stance time (s)	0.68 (-0.05, 0.91)	0.86 (0.48, 0.95)	0.93 (0.84, 0.96)
Swing time (s)	0.73 (0.03, 0.90)	0.64 (0.48, 0.76)	0.92 (0.86, 0.95)
Step length (m)	-	-	0.86 (0.77, 0.91)
Stride length (m)	0.60 (0.25, 0.78)	0.88 (0.79, 0.93)	0.85 (0.76, 0.91)
Gait speed (m/s)	0.70 (0.11, 0.87)	0.89 (0.71, 0.95)	0.88 (0.80, 0.93)
Variability gait characteristics			
Stride time variability (s)	0.01 (-0.02, 0.04)	0.04 (-0.04, 0.15)	0.56 (0.36, 0.71)
Step time variability (s)	0.01 (0.00, 0.04)	0.04 (-0.03, 0.14)	0.53 (0.31, 0.69)
Double support variability (s)	0.02 (-0.03, 0.08)	0.21 (-0.10, 0.51)	0.14 (-0.11, 0.38)
Stance time variability (s)	0.01 (-0.02, 0.05)	0.09 (-0.04, 0.30)	0.61 (0.42, 0.75)
Swing time variability (s)	0.00 (-0.03, 0.04)	0.02 (-0.03, 0.09)	0.44 (0.21, 0.63)
Step length variability (m)	-	-	0.74 (0.59, 0.83)
Stride length variability (m)	0.00 (-0.01, 0.03)	0.00 (-0.06, 0.08)	0.75 (0.61, 0.84)
Gait speed variability (m/s)	0.01 (-0.01, 0.04)	0.01 (-0.04, 0.09)	0.77 (0.65, 0.86)
Asymmetry gait characteristics			
Step time asymmetry (s)	0.11 (-0.06, 0.29)	0.16 (-0.05, 0.36)	0.44 (0.21, 0.62)
Double support asymmetry (s)	0.00 (-0.15, 0.16)	0.10 (-0.14, 0.33)	0.39 (0.16, 0.59)
Stance time asymmetry (s)	0.17 (-0.08, 0.41)	0.31 (0.01, 0.54)	0.57 (0.38, 0.72)
Swing time asymmetry (s)	0.22 (-0.09, 0.52)	0.29 (0.02, 0.51)	0.54 (0.33, 0.70)
Step length asymmetry (m)	-	-	0.72 (0.56, 0.82)

Ethical Compliance

The study of participants with PD was approved by The Tufts Health Sciences Institutional Review Board (#12371) and conducted at the Tufts Medical Center. The study of healthy participants was approved by the Schulman Institutional Review Board (#201500837), and conducted at Pfizer in Andover, Massachusetts. Written informed consent was obtained from all participants prior to testing. We confirm that we have read the journal's position on issues involved in ethical publication and affirm that this work is consistent with those guidelines.

Results

Accuracy of Gait Features Derived Using a Single Device

Gait features derived during the 2-minute walking task using GaitPy (single lumbar-mounted device) were compared with the same features derived using the APDM Mobility Lab (6 devices) for healthy participants and participants with PD with data from their 2 visits. Gait features derived using the APDM Mobility Lab were used as the reference since the APDM device has been validated against data from an instrumented treadmill and has been extensively used in both healthy populations and populations with PD [26,29]. Excellent agreement was observed between the 2 methods for stride time and step time in both healthy participants and participants with PD (ICC≥0.86), as shown in Figure 1. Furthermore, excellent agreement was observed for stance time, stride length, and gait speed in participants with PD (ICC=0.86, 0.88, and 0.89, respectively), and agreement was good in healthy participants (ICC=0.68, 0.60, and 0.70, respectively) (Figure 1). Bland-Altman analysis showed that mean difference between GaitPy and APDM Mobility Lab was smaller for longer stance times (Multimedia Appendix 3). Good agreement was also observed for swing time in both healthy participants and participants with PD (0.64≤ICC≤0.73) (Figure 1). In contrast, double support showed poor agreement in healthy participants (ICC=0.20) and moderate agreement in participants with PD (ICC=0.46) (Figure 1). Asymmetry and variability features also showed poor agreement (ICC≤0.31) between the 2 methods for both healthy participants and participants with PD (Figure 1).

Reliability of Gait Features Derived Using a Single Device

Test-retest reliability of gait features derived using GaitPy was assessed using the data collected from healthy participants. Excellent test-retest reliability (ICC≥0.85) (Figure 1) was observed for all spatial and temporal gait features. Asymmetry and variability features showed poor-to-excellent test-retest reliability (0.14≤ICC≤0.77) (Figure 1).

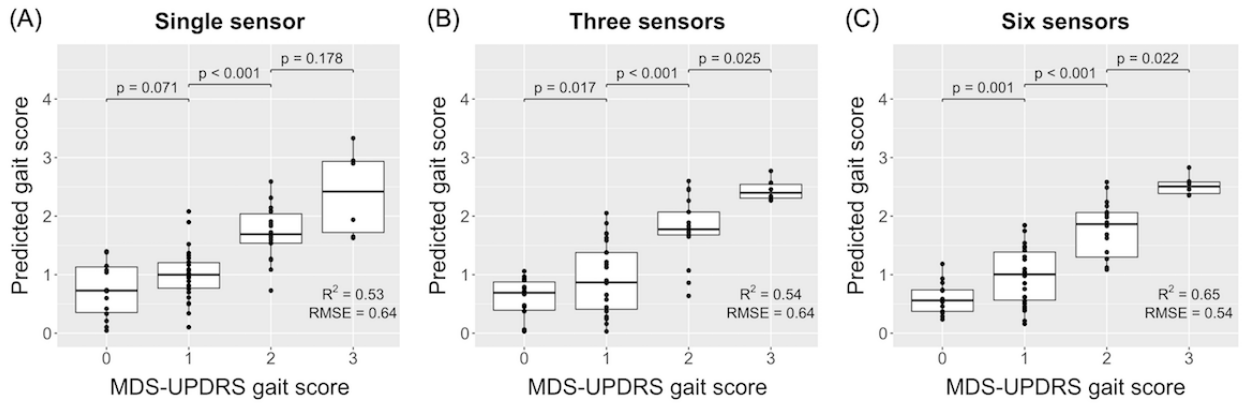
Criterion Validity of Sensor-Derived Gait Features

We assessed the ability of gait features derived by using methods relying on different device setups (single device, 3 devices, and 6 devices) to distinguish between MDS-UPDRS gait scores. Based on the APDM Mobility Lab documentation [30], we could determine which gait features are available for analysis with a 3-device setup and a 6-device setup. Therefore, for the purpose of this comparison, we limited our analysis to the 1-device setup (using GaitPy) and 3- and 6-device setups (using APDM Mobility Lab).

The spatial features of gait (ie, gait speed, stride length, and step length) varied most significantly with MDS-UDPRS gait scores in participants with PD (Multimedia Appendix 4). Using leave-1-subject-out cross-validation, the longitudinal mixed-effects regression model based on gait features derived using a single lumbar-mounted device predicted the clinician's gait score with an RMSE=0.64 and an R^2=0.53. The predicted score significantly distinguished between scores of 1 and 2 (P<.001), and marginally distinguished between scores of 0 and 1 (P=.07), and 2 and 3 (P=.18) (Figure 2A). Stance time (χ^2_1=12.8; P<.001), step length (χ^2_1=49.2; P<.001), and step length asymmetry (χ^2_1=6.7; P=.01) had significant effects on describing the MDS-UPDRS gait score.

Comparable performance was observed for a model based on gait features derived using data from 3 devices (RMSE=0.64; R^2=0.54). The R^2 value for the 3-device model was only slightly higher than the single-device model. The predicted gait score could significantly distinguish between MDS-UPDRS gait scores of 0 and 1 (P=.02), 1 and 2 (P<.001), and 2 and 3 (P=.03) (Figure 2B). Pitch at initial contact (χ^2_1=7.3; P=.007), maximum pitch (χ^2_1=10.5; P=.001), cadence (χ^2_1=14.9; P<.001), initial mid-swing duration (χ^2_1=4.5; P=.03), and pitch at toe off variability (χ^2_1=6.4; P=.011) had a significant effect on describing the MDS-UPDRS gait score.

Figure 2. MDS-UPDRS gait score model performance fit using gait features from (A) single device at the lumbar (L5) location (GaitPy), (B) 3 devices (APDM Mobility Lab), and (C) 6 devices (APDM Mobility Lab). MDS-UPDRS: Movement Disorder Society version of the Unified Parkinson Disease Rating Scale.

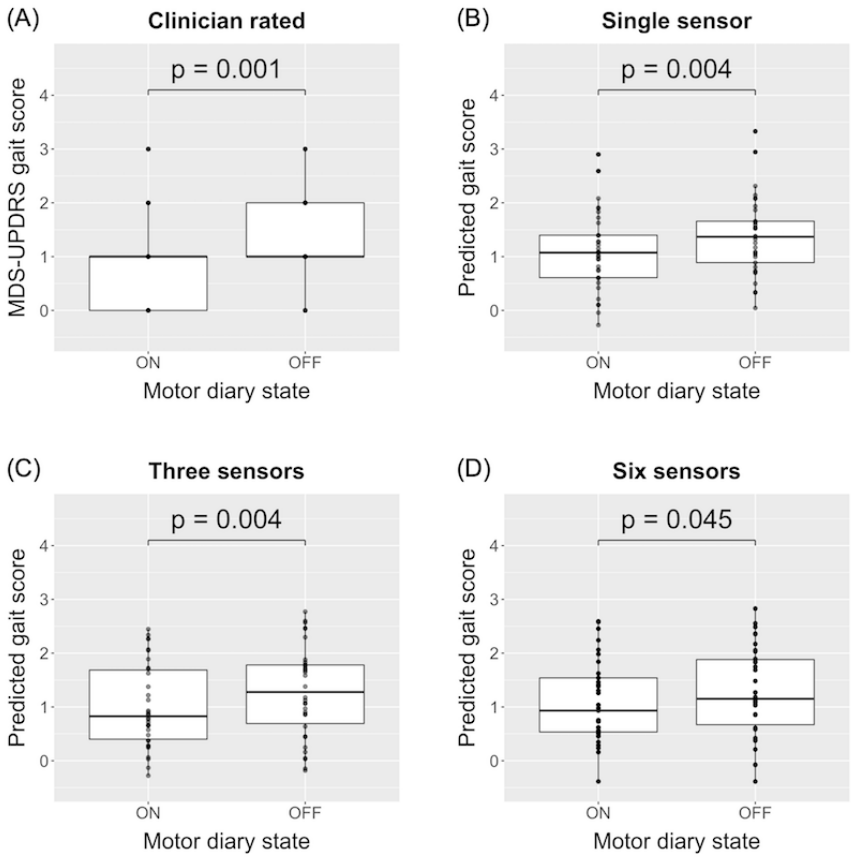


The model based on gait features derived using data from 6 devices achieved better performance than the single and 3-device model at predicting clinician gait score (RMSE=0.54; R^2=0.65). The predicted gait score significantly distinguished between MDS-UPDRS gait scores of 0 and 1 (P=.001), 1 and 2 (P<.001), and 2 and 3 (P=.02) (Figure 2C). Pitch at initial contact (χ^2_1=8.9; P=.003), maximum pitch (χ^2_1=5.4; P=.02), cadence (χ^2_1=19.8; P<.001), initial mid-swing duration asymmetry (χ^2_1=5.7; P=.02), trunk sagittal average angle (χ^2_1=18.9; P<.001), upper limb foot phase difference (χ^2_1=5.0; P=.03), maximum pitch variability (χ^2_1=8.6; P=.003), trunk sagittal average angle variability (χ^2_1=5.0; P=.025), BMI (χ^2_1=10.0; P=.002), and years since first symptom (χ^2_1=7.0; P=.008) had significant effects on describing the MDS-UPDRS gait score.

Discriminative Validity of Sensor-Derived Gait Features

We assessed the ability of predicted gait scores derived using methods relying on different device setups (single device, 3 devices, and 6 devices) to discriminate between On and Off motor states. As shown in Figure 3A, the clinician-rated MDS-UPDRS gait score was significantly different (P=.001) between the patient-reported On and Off state. Similarly, predicted gait scores, estimated from 1-, 3-, and 6-device models (Figure 3B-D), all significantly differentiated between On and Off states (P=.004, P=.004, and P=.045 respectively).

Figure 3. Distribution of the (A) clinician-rated gait score, (B) single device predicted gait score, (C) 3-device predicted gait score, and (D) 6-device predicted gait score, grouped by patient-reported On and Off motor states. MDS-UPDRS: Movement Disorder Society version of the Unified Parkinson Disease Rating Scale.



Discussion

Principle Findings

In this exploratory, noninterventional study involving healthy participants and participants with PD, we derived gait features from participants during 2 clinic visits using wearable devices. We found that gait features derived from a single lumbar-mounted accelerometer could predict the clinician-rated gait impairment score to a similar degree as gait features derived from 3 or 6 sensors. Additionally, analogous to clinician-rated scores, predicted gait scores using gait features derived from either 1, 3, or 6 devices all significantly distinguished between the On and Off medication states. Our results suggest that a subset of gait features, derivable using a single lumbar-mounted accelerometer, may be sufficient to measure the degree of gait impairment and the effects of treatment in patients with PD.

Accuracy and Reliability of Gait Features Derived Using a Single Device

Agreement of GaitPy with the reference system (APDM Mobility Lab) was assessed in both healthy participants and participants with PD. While we observed moderate-to-excellent agreement between the most temporal and spatial features of gait derived using GaitPy from a single device and gait features provided by APDM Mobility Lab using 6 devices, the agreement was poor for asymmetry and variability features. Notably, agreement was better in participants with PD for 4 out of 7 temporal and spatial features. The differences between ICC values for healthy participants and participants with PD were significant for stance time (0.86 vs 0.68), stride length (0.88 vs 0.60), and gait speed (0.89 vs 0.70). This result contrasts a prior study [14] where a good agreement with the reference system (gait mat) for both participants with PD and age-matched healthy controls was observed. However, unlike the prior study [14], the 2 groups in our study were not age-matched. To this end, patients with PD showed a wider range of values for gait speed and stride length compared to healthy participants, especially in the lower range, which may have contributed to a better agreement (Multimedia Appendix 5B and C).

We evaluated the test-retest reliability of gait parameters derived using GaitPy in a sample of 59 healthy participants. Test-retest reliability for GaitPy was excellent for all spatial and temporal features, whereas it was poor-to-excellent for asymmetry and variability features. These results suggest that the temporal and spatial features of gait can be reliably measured using a single accelerometer mounted on the lower back. However, as has been reported previously [14], the agreement and reliability of variability and asymmetry features might be sensitive to the employed measurement technique (eg, sensing modality or device location). This is partially because asymmetry and variability are small measurements, which are significantly affected by noise or error in the measurement of temporal or spatial features. Potential sources of measurement error for GaitPy include (1) biomechanical approximation of the inverted pendulum model, (2) error in the estimation of vertical displacement from vertical acceleration, and (3) distal location of the sensing device relative to the feet.

Tradeoffs Between Gait Features Derived Using Different Device Setups

We assessed the criterion and discriminative validity of MDS-UPDRS gait scores using linear mixed-effects models based on gait features derived using data from a single device, 3 devices, and 6 devices. Although a single device provides substantially fewer features of gait compared to either 3- or 6-device models, 17 of the 34 features that varied most significantly (P=.004) with MDS-UPDRS gait score can be derived using a lumbar-mounted sensor (Multimedia Appendix 4). This includes many gait features known to be affected in PD, including stance time, gait speed, step-to-step asymmetries, and gait variability [3,4].

While the 6-device model (RMSE=0.54; R^2=0.65) performed slightly better at estimating MDS-UPDRS gait score, performance of the 3-device model (RMSE=0.64; R^2=0.54) was comparable to the single device model (RMSE=0.64; R^2=0.53). However, unlike the 3 and 6 device models, the single device model was unable to significantly distinguish between the adjacent scores such as 0 and 1 or 2 and 3. A potential reason for this could be the small number of observations for class 3 (n=6). Additionally, gait features related to the pitch and mid-swing duration that were significant for both the 3 and 6-device models could not be derived using the single device model. This indicates features derived from the lower extremity (eg, foot) might have a higher predictive power. Indeed, 3 of 10 features in the 6-device model and 3 of 5 features in the 3-device model that were significant were related to the pitch of foot.

When we assessed the ability of gait scores predicted by the linear mixed-effects models to differentiate between On and Off motor states, we found significant differences (P=.045) for gait scores derived using 1-, 3-, and 6-device models. Additionally, the Off to On gait score directionality was largely consistent between those produced by each model and the clinician-rated gait score. In 10 of the 12 subjects, the clinician score and the predicted score differences between On and Off states were in the same direction (Multimedia Appendix 5A). This was comparable with the 3-device model (10/12) (Multimedia Appendix 5B) and 6-device model (10/12) (Multimedia Appendix 5C).

Limitations

Data analyzed in this study were collected during performance of motor assessments in the laboratory settings and could be affected by the observer effect and heightened awareness of the patient. Gait features derived using wearable devices were not validated against a gold-standard reference (eg, an instrumented walkway or a motion capture system). This limitation of our work is mitigated to some extent by prior work in which the authors evaluated the algorithm implemented in GaitPy against an instrumented walkway [31]. Another limitation of our work is that the healthy participants and participants with PD were not age matched. Therefore, the results for accuracy and reliability in our healthy cohort might be different in healthy older adults. Additional work is required to validate the results presented herein on an independent data set as well as to confirm the ability of GaitPy to accurately assess gait impairment in free-living conditions.

Conclusion

Our results suggest that a single triaxial accelerometer on the lower back may be sufficient to characterize gait impairments in patients with PD. Algorithms that estimate gait features from a lumbar-mounted sensor, such as GaitPy, could provide clinically meaningful measures of changes in the severity of gait impairments and changes in motor state associated with the effects of treatment in patients with PD. The long battery life of an accelerometer-only device and high degree of utility associated with a single device worn on the lower back enable further investigations to assess the validity of this approach for monitoring gait under free-living conditions. Comparing sensor-derived gait features with classical patient-reported motor diary–based approaches in their ability to detect treatment-related effects may provide an insight into the utility

of a single lumbar-mounted sensor in free-living environments. Our ongoing efforts are focused on performing a clinical validation in a semisupervised setting as an intermediate step between the clinic and at-home environment.

Acknowledgments

The authors would like to acknowledge Steve Amato, Paul Wacnik, Tairmae Kangarloo, and Jonathon Bruno for their contributions to study design, data collection, and manuscript processing. For reviewing and providing feedback on the manuscript, we would like to acknowledge Xuemei Cai, David Caouette, Joe Mather, and Timothy J McCarthy. The study involving participants with PD was a collaborative effort between Tufts Medical Center and Pfizer Inc. Pfizer Inc funded the work, and Tufts Medical Center was responsible for conducting the study and data validation/storage.

Authors' Contributions

MC organized and executed the research project, development of methods, and statistical analysis and wrote the first draft of the manuscript. CD contributed to the design, execution, and review of the statistical analysis and the review of the manuscript. MKE, VR, HZ, BH, and SP were involved in the conception, organization, and execution of the research project and reviewed the manuscript.

Conflicts of Interest

MC, CD, VR, HZ, and SP are current employees of Pfizer Inc. MKE is a former employee of Pfizer Inc and is currently employed by Biogen. BH has no competing interests.

Multimedia Appendix 1
Participants instrumented with six wearable devices (Opal, APDM, Inc) located bilaterally on the wrist and foot, and at the lumbar (approximately at the L5 vertebra) and sternum. *Adapted with permission from APDM Wearable Technologies.
[PNG File , 1025 KB - rehab_v7i2e17986_app1.png]

Multimedia Appendix 2
Gait features derived using GaitPy with a single lumbar-mounted device, APDM Mobility Lab with 3 devices, and APDM Mobility Lab with 6 devices. *Step length is not calculated by APDM Mobility Lab.
[DOCX File , 16 KB - rehab_v7i2e17986_app2.docx]

Multimedia Appendix 3
Bland-Altman analysis comparing (A) stance time, (B) stride length. and (C) gait speed agreement between GaitPy and APDM Mobility Lab in healthy volunteers (HV) and patients with Parkinson disease (PD).
[PNG File , 217 KB - rehab_v7i2e17986_app3.png]

Multimedia Appendix 4
Kruskal-Wallis rank sum statistics and *P* values for sensor-derived features of gait in participants with Parkinson disease that varied significantly (P≤.01) with MDS-UPDRS gait score in order of significance.
[DOCX File , 16 KB - rehab_v7i2e17986_app4.docx]

Multimedia Appendix 5
A comparison between MDS-UPDRS gait scores and predicted score changes between (Off - ON) visits in patients with Parkinson disease.
[PNG File , 80 KB - rehab_v7i2e17986_app5.png]

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Abbreviations

ICC: intraclass correlation coefficient
MDS-UPDRS: Movement Disorder Society version of the Unified Parkinson Disease Rating Scale
PD: Parkinson disease
RMSE: root mean square error

Edited by G Eysenbach; submitted 27.01.20; peer-reviewed by EA Aldayil, J Ruokolainen; comments to author 12.06.20; revised version received 07.08.20; accepted 16.08.20; published 21.10.20.

Please cite as:
Czech M, Demanuele C, Erb MK, Ramos V, Zhang H, Ho B, Patel S
The Impact of Reducing the Number of Wearable Devices on Measuring Gait in Parkinson Disease: Noninterventional Exploratory Study
JMIR Rehabil Assist Technol 2020;7(2):e17986
URL: http://rehab.jmir.org/2020/2/e17986/
doi:10.2196/17986
PMID:33084585

Original Paper

Rhythmic Haptic Cueing Using Wearable Devices as Physiotherapy for Huntington Disease: Case Study

Theodoros Georgiou[1], BSc, MSc, PhD; Riasat Islam[2], BSc, MSc; Simon Holland[2], PhD; Janet van der Linden[2], PhD; Blaine Price[2], BSc, MSc; Paul Mulholland[3], BSc, MSc, PhD; Allan Perry[4], BSc, DClinPsy, CPsychol

[1]School of Mathematical and Computer Sciences, Heriot-Watt University, Edinburgh, United Kingdom

[2]School of Computing and Communications, The Open University, Milton Keynes, United Kingdom

[3]Knowledge Media Institute, The Open University, Milton Keynes, United Kingdom

[4]PJ Care Limited, Peterborough, United Kingdom

Corresponding Author:
Theodoros Georgiou, BSc, MSc, PhD
School of Mathematical and Computer Sciences
Heriot-Watt University
Edinburgh Campus
Edinburgh, EH14 4AS
United Kingdom
Phone: 44 131 451 4132
Email: t.georgiou@hw.ac.uk

Abstract

Background: Huntington disease (HD) is an inherited genetic disorder that results in the death of brain cells. HD symptoms generally start with subtle changes in mood and mental abilities; they then degenerate progressively, ensuing a general lack of coordination and an unsteady gait, ultimately resulting in death. There is currently no cure for HD. Walking cued by an external, usually auditory, rhythm has been shown to steady gait and help with movement coordination in other neurological conditions. More recently, work with other neurological conditions has demonstrated that haptic (ie, tactile) rhythmic cues, as opposed to audio cues, offer similar improvements when walking. An added benefit is that less intrusive, more private cues are delivered by a wearable device that leaves the ears free for conversation, situation awareness, and safety. This paper presents a case study where rhythmic haptic cueing (RHC) was applied to one person with HD. The case study has two elements: the gait data we collected from our wearable devices and the comments we received from a group of highly trained expert physiotherapists and specialists in HD.

Objective: The objective of this case study was to investigate whether RHC can be applied to improve gait coordination and limb control in people living with HD. While not offering a cure, therapeutic outcomes may delay the onset or severity of symptoms, with the potential to improve and prolong quality of life.

Methods: The approach adopted for this study includes two elements, one quantitative and one qualitative. The first is a repeated-measures design with three conditions: before haptic rhythm (ie, baseline), with haptic rhythm, and after exposure to haptic rhythm. The second element is an in-depth interview with physiotherapists observing the session.

Results: In comparison to the baseline, the physiotherapists noted a number of improvements to the participant's kinematics during her walk with the haptic cues. These improvements continued in the after-cue condition, indicating some lasting effects. The quantitative data obtained support the physiotherapists' observations.

Conclusions: The findings from this small case study, with a single participant, suggest that a haptic metronomic rhythm may have immediate, potentially therapeutic benefits for the walking kinematics of people living with HD and warrants further investigation.

(JMIR Rehabil Assist Technol 2020;7(2):e18589) doi:10.2196/18589

KEYWORDS

physiotherapy; rhythm; haptic; tactile; wearable; cueing; Huntington; gait

Introduction

Background

Rhythmic cueing is a technique that is able to provide immediate improvements to asymmetrical or irregular gait for a variety of neurological conditions [1-5]. This paper presents a case study of the first reported application, to the best of our knowledge, of rhythmic cueing via haptics (ie, through the sense of touch) for a participant diagnosed with Huntington disease (HD).

HD is an inherited genetic disorder that results in the death of brain cells [6]. HD has a relatively low occurrence: around 10.6-13.7 individuals per 100,000 in western populations, and 1-7 individuals per million in Asian populations [7]. Even so, George Huntington, the person who first defined the disease in 1872, described it as follows: “Once it begins, it clings to the bitter end” [8]. There is currently no cure for HD [6].

Specific symptoms of HD vary between people [9]; however, HD symptoms generally start with subtle changes in mood and mental abilities [9]. These symptoms are then followed by a general lack of coordination and an unsteady gait [10]. In later stages of the disease, uncoordinated, jerky body movements become more apparent [9]. *Huntington chorea*—chorea, or χορεία, being the ancient Greek name for *dance*—is a name given to the hand and feet movements caused by HD because of their unfortunate loose resemblance to dancing.

Physical abilities gradually worsen, until coordinated movement becomes difficult, eventually affecting the person’s vocal cords, making them unable to talk [9,10]. Eventually, due to the gradual death of brain cells, mental abilities often decline into dementia [11]. Since HD is a genetic disease, symptoms can start at any age. However, symptoms do not usually become apparent until a person is between 30 and 50 years of age [6,11].

A small percentage of HD cases (about 8%) start before the age of 20 years, and typically present with symptoms more similar to Parkinson disease [11]. This is often defined as juvenile HD (JHD), and it differs in that it generally progresses faster, with affected individuals usually remaining alive no longer than around 10 to 15 years after signs and symptoms appear [12]. In such cases, chorea is generally exhibited only briefly, if at all. Additional signs of JHD include slow movements, clumsiness, frequent falling, rigidity, slurred speech, and drooling. A total of 30%-50% of persons with JHD often experience seizures [12,13].

Even though there is currently no cure [6], treatments [11] and frequent physiotherapy [14] can relieve some symptoms and, in some cases, improve quality of life [11]. Generally, full-time care is required in the later stages of the disease [10].

In the case of neurological conditions that affect gait more generally, asking survivors to match their steps to a steady external rhythm has been found to improve various gait characteristics, as we will now outline. This method of gait-related physiotherapy and rehabilitation, primarily using audio rhythms, has been widely explored in conditions such as hemiparetic stroke [15], cerebral palsy [16], and Parkinson disease [17,18] with promising results. More recently, steady rhythms mediated through the haptic, as opposed to auditory, modality (ie, mediated via the sense of touch) have been demonstrated to show very similar therapeutic benefits [5]. In some contexts, rhythmic haptic cueing (RHC) can have advantages over audio cueing, as it can be less obtrusive and leaves the sense of hearing free for other purposes [19].

In this case study, we tested RHC for assisting and enhancing current physiotherapy practices of HD and JHD. Even though physiotherapy for HD does not aim to fully restore walking abilities, it can have long-term therapeutic effects in delaying the disease’s progression; this could extend the period that a person with HD can be independently mobile, hence, providing better quality of life.

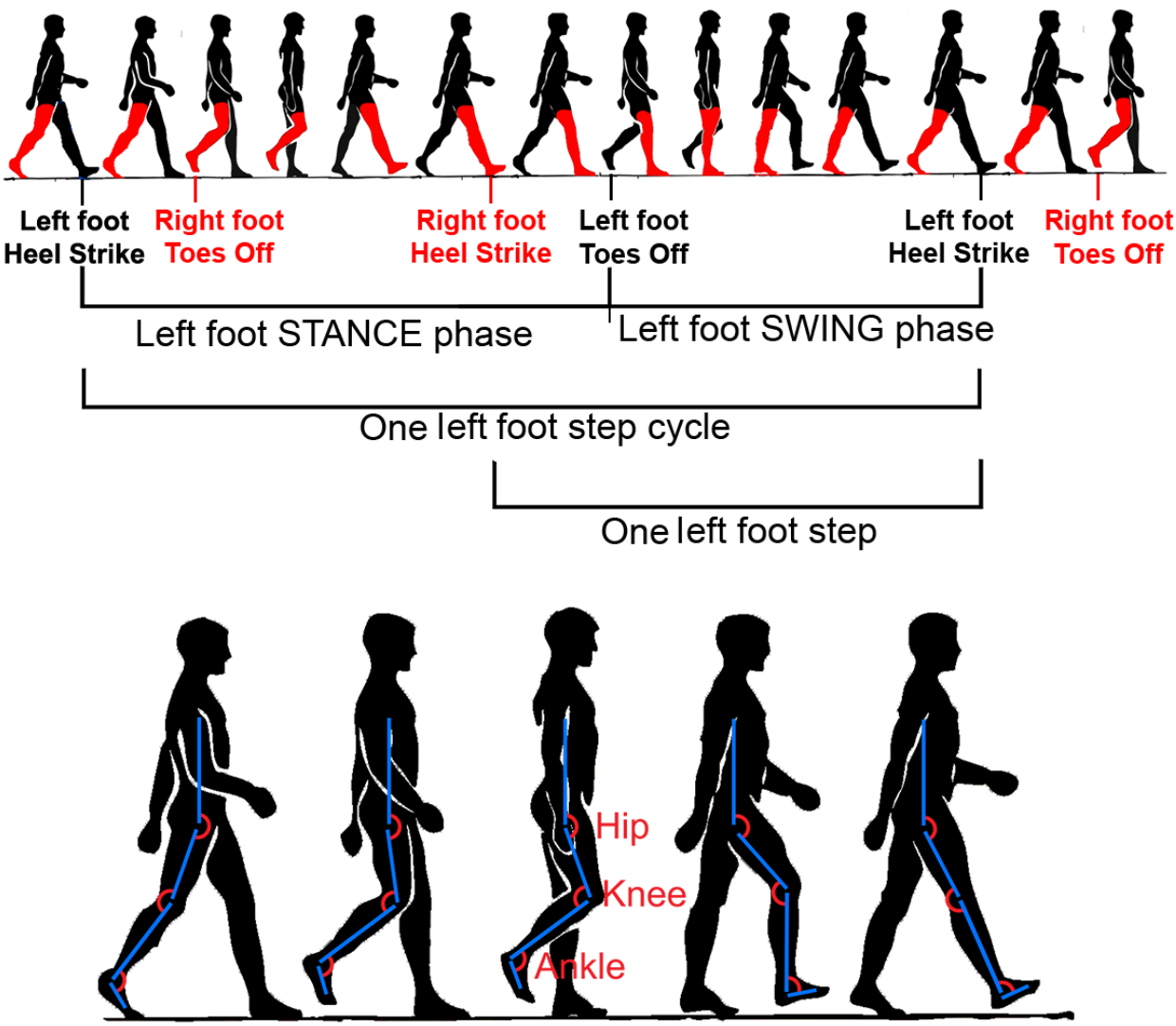
Results from a single participant with JHD in this study were analyzed qualitatively by an independent team of expert physiotherapists. They commented on the participant’s gait pattern and characteristics before cueing, during application of the rhythmic cue, and immediately after cueing.

Human Gait

Before moving on to the details of the study and the results obtained, it may be useful to clarify aspects of human gait and kinematics, including terminology used by physiotherapists to describe gait [20].

Each step, or step cycle, consists primarily of two phases: the swing phase and the stance phase. The swing phase, as the name suggests, happens from the moment the toes of the foot initiating a given step lift off the ground and the leg begins to swing forward (see Figure 1). This phase completes when the heel of that foot strikes the ground, beginning to support the body’s weight, thereby starting the stance phase (see Figure 1). Between each of two successive step cycles of alternating legs, there is what is known as the double-support phase, where both legs touch the ground, as illustrated in Figure 1.

Figure 1. Illustration of the human gait. The phases in human gait are shown at the top, and the joint flexions during one step are shown at the bottom.



The three principal lower-limb joints flex and extend during each step; these are the hip, the knee, and the ankle joint. A joint is said to flex during reduction of the joint angle and to extend when the angle increases. The relevant flexions and extensions of these joints during a typical step are shown at the bottom of Figure 1.

All of the above aspects of gait can be affected by neurological conditions such as HD, which affect the motor control centers in the brain. Precise effects can vary greatly depending both on the condition and the individual case. However, all of these conditions generally affect the activation patterns of one or more muscle groups, reducing the flexion capabilities of the lower-limb joints.

As briefly discussed in the sections below, walking to a steady rhythm can have various gait-related benefits. The next section considers entrainment, the underlying neurological mechanism that makes walking to a rhythm possible.

Entrainment

In physics, entrainment is a natural phenomenon where two or more periodic processes interact with each other to adjust to a common or related period. In the early 1990s, biological and specifically human aspects of entrainment were investigated in some detail. Studies showed that gait can be facilitated using rhythmic stimulation [1,21,22]. With these early studies, human capacity for biological entrainment became better understood, and applications for movement rehabilitation of neurological conditions were studied in more detail.

Applications included the use of auditory cues to synchronize human motor coordination into more stable temporal patterns. In such cases, entrainment mechanisms act between the external rhythm and the motor response to stabilize and regulate gait patterns [15].

Rhythmic Haptic Cueing

Haptics is a term used when referring to any form of communication involving the sense of touch [23] and can provide a valuable mode for mediating rhythmic cueing for entrainment and motor movement physiotherapy. RHC shows great potential in physiotherapy and rehabilitation, with similar and immediate benefits to the more established auditory cue; however, benefits from RHC can be achieved less obtrusively, while leaving the ears free for improved safety, social integration, and situation awareness [5,24]. Generally in

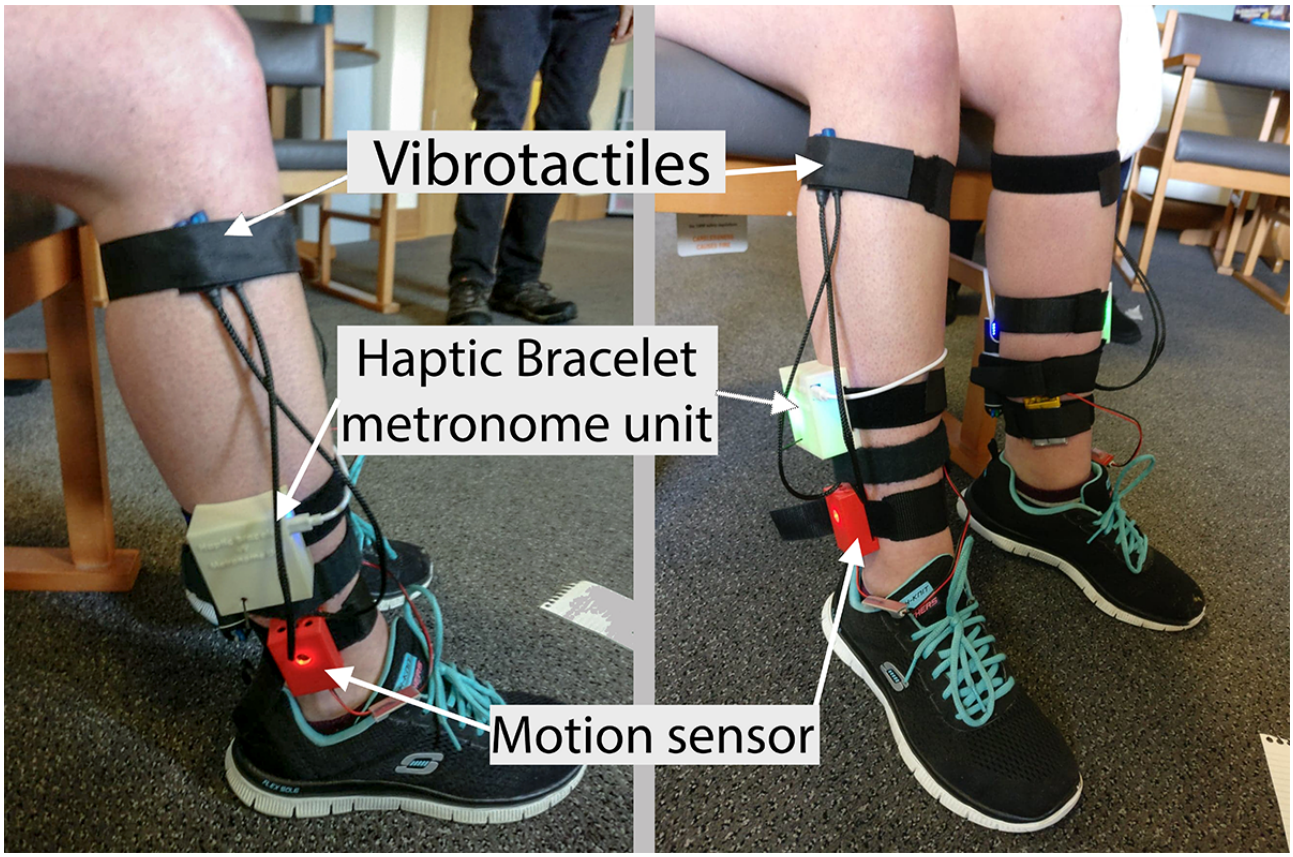
computing, particularly with mobile and wearable devices, uses of haptics are typically limited to notifications, such as alerts about incoming phone or text messages. This common mode of usage engages with relatively simple human stimulus-response mechanisms. By contrast, the mode of the considered use primarily does not engage with cognitively mediated nor reflex versions of stimulus-response mechanisms, but does engage with different human mechanisms that mediate human entrainment [25] and that are predictive rather than simply reactive [26]. Due to physiological delays, stimulus response is not a viable way to synchronize to rhythm [26].

The human capacity to entrain, on the other hand, can provide the fine-grained synchronization that allows movement to be coordinated, both physically and mentally [5], in synchrony to an external rhythm.

In this study, RHC was presented to the participant via the Haptic Bracelet system [5]. The Haptic Bracelet system is made up of prototype lightweight wearable devices, capable of providing RHC in the form of vibrations through carefully calibrated vibrotactiles on alternating legs, leaving the audio channel clear and free of distractions (see Figure 2). The Haptic Bracelet system includes a vibrotactile unit that produces the RHC. A vibrotactile unit is worn on each leg using Velcro straps. Each vibrotactile unit consists of an Arduino microprocessor board, a Wi-Fi board to communicate with an external control unit, a vibrotactile actuator, and vibrotactile motor drivers. The control unit consists of bespoke computer software that runs on a laptop and communicates with the vibrotactile unit via a Wi-Fi network. The researchers operate the system using the control unit. The Haptic Bracelet system also includes a motion sensor employing inertial measurement units that can track the motion of the participant as she walks on the runway. Detailed technical specifications of the Haptic Bracelet system have been previously published [5].

The next sections describe the methodology used and the initial results obtained.

Figure 2. The Haptic Bracelet wearable devices placed on the participant's legs (one device on each leg). The vibrotactiles used for delivering the haptic cues were strapped on near the knee using Velcro straps.



Methods

Study Design

The approach adopted for this study was a repeated-measures design that included *before* (ie, baseline), *with*, and *after* conditions, followed by an in-depth interview with a group of physiotherapists observing the session.

Research Participant and Setting

For this case study, in order to investigate the effects of RHC in the gait of people with HD, one female participant (RK; this is a pseudonym for the participant) was recruited from the PJ Care residential care home in the United Kingdom. The recruitment criteria included being diagnosed with HD, over 18 years old, and able to walk 10 meters independently. RK was 28 years old when the study was performed, and she was diagnosed with JHD at a young age. RK is a tip toe walker—physiotherapy partially addressed this. However,

frequent falls she recently experienced affected her confidence, causing her to be wheelchair bound when traveling outdoors. Her carer was present during the study for safeguarding.

RK provided written informed consent prior to this study. This study was conducted indoors within PJ Care's residential care center. The room used was large enough to accommodate a 10-meter-long, straight-line walking runway while at the same time allowing a group of physiotherapists to observe the walks. This room had carpeting that covered the entire floor.

The study received ethical approval from the London-Stanmore Research Ethics Committee of the National Health Service – Health Research Authority (17/LO/2050) and from The Open University's Human Research Ethics Committee (HREC/2017/2633/Holland1).

Procedure

Prebaseline

The participant (RK) was first asked to walk the length of a 10-meter runway six times without wearing the bracelets as a *prebaseline* measure. She was asked to walk as she normally would, allowing for the group of physiotherapists present to view how she walked without wearing any devices. These *prebaseline* walks made it possible to investigate whether wearing the devices would have any impact on her walk, even without cueing.

Baseline

For the next stage (ie, baseline), the Haptic Bracelet system components were attached to each leg, but without providing haptic cueing. RK was then asked to walk the length of a 10-meter runway six times (three times each way) to provide a baseline measure. The motion sensor unit tracked the motion for baseline measurements. A carer walked alongside RK for safety. A chair was placed on either end of the runway for RK to rest if needed between trials. Short breaks were scheduled between each session, but we also made clear to RK and her carer that they could request a break at any point during the study, even midtrial.

Familiarization Period

After completing the baseline set of trials without haptic cueing, the tactile metronome of the Haptic Bracelet system was switched on with RK simply sitting on a chair to feel the tactile cues. For the purpose of initial familiarization, a slow but arbitrary cueing rate was set. The tactile cue intensity was adjusted so that pulses could be felt clearly but without causing any discomfort. The placement of the vibrotactiles delivering the cues had been previously decided after consulting with physiotherapists during earlier studies [5,27] with stroke and brain injury survivors (see Figure 2 for vibrotactile placement).

Once the intensity was set to a comfortable level, the period of the metronome cue was adjusted for the participant to match her natural walking speed, as observed and calculated from the baseline condition. Setting the metronome's period to match the individual's natural walking rhythm is considered important for rhythm-based gait rehabilitation, generally, and for other conditions, as this approach has been found to help participants feel most comfortable in timing their steps to the beat of the rhythm [28].

Once the tactile intensity and the metronome period was adjusted, RK was asked to stand up and try to step in place following the metronome's rhythm without moving forward. At this stage, RK was asked again if she felt like she needed any further adjustments to be made on the metronome period or the vibrotactile intensity; we adjusted accordingly.

With-Cue and After-Cue Conditions

As previously noted, in addition to serving as a basis for comparison, the baseline measurements were used to establish a reference cadence for setting the tempo of the haptic cues for the *with-cue* condition. The with-cue condition consisted of six walks with haptic cueing switched on.

After a short 5-minute break, RK was invited to walk six more times while trying to walk to the rhythm from memory (ie, the *after-cue* condition). At this stage, RK has been walking for around 15 minutes in total, excluding break time. Even though RK was eager to walk, she exhibited higher levels of fatigue than we had anticipated, and her carer asked if we could end the session after four walks in the after-cue condition. In the interest of our patient's safety, we immediately complied.

Interview With Physiotherapy Experts

A group of five experienced and specialized physiotherapists were present in the room to observe the participant during all four conditions and to make detailed notes on their observations. After RK left the room, we held an in-depth interview with this group at the end of the session to discuss their observations. The physiotherapists also provided a formal gait-assessment report for each stage of this study, as shown in Table 1.

Table 1. Gait-assessment report by physiotherapists.

Phase	Participant (RK) movement	Observations
Prebaseline	RK mobilized 10 meters six times without wearing the haptic device.	Reduced hip flexion and no heel strike on stance phase
		Reduced hip and knee flexion during midswing
		Reduced toe-off
		Difficulty with turnings
Baseline	RK mobilized 10 meters six times while wearing the device that was not switched on.	Reduced hip flexion and no heel strike on stance phase
		Reduced hip and knee flexion during midswing
		Reduced toe-off
		Difficulty with turnings
With cues	RK mobilized 10 meters six times while wearing the device that was switched on.	Increased hip flexion and has a slight heel strike on stance
		Increased knee flexion during midswing
		Increased hip flexion, knee flexion, and toe-off, which help her clear the ground
After cues	RK mobilized 10 meters four times while wearing the device that was switched off to observe whether she was able to remember the rhythm.	Retains changes from previous trial
		Cannot fully comment on this, as this requires several trials to ascertain her ability to remember the sensation from the device by observing it through her gait pattern

Results

Observations From the Physiotherapists

Observations focused primarily on how RK's joint angles—hip, knee, and ankle (see Figure 1)—changed during her walking between conditions. The physiotherapists provided a gait-assessment report regarding RK for each phase of the study as summarized below in Table 1.

The gait patterns were further discussed in the interview following the walking trials. The two most senior physiotherapists in the team (ZN and AF; these are pseudonyms for these two PJ Care physiotherapists) led the conversation describing how RK walked in the prebaseline session (ie, walk with no devices). Specifically, both ZN and AF agreed that RK walked with reduced hip flexion causing her to land on the front part of her foot first (ie, toes area) showing no, or limited, heel strike during the beginning of her stance phase. ZN said, "RK has reduced hip flexion; knee flexion has reduced as well. There is decreased dorsi flexion, that's why she doesn't have any heel strike," and added, "reduced toe-off and not clearing the ground properly." According to the physiotherapists, RK showed reduced hip flexion during the swing phase and reduced knee flexion midswing, where knee flexion is normally at maximum. This caused RK to experience difficulties clearing the ground with her toes and may be a factor contributing to the frequent falls she is experiencing.

ZN and AF commented that there was no difference in the way that RK walked between the baseline and prebaseline conditions. This indicates that wearing the devices when switched off did not affect the way RK walked. However, both ZN and AF agreed that when the haptic metronome was switched on, and the devices gave RK a tactile cue on alternating legs matching her preferred pace, RK's hip flexion increased, giving her a slight heel strike at the beginning of her stance phase. ZN said the following:

> *I think when you put the bracelet [switch on haptic metronome] she has improved, because you can really see that there is a bit of hip flexion in there and then knee flexion. But there is no dorsi flexion; maybe it's just the point of her condition that's deteriorating. However, I saw that she also clears the ground more and because in Huntington's the basal ganglia [part of the brain] is affected and so gait initiation is difficult. That's why RK was swaying from side to side before making her first step.*

ZN then added, "The rhythm is helping with the initiation," and concluded, "The rhythm has helped with the flexion values; it is minimal but compared to baseline has improved."

Another change observed in this condition was that RK's knee flexion increased midswing, while her overall hip and knee flexion increased, allowing RK to have a better toe-off, clearing the ground better.

During the after-cue condition, when RK walked to the rhythm from memory (ie, when the haptic metronome was switched off again), the physiotherapists commented on how her walk pattern remained the same as in the with-cue condition. ZN said, "It's the same as I observed [as with-cue condition]. She has increased hip flexion, improved knee flexion but not dorsi flexion; she clears the ground better." RK's retaining of rhythm from memory is consistent with studies relating to other conditions [5] and suggests evidence of rhythm persistence, where a participant retains the rhythm in her head, and sustains gait improvements for a short period after cueing. This phenomenon has been observed in haptic cueing for the purpose of improving gait with other neurological conditions, particularly hemiparesis [5].

In addition to commenting on the changes in RK's gait, the physiotherapists explained how flexion and changes in joint angles are more relevant to HD rather than gait symmetry, which was important for hemiparetic stroke survivors as investigated in Georgiou et al [29]. They also mentioned that it seemed to them that "the devices have improved balance." For people living with HD, risk of falls is very high, and improving balance can help in reducing the frequency of falls. The physiotherapists observed that both when walking with the haptic metronome turned on and immediately afterward without the metronome, it seemed that RK had a better sense of balance when walking.

The physiotherapists also commented about the key parameters that can be useful to measure when using the wearable sensors to support the visual assessment. They have suggested measuring speed of walking, stride length, and joint angle kinematics for flexion angles to better understand toe-off and heel strike events. They also suggested, if it was possible, to measure "how far someone has walked," adding "possibly outdoor walking."

They provided critical feedback on certain issues that this study could not address; for example, the issue of turning and fatigue. They observed that RK was more comfortable with straight-line walking than turning. The nature of RHC is such that, at this stage, it can facilitate straight-line walking but cannot address turning. Also, the physiotherapists observed that RK was getting fatigued during the study, and RK's carer suggested to end the study before she could complete the six trials for the after-cue condition. However, it was not possible to determine the actual reason for RK's fatigue. It was not clear whether, due to RHC, the cost of energy of walking was increased, whether RK got fatigued as she was not used to walking independently, or whether she felt pressure to perform better while being observed.

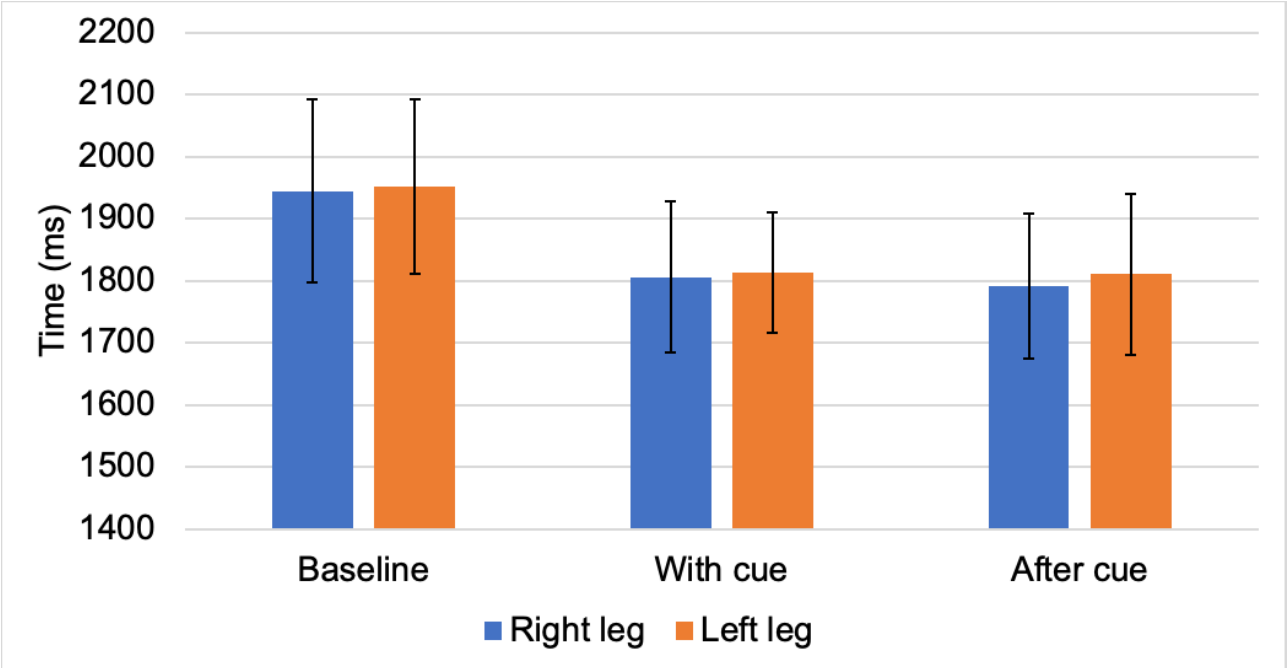
Data From the Motion Sensors

The motion sensors used in this study consisted of two inertial measurement units, one placed on each ankle of the participant. The data were sent to the control unit software running on the laptop via the Wi-Fi network. The data obtained were analyzed using bespoke algorithms running on MATLAB (The MathWorks, Inc) [5].

The following results show the temporal gait parameters for both legs in the baseline, with-cue, and after-cue conditions. Figure 3 shows the stride cycle time for both legs for the three experimental conditions. It is clear from the results that due to RHC, the time taken to complete a stride was reduced for both legs; in addition, the same rate was retained for the after-cue condition. This further supports the observations of the physiotherapists that RHC has changed RK's gait pattern and she has been able to retain the changes from memory.

The motion sensors used in this study could not measure the change in flexion and joint angles on which the physiotherapists commented. To measure such changes on joint angle kinematics, a different motion-tracking facility is required, such as a 3D, optical, motion-capture system or a seven-sensor inertial measurement unit system [30].

Figure 3. Temporal gait parameters (stride cycle time) for both legs in the baseline, with-cue, and after-cue conditions.



Discussion

Principal Findings

In this preliminary study, a single participant with JHD walked indoors following a steady rhythm. The steady rhythm was delivered haptically through carefully controlled tactile cues on alternating legs at a cadence set to match the participant's preferred pace, as measured during initial baseline trials. The participant's gait was visually observed by a group of experienced physiotherapists.

The team of physiotherapists reported changes in the flexion of RK's joints, rather than changes such as improved spatial and temporal symmetry, which are typically reported for other neurological conditions such as hemiparesis [5,31].

In this study, motion sensors were used to measure temporal gait parameters for the walking trials. Results from temporal data show both that RHC was associated with changes in gait pattern when the Haptic Bracelet system was switched on and that RK could retain a similar improved walking pattern after the cue was withdrawn. One of the limitations of this study is that the two ankle-worn motion sensors were not designed to measure all of the parameters relevant to all of the changes in gait kinematics that the physiotherapists' observed. A more sophisticated motion-tracking system would be required to measure changes in gait kinematics, such as joint angles. However, this was not practical in the case of this study. A potential alternative could be to use a portable, wearable, motion-tracking setup using seven inertial measurement units [30].

The team of physiotherapists concluded that RK assumed generally better walking kinematics, exhibiting better joint flexion, during both the with-cue and the after-cue conditions. This allowed for better ground clearance, potentially reducing RK's risk of falling.

Even though RHC can potentially improve gait features for straight-line walking, RHC's effect on turning is not clearly understood. The physiotherapists observed that RK was facing difficulties while turning. It is not yet clear whether the RHC was interfering with RK's turning motion or whether RK was being extra cautious, as people tend to have a higher risk of falls while turning [32]. RK might lack confidence in turning due to her history of frequent falls.

The physiotherapists observed that RK was experiencing fatigue toward the end of the study. It is not well understood whether RHC can be a contributing factor to fatigue. Other factors may cause fatigue; HD itself, for example, can be a contributing factor to fatigue, as this is one of the symptoms of the disease. Other possible causes of fatigue could be RK's overall lack of physical activity leading to low stamina or RK putting more effort into her walks because she was being observed. However, in general terms, it is not clearly understood whether RHC can increase the cost of energy of walking.

Conclusions

The observations from this preliminary study suggest that RHC may have immediate benefits for walking among individuals with HD, potentially extending the period of independent mobility for people with HD. This warrants further investigation.

Further Work

One of the limitations of the study is that there was only a single participant. Previous research on RHC using wearable devices has shown immediate changes to gait pattern for people living with neurological conditions such as hemiparesis [29]. To the best of our knowledge, this study is the first step in investigating how RHC using wearable devices can help people living with HD. A number of lessons can be drawn from this preliminary work that can feed forward to future research in this field.

Further studies with more participants with HD or JHD can be conducted to investigate whether the immediate benefits observed in this study can be replicated in others. Long-term studies can also be conducted to investigate whether the immediate benefits of RHC can be sustained for a longer period of time and how this might lead to extended periods of independent mobility for people with HD or JHD.

Acknowledgments

RI is supported by the Goldcrest Charitable Trust. BP is partly supported by the Engineering and Physical Sciences Research Council (grant Nos. EP/R033862/1, EP/R013144/1, and EP/P01013X/1).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary data: baseline stride time.
[XLS File (Microsoft Excel File), 29 KB - rehab_v7i2e18589_app1.xls]

Multimedia Appendix 2
Supplementary data: with-cue stride time.
[XLS File (Microsoft Excel File), 28 KB - rehab_v7i2e18589_app2.xls]

Multimedia Appendix 3
Supplementary data: after-cue stride time.
[XLS File (Microsoft Excel File), 28 KB - rehab_v7i2e18589_app3.xls]

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Abbreviations

HD: Huntington disease
JHD: juvenile Huntington disease
RHC: rhythmic haptic cueing

Edited by G Eysenbach; submitted 06.03.20; peer-reviewed by R Haghighi Osgouei, L Siqueira do Prado, B Jyoti; comments to author 30.04.20; revised version received 15.06.20; accepted 11.08.20; published 14.09.20.

Please cite as:
Georgiou T, Islam R, Holland S, van der Linden J, Price B, Mulholland P, Perry A
Rhythmic Haptic Cueing Using Wearable Devices as Physiotherapy for Huntington Disease: Case Study
JMIR Rehabil Assist Technol 2020;7(2):e18589
URL: http://rehab.jmir.org/2020/2/e18589/
doi:10.2196/18589
PMID:32924955

Original Paper

Data-Driven Personalization of a Physiotherapy Care Pathway: Case Study of Posture Scanning

Olli Korhonen[1], MSc; Karin Väyrynen[1], PhD; Tino Krautwald[2,3], MSc; Glenn Bilby[2], BSc, BPhysio, MBA; Hedwig Anna Theresia Broers[4], MSc; Guido Giunti[1], PhD; Minna Isomursu[1], PhD

[1]University of Oulu, Oulu, Finland

[2]Qinematic, Stockholm, Sweden

[3]Blekinge Institute of Technology, Karlshamn, Sweden

[4]Bright Cape, Eindhoven, Netherlands

Corresponding Author:
Olli Korhonen, MSc
University of Oulu
Pentti Kaiteran katu 1
Oulu, 90014
Finland
Phone: 358 294481952
Email: olli.korhonen@oulu.fi

Abstract

Background: Advanced sensor, measurement, and analytics technologies are enabling entirely new ways to deliver health care. The increased availability of digital data can be used for data-driven personalization of care. Data-driven personalization can complement expert-driven personalization by providing support for decision making or even by automating some parts of decision making in relation to the care process.

Objective: The aim of this study was to analyze how digital data acquired from posture scanning can enhance physiotherapy services and enable more personalized delivery of physiotherapy.

Methods: A case study was conducted with a company that designed a posture scan recording system (PSRS), which is an information system that can digitally record, measure, and report human movement for use in physiotherapy. Data were collected through interviews with different stakeholders, such as health care professionals, health care users, and the information system provider, and were analyzed thematically.

Results: Based on the results of our thematic analysis, we propose three different types of support that posture scanning data can provide to enhance and enable more personalized delivery of physiotherapy: 1) modeling the condition, in which the posture scanning data are used to detect and understand the health care user's condition and the root cause of the possible pain; 2) visualization for shared understanding, in which the posture scanning data are used to provide information to the health care user and involve them in more collaborative decision-making regarding their care; and 3) evaluating the impact of the intervention, in which the posture scanning data are used to evaluate the care progress and impact of the intervention.

Conclusions: The adoption of digital tools in physiotherapy has remained low. Physiotherapy has also lacked digital tools and means to inform and involve the health care user in their care in a person-centered manner. In this study, we gathered insights from different stakeholders to provide understanding of how the availability of digital posture scanning data can enhance and enable personalized physiotherapy services.

(JMIR Rehabil Assist Technol 2020;7(2):e18508) doi:10.2196/18508

KEYWORDS

digital health services; information systems; case reports; qualitative research; physiotherapy; posture

Introduction

Background

Health care is becoming increasingly data-driven [1,2]. Availability of digital data creates opportunities to deliver care in entirely new ways and to enhance current care models. Collectively, data-driven health care is enabled by information systems that seamlessly integrate the data and best care practices for health service delivery [3,4]. Information systems are powerful tools that can capture, store, process, and communicate timely information that can be used for the personalization of care [5] and can provide the right information to the right person in the right format [6]. Big data approaches [7], telehealth technologies [8], novel interactive visualization techniques [9], and artificial intelligence (AI)–based solutions [10] represent some ways in which information systems can be used to enable care that is more data-driven but is also aligned with the needs of the individual health care user in a personalized manner. Current care models highlight the importance of placing the health care user at the center of their care [11], which is often referred to as patient-centered care [12]. Personalization can be used to empower health care users to understand what matters to them [13].

Researchers have envisioned that in this form of participatory health care, the role of the health care professional is to complement the health care user's own resources in managing their health so that the combined resources of these stakeholders will lead to the most optimal decisions regarding care [6]. A participatory approach to health care is often applied in physiotherapy, where user involvement is imperative for care, as the health care user drives the intervention and participates in decisions on how the intervention is sustained [14,15].

In health care, personalization often takes place in the interactions between the stakeholders; it involves the collective use of different health care technologies and the health care service system where the service is delivered [16,17]. However, in the field of personalization, there is a lack of research focusing on personalization at the level of the entire care process [17] and on the use of theoretical personalization frameworks in the design of health care technologies [18]. Increasing numbers of health care technologies are becoming available for different chronic conditions [19]; however, in physiotherapy, a common problem is that health care users are not readily provided with tools and information that enable them to participate in the care process in a person-centered manner [20].

Many studies have concluded that adoption of digital tools to support rehabilitation practice remains low, even though physiotherapists see potential in digitally supported rehabilitation [21]. Personalization has been found to be a key factor in acceptability and adoption of digital technologies in a rehabilitation context and in value creation [22,23]. Previous attempts to achieve more personalized physiotherapy with adoption of information systems include a checklist for choosing the most suitable health care users for blended physiotherapy [24] and an investigation of how adoption of information systems alters bodily action during clinical encounters and perception of agency in care-related interactions [25].

Service design is a set of design methods which integrate the possibilities and means to design and deliver a service while keeping the stakeholders, context, and other service development challenges at its heart [26]. Service design takes all the different stakeholders who are part of the service delivery into consideration to understand their needs and expectations [27,28]; this also applies to health care [29]. The importance of considering the health care user's experience and the service encounters between the health care user and health care provider in health care service design has been identified in prior research [30]. However, in the design of health care technologies, the viewpoints of relevant stakeholders who are involved with and impacted by the service system are still often not addressed [31].

Goals

In this study, we aimed to investigate how the availability of a new set of digital data, namely posture scanning data, can enhance and enable more personalized delivery of physiotherapy. The research question we asked is: *How does posture scanning data enable more personalized delivery of physiotherapy?*

Methods

Study Design

To answer our research question, we conducted a case study. Case studies are useful when there is a need to understand a complex social phenomenon that occurs in a real-world setting [32,33]. Our unit of analysis was an information system called a posture scan recording system (PSRS). The PSRS can be used to digitally record, measure, and report human movement when a health care user visits a physiotherapist. We selected this specific case because it allowed us to explore a real-world setting where an information system is used in a health care context for personalizing care to fit the needs of a specific health care user. Our aim was to gain insights from the different stakeholders involved in physiotherapy: the developers of the PSRS as well as the health care professionals and health care users who can use the PSRS to design novel personalized health care services in physiotherapy.

Setting

The study was conducted as part of a development and research project involving four partners in three countries: Finland, Sweden, and the Netherlands. The PSRS was designed by the Swedish company Qinematic AB, has been commercially available since 2017, and has been continuously developed since then. The data collection and analysis were led by the University of Oulu in Finland in collaboration with the Swedish research institute RISE SICS and Bright Cape. Interviews with Qinematic personnel and the health care users were conducted in Sweden. Interviews with the health care professionals were conducted in the Netherlands.

The PSRS

The PSRS is an information system solution that can be used in physiotherapy to record, measure, analyze, and report a health care user's movement and posture at the point of care. This

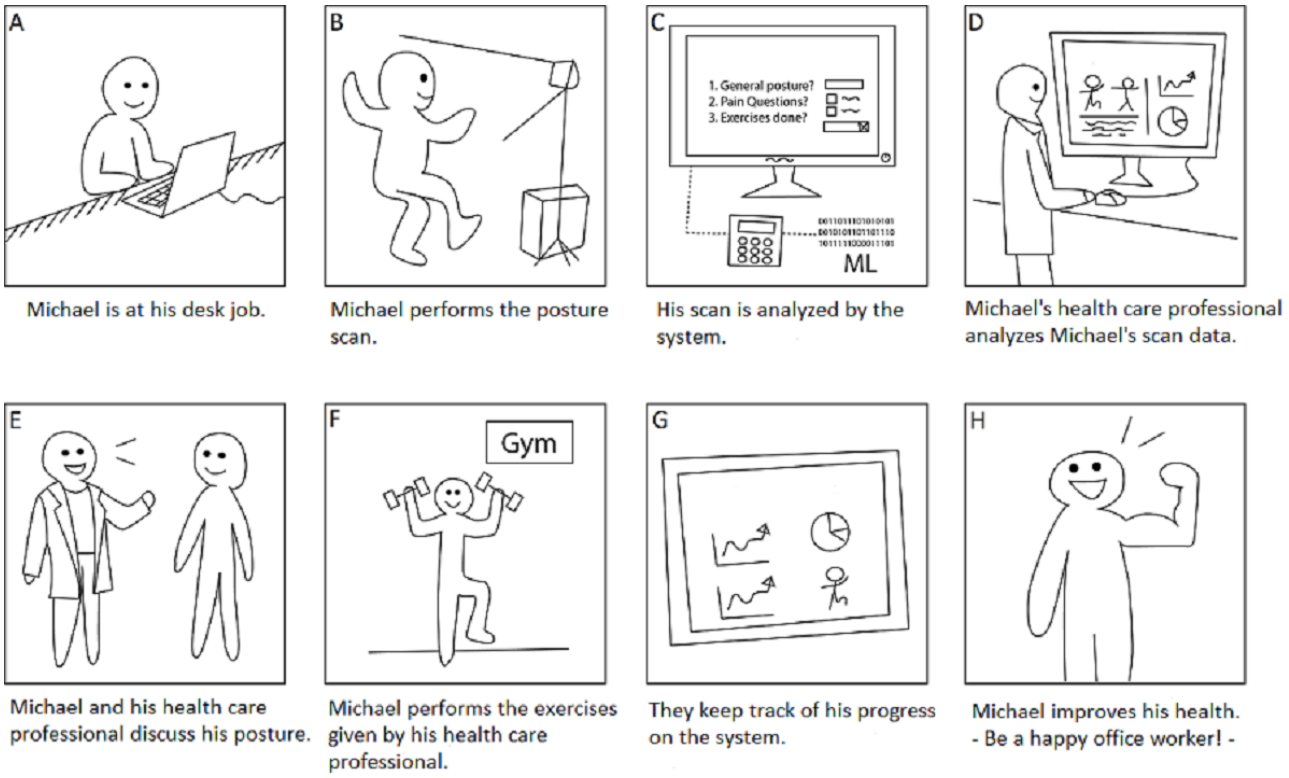
functionality is expected to increase the personalization of care by providing a more accurate understanding of the physiology of a specific health care user, better communication of the user's medical condition and the effectiveness of care, and better targeting of care. The PSRS consists of two main information system components: Qinematic Posture Scan and Qinematic Movement Lab. The first component, PSRS Posture Scan, is used by the health care professional to objectively assess the health care user's movement through an image processing system. The second component, the PSRS Movement Lab, is used as a communication and reporting tool between the health care professional and the health care user. Health care professionals can use this system to create a therapy training plan that includes rehabilitation-related exercises (type, interval, and frequency of exercise), administer questionnaires, and schedule follow-up physiotherapy assessments. Health care users can report their exercise adherence and respond to prompted questionnaires (eg, to report pain).

At the time of the interviews, the PSRS Posture Scan was fully developed and in use, whereas the PSRS Movement Lab was still under development. Therefore, as no functional software for the PSRS Movement Lab existed at the time, a paper prototype [34] of the PSRS Movement Lab was used to illustrate its implemented and future functionalities to the health care users and professionals. A detailed description of the PSRS in the form of a storyboard is provided for more context.

PSRS Storyboard

A storyboard is a narration that describes the stakeholders' activities when using a service [35]. We used a storyboard to illustrate the roles of the different stakeholders and the posture scanning in the physiotherapy care pathway using a fictional persona, a health care user named Michael. Care pathways (also known as clinical pathways) are longitudinal and multidisciplinary treatment plans that describe all desired diagnostic and treatment steps for ensuring coordination and continuity of care [36,37]. The storyboard of the physiotherapy care pathway is depicted in Figure 1.

Figure 1. Storyboard depicting the use of posture scanning in the physiotherapy care pathway.



The storyboard starts by presenting Michael, a sedentary worker who suffers from pain and decreased movement (A). Michael consults a health care professional; after providing certain information, such as gender, age, body weight, a discomfort report with International Classification of Disease, Tenth Revision (ICD-10) comfort pain areas, and a fall report as a potential indicator of inability to perform the movements to be scanned, he is scanned by the Posture Scan at the point of care (B). The Posture Scan uses machine learning algorithms to analyze Michael's movement levels (C). Once the scan is completed successfully, a report about Michael's movement is generated for Michael and the health care professional. The health care professional analyzes the aggregated data (D) and discusses the results with Michael (E) to create a personal training plan for Michael using Movement Lab. Michael can see the therapy training using the Movement Lab application and commits to performing the prescribed exercises at home (F). Michael reports his progress to the health care professional using Movement Lab (G). After some time, Michael's posture may improve (H), and the improvement will become visible in a new Posture Scan. Between the initial posture scan and the possible improvement of Michael's posture, Michael and the therapist may be in contact via the PSRS Movement Lab and

may have physical meetings to evaluate the effects of the exercises and adjust them if necessary.

Data Collection

The interviews represent our primary data. The data were collected between February and May 2018. The participants were informed of the nature of the study and signed an informed consent form. The stakeholders interviewed were Qinematic staff, healthy individuals who represented health care users, and health care professionals in the physical therapy domain. In the interviews, we followed a protocol where one researcher always led the conversation while a second researcher took field notes. All interviews were audio-recorded and transcribed. Interviews with Qinematic staff and health care users were conducted in English, while the interviews with health care professionals were conducted in Dutch. Dutch to English translation was performed by AB, who conducted the interviews with the health care professionals and is a native Dutch speaker.

1. Qinematic staff: We conducted a group interview (90 minutes) with a service designer and a human movement scientist. The aim was to gain a general understanding of the design and development of the PSRS, the role of the PSRS in health care, and the challenges and decision-making process regarding personalization. We also asked about the role of the PSRS in supporting the health care professional and the health care user in personalization.
2. Health care users: We conducted seven semistructured interviews (average 45 min) with healthy individuals (all adult volunteers) who were recruited for the user study to collect user experiences and expectations regarding the use of the PSRS. Personalization was a theme in the interview. The interviewees were asked to consider how the PSRS could ideally be integrated with their needs, what value this could create, and what type of personalization they would expect to receive while using the PSRS. As the interviewees did not have prior experience with the PSRS or with any other form of human movement analysis system, they each underwent a Posture Scan (at the Swedish research institute) and had a discussion with the health care professional before the interview.
3. Health care professionals: We conducted two group interviews and nine semistructured interviews (average length: 45 minutes) with 13 health care professionals (5 general physiotherapists, 2 personal trainers, 3 occupational physiotherapists, 1 movement therapist, and 2 manual therapists) who worked with health services in physiotherapy. Interview themes concerned the role and use of information systems as part of health service delivery and the professionals' work practices in general, with more focused questions about the support that the PSRS can provide for the health care professional to treat the individual health care user. As only one health care professional had prior experience with the PSRS, we demonstrated the Posture Scan and reporting procedure of the Movement Lab with paper prototypes before the interviews.

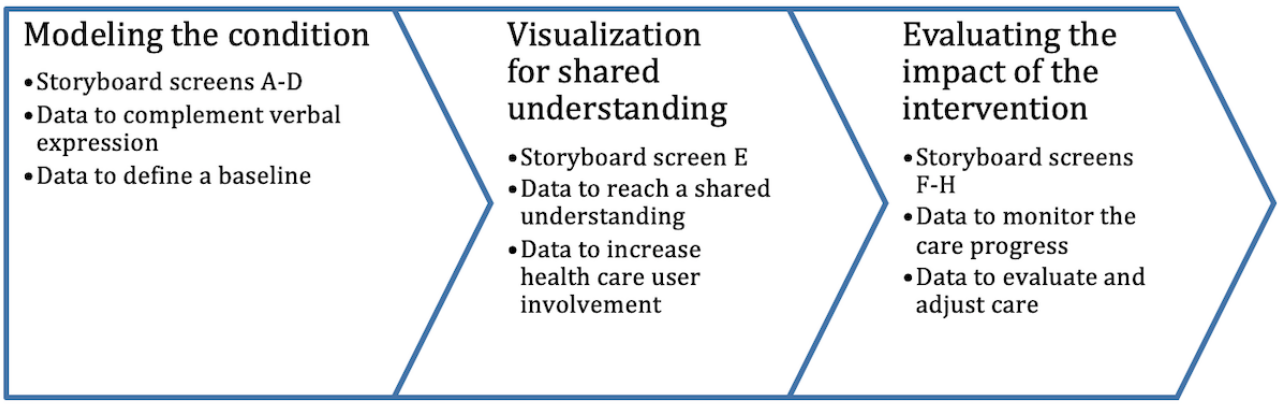
Data Analysis

The collected data were analyzed thematically [38]. In the thematic analysis, we first familiarized ourselves with the data (a total of 117 A4 pages of transcript material). Second, we analyzed the viewpoints of the different stakeholders separately to form a general understanding of the themes in each viewpoint. Third, we compared the themes between the viewpoints, and the authors held extensive discussions to generate the higher-level themes that we found to be shared by the different stakeholders. As a result, we identified three main types of support that posture scanning can provide to enhance and enable more personalized delivery of physiotherapy.

Results

Based on our data analysis, we identified three different types of support that posture scanning can provide to enhance and enable a more personalized delivery of physiotherapy: 1) Modeling the condition, in which the posture scanning data are used to understand the health care user's current condition and the root cause of the possible problem or pain; 2) visualization for a shared understanding, which includes themes about the use of posture scanning data to enable health care users to be more informed about and involved in their care decisions; and 3) evaluating the impact of intervention, which includes themes related to the use of posture scanning data as a new means for the stakeholders to monitor and evaluate the impact of the intervention. An overview of the three types of support is shown in Figure 2.

Figure 2. Three types of support posture scanning can provide for data-driven personalization of physiotherapy.



Modeling the Condition

The first type of support concerns the use of posture scanning data to model the current movement levels and condition of the individual health care user who is seeking help. As the health care user consults the health care professional (Screen A in the storyboard) and verbally expresses discomfort, the posture scanning data can provide information to complement the health care user's verbal description. However, the actual root cause of the problem may be a dysfunction that is challenging for the health care user to verbally describe. With vague descriptions, the evaluation of the health care user's current condition may take longer; however, the data can support the health care professional in understanding the condition and the possible root cause of the pain (Screen B):

> *(If the health care user has pain in the knee) the health care professional can see that the knee is not the problem. The problem is the weak hip that causes the pain to the knee.* [Information System Developer 1]

> *If the problem of the health care user is not clear [for example difficulty with getting out of the chair], it can be a trigger to do the Posture Scan because that can yield results sometimes. If it is a medical thing you need a physiotherapist, but with vague complaints the Posture Scan can give some useful information.* [Health Care Professional 4]

The posture scanning data is processed through machine learning algorithms (Screen C) that quantify movement and enable monitoring of progress and potentially identify the cause of pain. The quantification of movement levels supports the health care professional in defining the baseline for care (ie, the care starting point for the individual health care user) (Screen D).

Visualization for Shared Understanding

The second type of support concerns the use of posture scanning data in reaching a shared understanding on the care options. Posture scanning can be used to visualize the health care user's movement levels through data displays, which can then be used to guide the discussion between the health care professional and the health care user. The health care users were expecting the health care professional to be active in explaining the care options and leading the decision-making regarding the care options; however, the visualization through data displays also provided a means for the health care user to be more informed and involved in the discussions:

> *We call this like a communication tool between health care professional and health care user. With this system, the health care professional can say to a health care user that you still have pain, but your movement is much better so keep going with [the rehabilitation].* [Information System Developer 1]

> *The communication with the health care user now goes via WhatsApp and that is just easily accessible and quick. Via PC it is a step back. I would use the scan to show progress. Then I can numerically show people that they are doing better.* [Health Care Professional 10]

The importance of reaching common ground and keeping the health care user informed was also prevalent in the case of motivation. The level of motivation to commit to the exercises was discussed by the health care professionals, as they reported using different motivational techniques and pep talks to address the importance of the exercises. The need for these techniques was apparent, as the health care users were not always motivated to commit to and follow the care options that were verbally discussed and agreed upon at the appointment:

> *Most people just do not want to do exercises. Of course, these exercises are somewhat boring, but that is why you have to try and find a way and think with your health care user. What they have to do and when.* [Health Care Professional 1]

Visualization through data displays can be an informative and illustrative way to represent the movement levels to the health care user (Screen E). Visualizing the potentially decreased movement levels can be a more concrete way to illustrate the connection between the potential problem or pain and the care options and prescribed exercises.

Evaluating the Impact of the Intervention

The third type of support concerns the impact evaluation of the intervention. As the health care user conducts the prescribed exercises using the Movement Lab (Screen F), the aggregated data help the health care professional monitor the care process. The data also provide evidence that the prescribed exercises have been effective (Screen G) and that the movement has potentially improved. In some cases, the health care user's pain level may not yet have changed, even though their movement levels may have already improved:

> *If, for example, my back pain has not improved, I expect some personalized help from the health care professional. Maybe exercises need to be changed or the time plan.* [Health Care User 1]

In such cases, the aggregated data were seen to be especially useful:

> *I would use the scan to show progress. Then I can numerically show people that they are doing better.* [Health Care Professional 10]

The evaluation of the impact of the intervention also included a comparison of the aggregated data sets. Comparison of data can show whether the health care user's movement levels have improved (Screen H). In addition, the data aggregated by Posture Scan and the data that health care users report using Movement Lab can be used as a basis to collaboratively evaluate why the movement levels and pain levels have not (yet) improved:

> *You can compare scan 1 and 2. The health care user can say that s/he has done the exercises but has not improved. The exercise may be wrong, or the health care user has done the exercise wrongly or has not done the exercises at all.* [Information System Developer 2]

In the case that their condition did not improve, the health care users expected personalization of care in a way that considered the aggregated data:

> *If I get exercises to do every day, I will do it, but I also want to do another scan to see the progress. If there has been progress, fine, but if not then I want to contact the health care professional and get an appointment.* [Health Care User 5]

The aggregated data provide a means for the health care professional and the health care user to consider and evaluate the potentially changed movement levels and pain levels of the health care user. The aggregated data also provide evidence for the health care professional to evaluate the impact of the intervention and to consider with the health care user what to change and do differently; this can result in a more personalized care process.

Discussion

Principal Findings

This study investigated how the availability of a new set of digital data, namely posture scanning data, can support and enable more personalized delivery of physiotherapy. We propose that posture scanning data can provide three different types of support to enhance traditional expert-driven physiotherapy and to help personalize the delivery of physiotherapy. The three types of support that we identified and described are 1) modeling the condition, 2) visualization for shared understanding, and 3) evaluating the impact of the intervention. Through our case study, we also described the potential to create value from the data. This knowledge can help to ease the adoption of information systems in physiotherapy, which still remains low in practice [21].

The findings of this study show that posture scanning data can provide new means to deliver and co-create a care service. The aggregated posture scanning data can be used to quantify the health care user's movement levels, which provides new means for the health care professional to evaluate the health care user's movement condition. The visualization of data can also be illustrative for the health care user to be more involved and informed regarding their movement and physical therapy. This provides new possibilities to increase the agency of the health care user, which can improve their quality of health (eg, through better adherence) [39].

Our findings show how the posture scanning data can be blended into the traditional physiotherapy service encounter and how they can be seamlessly integrated into the care practice. Increasing amounts of data about the individual health care user can be aggregated through different devices and sensors. The findings of this study increase our understanding of the value of these data for the core stakeholders in the context of physiotherapy.

Comparison With Prior Work

As people collect more personal data about themselves and organizations store information on their interactions with people [40], data are becoming a core component of current care models [12]. Information systems are among the main facilitators of these care models; they facilitate the integration of different data sets and best care practices to enable seamless health service delivery in a person-centered manner [3,4,11]. The aggregated data can support health care professionals in complementing the health care user's own resources in managing their health [6]. As health care users are also increasingly using different technologies and data sources to manage their health [41], health care professionals may need to be ready to support health care users in interpreting and using the data stored and processed by the various different technologies used in care [42-44]. This study contributes to this area of research and practice by providing insights on how the availability of digital data can enhance and personalize physiotherapy services. The findings are derived from the insights gathered from the stakeholders. This is rarely done in the field of personalization [45]. In their study, Cena et al [45] used a personal informatics system to collect evidence from users to aid the research and practice of personalized services. The findings of this study therefore extend this area of personalization research, where personalization is examined through the viewpoints of stakeholders who co-created the service.

Lee [30] proposed a model of health care service pathway design which takes into account the influence of different service encounters by technologies (including mobile apps and websites), health care user interactions with health care professionals, and care service outcomes on the health care user experience. Our study provides a concrete example of how advanced technology in the form of a posture scanning system can be integrated into the design of physiotherapy services and of the different types of support such a system can provide for the interaction between the physiotherapist and health care user; this will hopefully result in better health service outcomes.

Service design is not often used in health care [46], as different quantitative approaches and statistical outcomes have been more valued than qualitative methods [47]. The service design approach considers the needs and expectations of the different stakeholders who are involved in and impacted by the service [27]. More recently, the service design approach has shown benefits in the design and implementation of different health care technologies, such as the implementation of an electronic health record (EHR) [28]. The continuous development of different technologies provides new possibilities for the design of service encounters [48]. This study demonstrates the use of the service design approach to explore the needs and expectations of different stakeholders who are involved in and impacted by the service. Our study shows how these viewpoints can be taken into account in the design of information system solutions and new care models that can better support personalization.

Limitations

Like most research, this study has limitations. First, the reported case study was conducted in Northern European countries, and all the study participants were working in these countries. Therefore, this study does not account for cultural differences worldwide, which can be considered as a limitation to the generalizability of the results. Second, we collected data from different stakeholder viewpoints; however, for ethical reasons, the health care users were healthy individuals who were recruited through purposeful sampling. However, as the PSRS

can also be used to provide data for healthy individuals who are interested in their movement levels, we believe that even though the users were not currently in need of physiotherapy, they were capable of reliably expressing a user's viewpoint, opportunities, and expectations regarding personalization.

Conclusions

Health care is becoming increasingly data-driven. The availability of digital data can be used for data-driven personalization, providing opportunities to align the care process more closely with the needs of an individual health care user in a person-centered manner. In physiotherapy, the adoption of digital tools that can support rehabilitation practice has remained low; however, personalization is considered to be the key factor in the adoption of digital technologies. This study contributes to this area of research by proposing three different types of support that digital data acquired from posture scanning can provide to enhance and enable more personalized delivery of physiotherapy. The results of this work provide insights for the design of personalized health care services that consider the viewpoints of different stakeholders in the future of personalization. Future research could also investigate and measure the effects of using a posture scan system and its data on the outcome of the physiotherapy service—for example, does the use of the system shorten the time required for health care users to recover from a certain type of health problem or overcome pain in a specific body part? Future research could also investigate in more detail how the viewpoints of the three different stakeholder groups—health care professionals, health care users, and information system providers—should be integrated when designing personalized health care services.

Conflicts of Interest

Author GB is the founder of Qinematic, and author TK is an employee of Qinematic.

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Abbreviations

AI: artificial intelligence
EHR: electronic health record
ICD-10: International Classification of Disease, Tenth Revision
PSRS: posture scan recording system

Edited by G Eysenbach; submitted 02.03.20; peer-reviewed by CF Chung, M Ainsworth; comments to author 20.04.20; revised version received 04.06.20; accepted 25.06.20; published 15.09.20.

Please cite as:
Korhonen O, Väyrynen K, Krautwald T, Bilby G, Broers HAT, Giunti G, Isomursu M
Data-Driven Personalization of a Physiotherapy Care Pathway: Case Study of Posture Scanning
JMIR Rehabil Assist Technol 2020;7(2):e18508
URL: http://rehab.jmir.org/2020/2/e18508/
doi:10.2196/18508
PMID:32930667

Original Paper

Acceptability of a Mobile Phone–Based Augmented Reality Game for Rehabilitation of Patients With Upper Limb Deficits from Stroke: Case Study

Nina LaPiana[1], BS; Alvin Duong[2], BS; Alex Lee[3], BS; Leon Alschitz[3], BS; Rafael M L Silva[3], BS, MS; Jody Early[2], PhD, MS, MCHES; Aaron Bunnell[4], MD; Pierre Mourad[1,3], PhD

[1]Department of Neurological Surgery, University of Washington, Seattle, WA, United States
[2]Nursing and Health Studies, University of Washington Bothell, Bothell, WA, United States
[3]Department of Engineering and Mathematics, University of Washington Bothell, Bothell, WA, United States
[4]Rehabilitation Medicine Clinic, Harborview Medical Center, Seattle, WA, United States

Corresponding Author:
Nina LaPiana, BS
Department of Neurological Surgery
University of Washington
1959 NE Pacific St
Seattle, WA, 98195
United States
Phone: 1 206 221 8967
Email: lapiana@uw.edu

Abstract

Background: Upper limb functional deficits are common after stroke and result from motor weakness, ataxia, spasticity, spatial neglect, and poor stamina. Past studies employing a range of commercial gaming systems to deliver rehabilitation to stroke patients provided short-term efficacy but have not yet demonstrated whether or not those games are acceptable, that is, motivational, comfortable, and engaging, which are all necessary for potential adoption and use by patients.

Objective: The goal of the study was to assess the acceptability of a smartphone-based augmented reality game as a means of delivering stroke rehabilitation for patients with upper limb motor function loss.

Methods: Patients aged 50 to 70 years, all of whom experienced motor deficits after acute ischemic stroke, participated in 3 optional therapy sessions using augmented reality therapeutic gaming over the course of 1 week, targeting deficits in upper extremity strength and range of motion. After completion of the game, we administered a 16-item questionnaire to the patients to assess the game's acceptability; 8 questions were answered by rating on a scale from 1 (very negative experience) to 5 (very positive experience); 8 questions were qualitative.

Results: Patients (n=5) completed a total of 23 out of 45 scheduled augmented reality game sessions, with patient fatigue as the primary factor for uncompleted sessions. Each patient consented to 9 potential game sessions and completed a mean of 4.6 (SE 1.3) games. Of the 5 patients, 4 (80%) completed the questionnaire at the end of their final gaming session. Of note, patients were motivated to continue to the end of a given gaming session (mean 4.25, 95% CI 3.31-5.19), to try other game-based therapies (mean 3.75, 95% CI 2.81-4.69), to do another session (mean 3.50, 95% CI 2.93-4.07), and to perform other daily rehabilitation exercises (mean 3.25, 95% CI 2.76-3.74). In addition, participants gave mean scores of 4.00 (95% CI 2.87-5.13) for overall experience; 4.25 (95% CI 3.31-5.19) for comfort; 3.25 (95% CI 2.31-4.19) for finding the study fun, enjoyable, and engaging; and 3.50 (95% CI 2.52-4.48) for believing the technology could help them reach their rehabilitation goals. For each of the 4 patients, their reported scores were statistically significantly higher than those generated by a random sampling of values (patient 1: P=.04; patient 2: P=.04; patient 4: P=.004; patient 5: P=.04).

Conclusions: Based on the questionnaire scores, the patients with upper limb motor deficits following stroke who participated in our case study found our augmented reality game motivating, comfortable, engaging, and tolerable. Improvements in augmented reality technology motivated by this case study may one day allow patients to work with improved versions of this therapy independently in their own home. We therefore anticipate that smartphone-based augmented reality gaming systems may eventually provide useful postdischarge self-treatment as a supplement to professional therapy for patients with upper limb deficiencies from stroke.

(JMIR Rehabil Assist Technol 2020;7(2):e17822) doi:10.2196/17822

KEYWORDS

augmented reality; stroke; upper limb rehabilitation; gamification; motor rehabilitation; motivation; participation

Introduction

Background

Stroke induces a variety of functional impairments, as well as pain and other ailments, depending on its type and location [1]. Common deficits associated with ischemic stroke include motor function, spatial neglect, and psychological changes [1]. Motor function deficits after stroke often include partial or total loss of function of the upper or lower limbs on a given side, with associated muscle weakness, poor stamina, lack of muscle control, and even paralysis [2]. These deficits impact the patient's independent lifestyle and decrease their performance of activities of daily living [1]. According to the National Institute of Neurological Disorders and Stroke, the most important part of rehabilitation programs is "carefully directed, well-focused, repetitive practice [3]."

Prior Work

Patients who engage in rigorous, time-intensive, and challenging therapeutic exercises after ischemic stroke tend to experience greater functional recovery, while if ignored or insufficiently treated, impairments may remain [4,5]. The dosage of motor skill practice correlates to the extent of motor recovery following a stroke [4]. In addition, the type of therapy delivered relative to patient's impairment determines outcomes after therapy. For example, for those who have upper limb motor impairment, best therapeutic practice modifies the prescribed exercises as the patient's symptoms evolve [5,6]. Regrettably, patients report their experiences of conventional repetitive stroke rehabilitation therapies as tedious and difficult to hold their interest, which conflicts with the fact that patient motivation is often required to obtain good clinical outcomes [7-10].

Rehabilitation doctors and medical staff, therefore, face a significant problem: how can they provide high intensity therapy in large quantities for upper limb impairments with this seemingly intrinsic motivational deficit? Especially problematic are patient's therapeutic needs after their discharge from the hospital—their therapeutic needs still exist, but medical staff have substantially reduced access to the patient to provide targeted care. Given the difficulty of this problem, an insufficient percentage of patients regain the full functional potential of their upper limb after ischemic stroke [11]. This regrettable outcome motivates an ongoing search for new therapeutic approaches that provide acceptable (motivational, comfortable, and engaging) experiences, hence, effective therapy, especially at the patient's home.

Use of commercial augmented reality devices has found recent application in stroke rehabilitation using existing expensive commercial headsets [4,6-17]. However, there are few studies that assay the acceptability of augmented reality gaming system–based patient rehabilitation after stroke [10,12,17-19], and then, only in a cursory fashion. For example, 30 patients recovering from stroke were surveyed for their opinions on game-based rehabilitation, and the researchers concluded that though games for patients recovering from stroke existed, they were primarily designed for efficacy, not entertainment [10]; they suggest investing in a single, affordable gaming platform for patient rehabilitation after stroke that also focuses on entertainment and provides diverse gaming content [10]. Augmented reality technology and an upper-limb assistive device were tested on 3 individuals recovering from stroke for 6 weeks, and the study reported that both the user and therapist believed that their augmented reality environment was user friendly due to the lightness of the assistive devices and the simplicity of set-up [18]. Finally, a study of 4 patients recovering from stroke who were exposed to several gaming platforms reported that manually adjusting the difficulty of games to provide a challenge and creating games with deeper story lines helped the patients stay motivated to perform their gaming exercises [17]. To the best of our knowledge, our case study is the first of its kind that analyzes the opinions of patients recovering from stroke regarding the problems of current augmented reality–specific game-based rehabilitation systems to provides insight into future designs of augmented reality game-based stroke rehabilitation systems. Augmented reality, provided by one of a variety of device designs, represents one such approach. Augmented reality projects a live camera view of a user's environment and computer-generated objects with a variety of properties—movement and sound, typically. As an example, Pokémon Go, a smartphone-based augmented reality game, has had documented success sustaining the interest of users for extended periods of time while consistently increasing their physical activity [13], making augmented reality a prime candidate for facilitating otherwise tedious therapy.

Hypothesis

Since patient motivation often drives a larger dosage of rehabilitation therapy, hence, improved clinical outcomes [20,21], we hypothesized that augmented reality deployed on a relatively inexpensive and readily available platform—a smartphone—could provide a motivational, comfortable, and engaging rehabilitation experience. To test this hypothesis, we first developed a candidate rehabilitation game on a smartphone that could encourage a patient's hand motions through use of simple visual cues with a custom-made app. We then asked patients with acute upper-motor stroke to use this system and report their experiences via a questionnaire that assayed the acceptability of the game in terms of motivation to continue to play, comfort, and engagement.

Methods

Overview

This acceptability study was conducted at Harborview Medical Center in Seattle, Washington from November 2018 to March 2019. Inpatients who were recovering from an acute ischemic stroke participated and provided consent. These patients had

impaired strength as determined by physical and occupational therapists. To be included in the study, they had to have at least antigravity strength in deltoid or biceps muscles as well as the ability to perform internal and external shoulder rotations. All patients in this study had a Medical Research Council manual muscle score of 3 or 4 in the affected limb.

Intervention

We designed and built an augmented reality game using Unity (Unity Technologies) that is deployable on any modern smartphone with a camera (Table 1 and Figure 1). The game presents users with a view of an augmented reality dolphin swimming under the ocean with the task of capturing fish and feeding turtles, worn on the hand associated with the upper-limb deficit (Multimedia Appendix 1). To experience the game, patients wore an augmented reality headset, which did not obscure the camera mounted on the phone, and a custom device on their hand. We used two headsets—the Google Daydream headset, which required us to remove the front panel that held the phone in place, and the Merge augmented reality/virtual reality headset, which did not require any modification (Figure 1). The game also required users to place the hand associated with their motor deficits within a padded box that replaced their hand as seen in augmented reality with a dolphin (Figure 1). Finally, we required the user to look at a complex landscape through their headset while wearing the padded box and while playing the game. Instead of holding the phone, the headset supported the phone for the user. We built customized controllers with different interior sizes that changed the effective grip strength of the controller; this was important because our patients' ability to hold the controllers varied. Viewing the complex landscape through the augmented reality system caused our software to create a seascape that contained a turtle, fish, and other underwater flora and fauna (Multimedia Appendix 1). Successful placement of the dolphin over a fish allowed the dolphin to capture the fish. Placement of the dolphin plus fish over the turtle allowed the user to feed the turtle, thereby winning points.

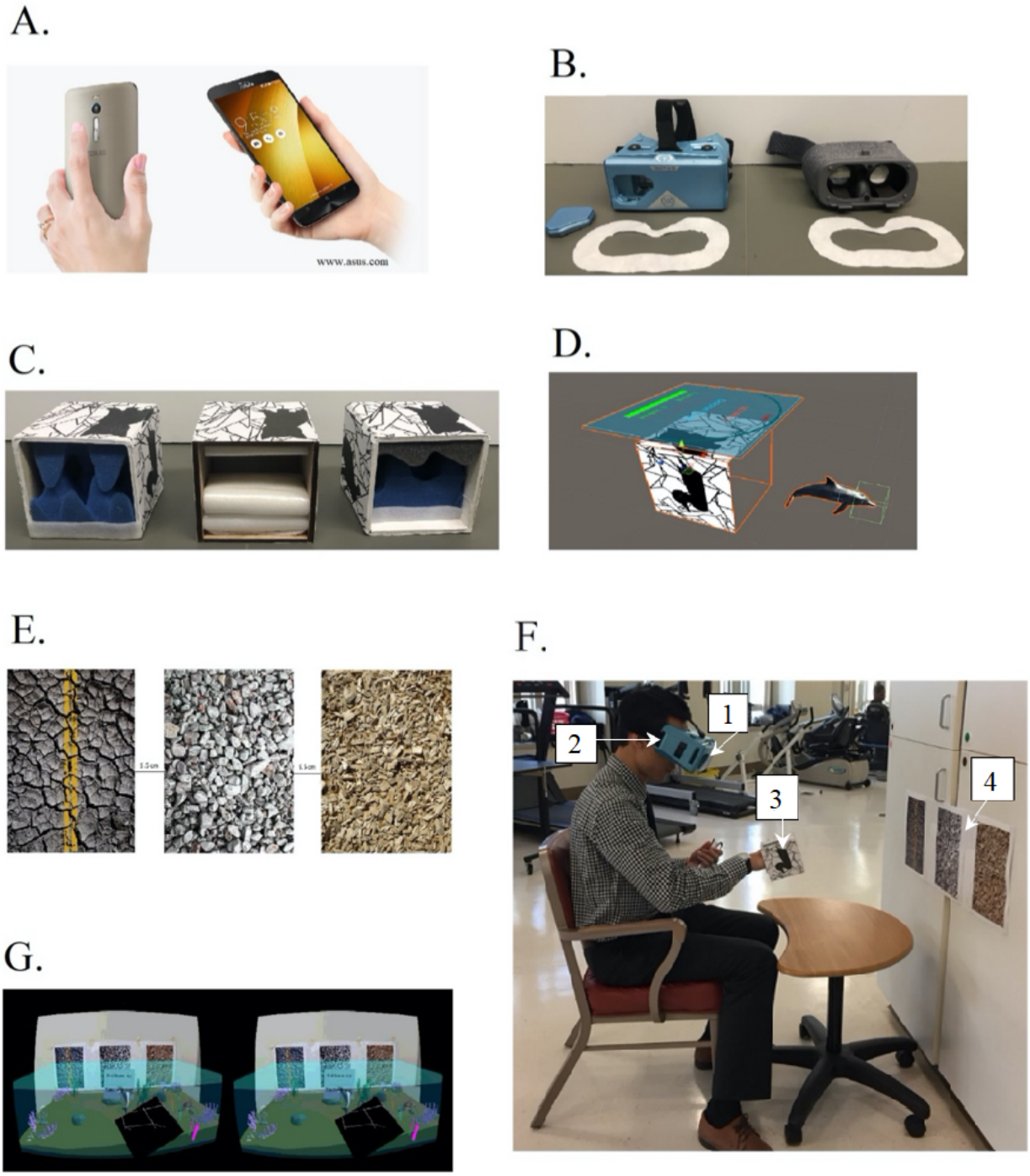
Notably, we used the TeamViewer (TeamViewer AG) app to project the screen view of the patient from the phone to a laptop, so we could see the patient's view with, however, the complex landscape was also projected in the background, so we could check the viewer's alignment with the landscape while they played (Figure 1).

Set-up of the game, to ensure that system function was verified, occurred prior to patients using the system. Patients followed verbal directions and instructions from study staff on how to use the system, facilitated by demonstration of the game using the TeamViewer app. Examples of directions included how to start the game, the actions required to pick up the fish, and how to colocate the dolphin plus fish with the turtle for point accumulation. Some patients required physical assistance to adjust the view of the environment. Examples of physical assistance included moving the patient's chair or wheelchair closer or farther away from the images recognized by the camera (Figure 1).

Table 1. Vuforia compatible mobile devices.

Device operating system		Development operating system		Unity version	
Android	4.4+	Windows	7+	Windows	2018.2+
iOS	9+	OS X	10.13+	OS X	2018.2+

Figure 1. (A) phone: Asus Zenfone 2, phone operating system: Android 7 Nougat, Unity version: 2018.2.10, developer operating system: Windows 10; (B) headsets: Google Daydream (left) Merge augmented reality/virtual reality goggles (right); (C) controllers with various grip sizes consisting of soft foam inserts; (D) virtual dolphin avatar; (E) image target; (F) study staff during game play with (1) smartphone (2) headset (3) controller (4) image target; (G) user experience.



Procedures

In this study, we asked the patients to complete 3 30-minute multigaming sessions on separate days over the course of 1 week while the patients continued their standard therapy schedule. Sessions were conducted after all prescribed therapy so as not to interfere with the patient's schedule. We gave patients the choice to start with their affected or unaffected hand each game while encouraging them to try their affected hand.

Before gaming, we fitted the patient with a nitrile glove. Before and after every gaming session the headsets, smartphone, and TeamViewer laptop were wiped with hospital-grade bleach wipes and left to dry for at least 2 minutes. Each game lasted approximately 4 minutes and was always played in a seated position. The game displayed a score to the user in real time

and at the end of the game. We recorded final scores for each user and game. We also recorded which hand the patient used for each game. After each game, we removed the headset and restarted the game on the mobile phone. During a 2-minute break after each game, we asked the user to describe their experience and took notes on their verbal commentary. Our goal was for each patient to play 9 games over the course of 1 week.

Outcome Measures

To test our hypothesis, we provided an 8-question questionnaire that assayed the patient's perceived engagement and the acceptability of their experience at the end of the third completed session. This questionnaire assessed the patient's feelings regarding the gaming experience, their perceived acceptability of the experience in terms of its motivational qualities, their perception of comfortability, and their enjoyment of the game (1 - very negative, 2 - negative, 3 - neutral, 4 - positive, 5 - very positive). We also asked an additional 8 questions about their previous experiences with videogames and the likelihood that such a system would be used by them in the future.

We determined the statistical significance of the answers to the first 8 questions by comparing the numerical distribution of each patient's answers against those of a random distribution of answers to the same questions (Multimedia Appendix 2).

Results

Participants

We recruited 5 patients in rehabilitation into the study. Patient 1 was a 58-year-old man with right thalamic intraparenchymal hemorrhage and presented with left-sided hemiparesis with major fatigue in the left arm post–daily therapy. Patient 2 was a 70-year-old man with bilateral right>left pontine ischemic stroke with visual impairment and double vision in the left eye. The patient had limited range of motion in his right arm and hand with function that increased sufficiently after admittance that he met our inclusion criteria. Patient 3 was a 67-year-old man with left middle cerebral artery ischemic stroke. His left arm was his nondominant hand and was self-reported to be functioning at "100%." His affected right hand was his dominant hand and self-reported to be functioning "at 50%." Patient 4 was a 50-year-old woman with right thalamic intraparenchymal hemorrhage. The patient's left hand was affected. Patient 5 was a 65-year-old man with right anterior cerebral artery ischemic stroke. The patient typically wore glasses. He said it was "small double vision/blurriness in his right eye."

The mean age of the 5 patients was 62 years old. Of the 4 patients who completed our questionnaire, all 4 lacked experience with augmented reality while 3 out of 4 had no experience with videogames. Finally, 1 patient reported little experience with videogames (less than 3 times in 24 months).

Intervention

Table 2 summarizes patient participation. All patients completed at least one game session with their affected hand. Together, patients completed 23 out of the 45 game sessions. Each game module lasted approximately 4 minutes. Each patient had consented to 9 possible game sessions. The mean number of games played by each patient was 4.6 (SE 1.3).

Table 2. Patient game sessions with the number of points scored, the hand chosen by the patient for play during a given game, and the functional status of the hand.

Patient games	Session 1		Session 2		Session 3	
	Score	Hand	Score	Hand	Score	Hand
Patient 1						
Game 1	260	right (unaffected)	380	both	110	both
Game 2	210	both	0	both	240	both
Game 3	—	fatigue	—	N/A[a]	320	both
Patient 2						
Game 1	0	right (affected)	0	right (affected)	0	right (affected)
Game 2	—	N/A	—	N/A	—	N/A
Game 3	—	N/A	—	N/A	—	N/A
Patient 3[b]						
Game 1	0	right (affected)	—	N/A	—	N/A
Game 2	—	fatigue	—	N/A	—	N/A
Game 3	—	fatigue	—	N/A	—	N/A
Patient 4						
Game 1	0	right (unaffected)	190	right (unaffected)	0	right (unaffected)
Game 2	0	left (affected)	150	right (unaffected)	120	right (unaffected)
Game 3	90	right (unaffected)	—	malfunction	30	right (unaffected)
Patient 5						
Game 1	210	left (affected)	130	left (affected)	—	N/A
Game 2	280	right (unaffected)	450	right (unaffected)	—	N/A
Game 3	—	N/A	—	N/A	—	N/A

[a]N/A: not applicable because the patient dropped out.

[b]Patient was discharged early.

Adverse Events

No adverse medical events occurred during our study. Patient 2, despite the relative severity of his reduced function, felt sufficiently motivated to try the game for each of the 3 sessions. Patient 3 was discharged early, and therefore, did not complete 6 of 45 possible sessions (13%) across all patients. A total of 3 of 45 sessions (7%) from 2 patients were incomplete due to their fatigue from daily rehabilitation sessions; 12 of 45 sessions (27%) from 3 patients were incomplete due to discontinuation of the study session. Finally, 1 of 45 sessions (2%) was incomplete due to malfunction of the gaming apparatus.

Patient Satisfaction—Quantitative Results

Patients 1, 2, 4, and 5 completed the questionnaire that we gave at the end of their final session; patient 3 was discharged before completion of their participation in the study. Table 3 shows the individual scores while Figure 2 shows the distribution of the scores. Organized by theme, the patients reported a mean score of 4.25 (95% CI 3.31-5.19) for motivation to follow the instructions and finish the augmented reality experience to the end of a given gaming session, 3.75 (95% CI 2.81-4.69) for motivation to try other game-based therapies, 3.50 (95% CI 2.93-4.07) for desire to do another session, and 3.25 (95% CI 2.76-3.74) for motivation to perform other exercises in support of their daily rehabilitation. Organized by comfort, the patients reported an average score of 4.00 (95% CI 2.87-5.13) for the overall experience, 4.25 (95% CI 3.31-5.19) for comfort. Organized by engagement, patients reported an average score of 3.25 (95% CI 2.31-4.19) for finding the study fun, enjoyable, and engaging; and 3.50 (95% CI 2.52-4.48) for believing this technology could help them reach their rehabilitation goals.

P values for each patient are reported in Table 4. For each of the 4 patients, the reported scores were statistically significantly higher than those generated by a random sampling of values (patient 1: P=.04; patient 2: P=.04; patient 4: P=.004; patient 5: P=.04) consistent with the interpretation that the patients found our augmented reality game acceptable.

Table 3. Results and response comparison of acceptability questionnaire.

Assessment	Patient				Score
	1	2	3	4	Mean (95% CI)
Questions					
A. How do you feel about the experience you just performed?	5	3	5	3	4.00 (2.87, 5.13)
B. How would you rate the comfort of the experience?	4	3	5	5	4.25 (3.31, 5.19)
C. How do you feel about doing another session?	4	3	4	3	3.50 (2.93, 4.07)
D. The game was fun, enjoyable and/or engaging	4	2	4	3	3.25 (2.31, 4.19)
E. During the session, I was motivated to follow the instructions and keep playing the game until the end	5	3	5	4	4.25 (3.31, 5.19)
F. This session made me feel motivated to try other game-based therapies	3	3	5	4	3.75 (2.81, 4.69)
G. I think gaming with this technology will help me reach my rehabilitation goals	3	3	5	3	3.50 (2.52, 4.48)
H. The game also made me feel motivated to perform other exercises in support of my rehabilitation	3	3	3	4	3.25 (2.76, 3.74)
P value (comparison with random sampling)	.04	.04	.004	.04	

Figure 2. Patient ratings on a scale from 1 (very negative) to 5 (very positive).

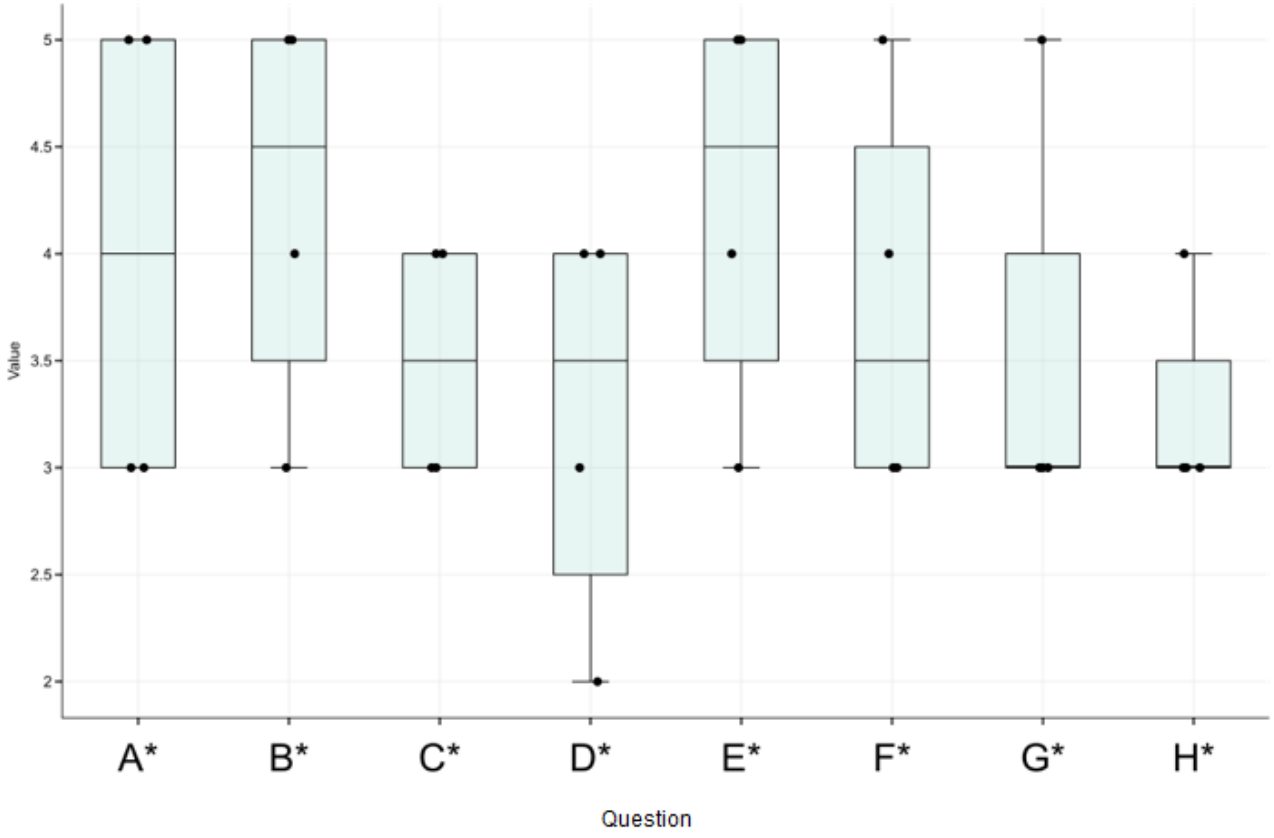


Table 4. Patient comments.

Question	Response
Did you experience any negative symptoms during or after game play such as nausea, dizziness, pain, fatigue, headache, general discomfort, etc?	"no" [Patient 1] "no" [Patient 2] "no" [Patient 4] "none" [Patient 5]
Did you have trouble playing the game? If yes, please describe.	"sometimes it was difficult to reach the far turtle to drop off fish." [Patient 1] "yes" [Patient 2] "was difficult to navigate the dolphin to the target" [Patient 4] "only in lining up the controller to the camera" [Patient 5]
Please provide any additional comments which will help us understand your experience while using the Augmented Reality system.	"better controllers to be able to hit the targets maybe a glove of some kind. also in the beginning to help stroke patients maybe simplify not have moving targets something of a push the target on the first level then move to upper levels of moving targets as thing progress for the patients." [Patient 4] "Hard for me to judge im 65 no experience" [Patient 5]

Patient Questionnaire Comments

Here we report all of the patient comments offered to us. A common theme expressed by the patients was their desire to have better hand-held controllers for the game than the custom boxes, since the boxes made it difficult to navigate the dolphin to the target. Patient 3 did not complete the questionnaire due to early discharge. Some patients chose not to comment on all 3 open response questions.

Discussion

Principal Results

In our observational case study on the acceptability of a therapeutic smartphone-based augmented reality gaming for patients with upper limb motor impairment from acute ischemic stroke, 5 users with ages in the range of 50 to 70 years volunteered and completed a total of 23 of 45 possible gaming sessions; 4 patients who remained in the rehabilitation unit completed a questionnaire after completing their gaming sessions and before their discharge. The patients rated their motivation, comfort, the value of their experience, and desire to play another round of the game the highest. In contrast, the lowest rated aspects were enjoyability of the game itself and motivation to try other rehabilitation technologies. It is worth noting, however, that all scores were equal to or better than neutral scores. In this study, point accumulation was unrelated to acceptability. Nonetheless, even when a patient did not earn any points during a given game, they reported that our augmented reality game was generally comfortable and that they were motivated to try to play the game again.

Limitations

While 3 out of 4 of the patients engaged in all 3 of their gaming sessions, 1 patient left the study due to their early discharge, which reduced the total number of games by 13%. Enrolling more patients would address this issue.

Another limitation was the quality of the game, affected in part by limitations imposed by our use of state-of-the-art but limited camera control software and our box-shaped controller, whose size—necessitated by the need to encompass the hand of the patient—made it difficult for users to select a moving target with their affected hand even with additional verbal cues. Compared to virtual reality, state-of-the-art augmented reality programs deployable on smartphones currently lack features and stability mainly due to outdated hardware specifications. This resulted in some frustration and lower participant satisfaction scores as reflected by questionnaire responses.

Given our focus on assaying the patient's experience of the augmented reality game, another limitation was that we did not include a comparison of the patient's experience with standard therapy plus the game versus a separate group of patients who experienced only their standard therapy. Future work will include this comparison as part of an efficacy study, once we improve the mechanics of the game itself.

The fatigue experienced by patients during the day of their sessions also impacted their experience with our technology. Recall that all test patients experienced our augmented reality technology after completing their regularly schedule therapy. While all patients reported fatigue, 2 out of 5 patients dropped out of at least 1 game session due to postrehabilitation fatigue.

Also, most of our patients who participated in the study had little to no experience with augmented reality and videogames. They, therefore, could not compare our game with other such games. This minimal experience with augmented and virtual reality is typical of this demographic of adults 50 years and older [22], a fact that game designs must take into account when considering therapeutic applications. They can do so by developing a greater understanding of what can motivate a patient to do more sessions and by establishing a closer alignment of game movements with their rehabilitation goals.

Future Studies

With this case study, we report our initial findings regarding the acceptability of our augmented reality approach to acute stroke rehabilitation, in anticipation of future studies that would test for efficacy. This allows us to gauge the requirements for more formal, and eventually, long-term studies of augmented reality game rehabilitation in an older stroke population. The next logical step is to refine the augmented reality platform and therapeutic gaming software to make it more engaging and with

more robust functionality. For example, body ownership studies suggest that the visual feedback a patient receives from viewing their own limb may be more beneficial while recovering from stroke than that of an unrelated virtual component [16,23,24]. We will therefore explore reduction of the hand marker so the hand itself has more visual impact, perhaps by using the patient's hand instead of an avatar during the gaming experience. Other improvements that we would like to make when we repeat this study are to include increasing difficulty as the user improves their range of motion and speed (beginning with stationary targets), multiple environments and levels for the user, and more visually effective controllers. We may also incorporate optional bilateral gaming elements. In our next therapeutic gaming technology, range of motion measurements will be implemented into our hardware and compared with patient Wolf Motor Function [25] or Fugl-Meyer [26] range of motion data. With such improvements in hand, a prospective efficacy comparison of standard therapy to augmented reality therapy with standard therapy and home-setting studies are anticipated.

Conclusion

Members of an older population recovering from acute stroke found smartphone-based augmented reality game targeting therapy of the upper limb acceptable. We also identified improvements to the experience that will inform the next study of this potential therapy. Of importance, such a gaming set-up could be used for home-based therapy due to its relatively low cost and ease of use. Therefore, this work informs the next formal study of this technology for upper limb motor rehabilitation. We anticipate eventual study of this technology in the home setting, after acute rehabilitation, which is of interest since patients spend most of their time at home performing rehabilitation exercises after a stroke. We anticipate that a sufficiently engaging smartphone-based game will lead to more use and greater therapeutic benefit experienced by the patient, as well as possibly improved clinical outcomes for patients.

Acknowledgments

We thank Dr. Caren Marzban and Ethan Marzban for their statistical guidance. We thank the School of STEM at the University of Washington's Bothell campus for financial support.

Conflicts of Interest

None declared.

Multimedia Appendix 1
User experience video.
[MP4 File (MP4 Video), 34469 KB - rehab_v7i2e17822_app1.mp4]

Multimedia Appendix 2
Patient feedback RedCap questionnaire.
[PDF File (Adobe PDF File), 77 KB - rehab_v7i2e17822_app2.pdf]

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Edited by G Eysenbach; submitted 14.01.20; peer-reviewed by K Kanno, M Ozkan, T Tunur; comments to author 20.05.20; revised version received 25.06.20; accepted 06.07.20; published 02.09.20.

Please cite as:
LaPiana N, Duong A, Lee A, Alschitz L, Silva RML, Early J, Bunnell A, Mourad P
Acceptability of a Mobile Phone–Based Augmented Reality Game for Rehabilitation of Patients With Upper Limb Deficits from Stroke: Case Study
JMIR Rehabil Assist Technol 2020;7(2):e17822
URL: http://rehab.jmir.org/2020/2/e17822/
doi:10.2196/17822
PMID:32876580

Original Paper

Rehabilitation Exergames: Use of Motion Sensing and Machine Learning to Quantify Exercise Performance in Healthy Volunteers

Reza Haghighi Osgouei[1], PhD; David Soulsby[2], BSc; Fernando Bello[1], PhD

[1]Imperial College Centre for Engagement and Simulation Science (ICCESS), Faculty of Medicine, Department of Surgery and Cancer, Imperial College London, London, United Kingdom

[2]Children's Services and Dietetics, Chelsea and Westminster Hospital, London, United Kingdom

Corresponding Author:
Reza Haghighi Osgouei, PhD
Imperial College Centre for Engagement and Simulation Science (ICCESS)
Faculty of Medicine, Department of Surgery and Cancer
Imperial College London
Room H 3 8, ICCESS, Chelsea and Westminster
369 Fulham Road
London, SW10 9NH
United Kingdom
Phone: 44 940419331
Email: r.haghighi-osgouei@imperial.ac.uk

Abstract

Background: Performing physiotherapy exercises in front of a physiotherapist yields qualitative assessment notes and immediate feedback. However, practicing the exercises at home lacks feedback on how well patients are performing the prescribed tasks. The absence of proper feedback might result in patients performing the exercises incorrectly, which could worsen their condition. We present an approach to generate performance scores to enable tracking the progress by both the patient at home and the physiotherapist in the clinic.

Objective: This study aims to propose the use of 2 machine learning algorithms, dynamic time warping (DTW) and hidden Markov model (HMM), to quantitatively assess the patient's performance with respect to a reference.

Methods: Movement data were recorded using a motion sensor (Kinect V2), capable of detecting 25 joints in the human skeleton model, and were compared with those of a reference. A total of 16 participants were recruited to perform 4 different exercises: shoulder abduction, hip abduction, lunge, and sit-to-stand exercises. Their performance was compared with that of a physiotherapist as a reference.

Results: Both algorithms showed a similar trend in assessing participant performance. However, their sensitivity levels were different. Although DTW was more sensitive to small changes, HMM captured a general view of the performance, being less sensitive to the details.

Conclusions: The chosen algorithms demonstrated their capacity to objectively assess the performance of physical therapy. HMM may be more suitable in the early stages of a physiotherapy program to capture and report general performance, whereas DTW could be used later to focus on the details. The scores enable the patient to monitor their daily performance. They can also be reported back to the physiotherapist to track and assess patient progress, provide feedback, and adjust the exercise program if needed.

(JMIR Rehabil Assist Technol 2020;7(2):e17289) doi:10.2196/17289

KEYWORDS

rehabilitation exergames; performance assessment; similarity score; motion sensing; machine learning; dynamic time warping; hidden Markov model

Introduction

Background

Rehabilitation is essential to regain lost or weakened functionality after injury or surgery. Although it is commonly initiated in a clinic and supervised by a physiotherapist, the prescribed therapeutic exercises will normally need to be practiced at home by patients on their own. Lack of motivation and compliance may hinder the healing process and, in some cases, even worsen the injury. Advances in virtual reality technologies have resulted in various virtual rehabilitation platforms introduced to address this issue [1-3]. They are generally equipped with sensory devices to track and monitor the patient's movement when performing the exercises. Among them are systems based on the concept of *exergaming* and exercise gaming. These are interactive video games with some simple scenarios that enable a patient to perform a therapeutic exercise by playing the game. Exergames are a subgenre of serious games developed for the purpose of encouraging exercise and activity. Although sharing some aspects with medical simulation, in exergames, the emphasis is more on the added educational value of fun and entertainment. Accessibility (not needing the constant presence of a physician) and entertainability (turning repetitive tasks to playful activities) are 2 key advantages of such systems.

The impact of serious games on physical therapy has been studied in terms of effectiveness [4-6] and motivational determinants [7,8]. However, as a virtual guide replacing or complementing a real physician, exergaming systems tend to lack objective, clinically meaningful evaluation of patient performance. At best, game scores, the extent to which the player achieved the goals of the game, are reported at the end of the session along with statistics such as completion time. The work presented in this study aims to fill this gap by introducing an approach to compare a patient's performance with that of a reference, using the Medical Interactive Recovery Assistant (MIRA) rehabilitation platform. We explore 2 different machine learning techniques: dynamic time warping (DTW) and hidden Markov model (HMM). They have been widely used for gesture recognition to study acquired motion trajectories [9-14]. The former belongs to model-less time domain methods, whereas the latter is a model-based probabilistic technique for time-series analysis. Comparing the patient's trajectory with that of a physiotherapist as a reference, each approach generates an objective similarity score indicating how similar the performance was.

Related Work

Rehabilitation Platforms

The concept of exergaming enables exercising when playing games. For players, it is an opportunity to play games in a more active and less passive manner. For patients, it offers the opportunity to practice therapeutic tasks in a more playful and less repetitive manner. Exergames offer various activities, such as aerobic exercises and dancing; balance and stretching workouts; and recreational simulations, such as golf, skiing, and more. However, they require additional hardware and software. In terms of hardware, they require proper sensory equipment to track the user's motion. In terms of software, the game scenario must accommodate whole body interaction. There are various commercially available game consoles that enable exergames, including Xbox (Microsoft), PlayStation (Sony), and Wii (Nintendo). Each comes with its own dedicated input device for enabling user interaction with the games, that is, Kinect for Xbox, Move for PlayStation, and Remote Plus for Wii.

Among them, Kinect has gained higher popularity owing to its acceptable performance and versatility [15]. Microsoft introduced Kinect in 2010 as a peripheral input device for its gaming console Xbox and discontinued it in 2017. Kinect enables interaction with virtual environments using gestures rather than conventional controllers. The device includes an RGB camera and a depth sensor, which combines full body 3-dimenonal (3D) motion capture capabilities and gesture recognition. Using the Kinect SDK 2.0, the position of 25 human skeleton joints can be accessed with a sample rate of 30 fps. Since its launch, researchers have used the Kinect for various applications, including rehabilitation [16-21]. Other similar motion-sensing devices capable of tracking the 3D position of the joints include Azure Kinect (Microsoft), Astra (Orbbec), RealSense (Intel), Structure Sensor (Occipital), and BlasterX Senz3D (Creative).

Kinerehab was introduced by Chang et al [16] to assist therapists in rehabilitating students at a public school. By conducting a user study with two patients, the authors compared two experimental phases, baseline (without assistive technology) and intervention (with Kinerehab), lifting both arms to the front, to the side, and upward. The data showed a significant increase in motivation (willingness to keep practicing) among participants and hence improved exercise performance using Kinerehab compared with performance in the presence of a therapist. A Kinect-based serious game for physiotherapy (KSGphysio) was proposed by Duarte et al [17] that had a mobile interface to facilitate the analysis of patient progress by generating relevant statistics. Cary et al [18] developed a web-based serious game called Therasoup to improve the patient's motivation when performing exercises and to provide technical data to the physiotherapist, which helped in the assessment. The game tries to simulate daily life activities such as cooking, where the player controls an avatar to pick the ingredients from shelves and put them in a pan at the center. Su et al [19] developed a Kinect-enabled home-based rehabilitation system (KEHR) to assist patients in conducting safe and effective off-hospital rehabilitation without the immediate supervision of a physician. KEHR supported 3 different shoulder rehabilitation exercises: shoulder abduction, shoulder anterior elevation, and shoulder external and internal rotation. A serious game framework for therapy (Theragame) providing options to imitate the actions performed by an avatar or to play a game that trains specific parts of the body was introduced by Ferreira et al [20]. A web-based platform for physical telerehabilitation for patients after hip replacement surgery was described by Rybarczyk et al [21] with 2 goals in mind: making use of a low-cost motion capture device (Kinect) and real-time automatic assessment of performance. A comprehensive review of the technical and

clinical impacts of the Kinect in physical therapy and rehabilitation is given by Mousavi et al [15]. The survey covers rehabilitation systems before and after Kinect as well as platforms with and without clinical evaluation. Although Kinect-based rehabilitation systems are accepted by both patients and therapists, the lack of objective, clinically meaningful evaluation of performance raises questions regarding their effectiveness.

Commercially available rehabilitation platforms based on Kinect and exergames include MIRA [1], VirtualRehab [2], and REHABILITY [3]. All these platforms have the capacity to be used at home to encourage and monitor performance or at a hospital to assist and support physiotherapists. MIRA is a class I medical device that uses games built based on best clinical practice and expertise from specialist physiotherapists to keep patients engaged and motivated throughout the therapy. VirtualRehab, a Conformitè Europëenne–certified class I medical device, is a product that can be used in clinics and hospitals as well as in patients' homes, allowing them to continue their rehabilitation treatment. With REHABILITY, patients can perform rehabilitation exercises at the clinic and hospital or remotely, but with constant medical supervision. None of these systems offers automatic, objective assessment comparing patient performance with that of a reference. They offer game scores such as number of hits and statistics such as execution/completion time.

Performance Evaluation

Automatic performance evaluation of a user carrying out a task has always been a challenge among researchers in both medical and nonmedical domains. Such evaluations are usually subjective and, in the real world, are performed by judges who are experts in the given field. For example, evaluation of the quality of a dance, a gymnastic performance, or a physiotherapy/rehabilitation exercise may be performed by expert dancers, sport athletes, and professional therapists, respectively. Such evaluations require the presence of human specialists who may not be easily accessible or affordable. In addition, the fact that the assessment is subjective indicates that a different expert might have a different opinion. The ability to conduct objective automatic evaluations that are repeatable is thus highly desirable. A real-world example is a video game called Just Dance, which is developed by the French company Ubisoft for Microsoft Xbox. Using the Kinect sensor, the players must mimic the onscreen dancer's choreography to a chosen song. The system then continuously evaluates in real time the quality of a user's dance movements in terms of being "Ok," "Good," "Super," or "Perfect" and reports a total numeric score at the end [22].

Studies in the literature concerned with automated evaluation of therapy motions are scarce [23-26], and not much attention has been paid to the development of metrics for performance evaluation [27]. As a common scheme, a reference model is first captured as the ground truth. Then, a user's performance can be compared with the reference using machine learning approaches. A comprehensive taxonomy of the metrics for evaluation of patient performance in physical therapy was proposed by Vakanski et al [27]. The metrics are classified into quantitative and qualitative categories. Further, quantitative metrics are divided into model less (based on raw measurements of motions) and model based (based on a mathematical model of the motions). Of the reviewed metrics, root mean square distance, Kullback Leibler divergence, log likelihood, and Fugl-Meyer assessment were used to classify a set of 5 human motions captured with a Kinect sensor.

Using KEHR, Su et al [19] applied DTW and fuzzy logic to detect real time subjective discrepancies between the model exercise and the performance of the patient. Before applying either algorithm, the user's execution of the prescribed exercise was recorded under the supervision of a professional. Then, 2 factors were included for the assessment: (1) trajectory disparity, the motional path created by each joint over time, and (2) speed variation, the time used to complete a designated exercise. Applying HMM and defining an accept/reject interval, a method to detect deviations from normal repetitions in therapeutic activities was presented by Palma et al [23]. The authors later compared the performance of their HMM-based technique with that of DTW [28]. A similar approach using HMMs to assess the correctness of telerehabilitation exercises was employed by Deters et al [24], whereas a cloud-based physical therapy monitoring and guidance system that applies DTW to produce subjective assessments in terms of being too slow/fast or overdone/incomplete was proposed by Wei et al [25]. Richter et al [26] presented an error classification algorithm for therapy exercises based on incremental DTW to classify the incorrect motions in a hip abduction exercise into 4 discrete categories: bent knee, foot outside, upper body, and wrong plane. A variance of DTW called multi-template, multi-match DTW was used by Yurtman and Barshan [29] to detect and evaluate physical therapy exercises using wearable motion sensors, providing a quantitative measure of similarity between an exercise execution and previously recorded templates. A continuous time warping algorithm based on automatic motion assessment learning was introduced by Tal and Shimshoni [30]. The resulting models produced numerical scores comparable with those of the Fugl-Meyer assessment. Recently, a DTW-based algorithm was developed for assessing Kinect-enabled home-based rehabilitation exercises to support auto coaching in a virtual gaming environment [31]. Using a simple but innovative method, the DTW distances are converted to meaningful performance scores in terms of percentage. By conducting a user study, the scores are then validated with the expert ratings showing a strong positive linear relationship. In another recent work, a deep learning–based framework for the assessment of rehabilitation exercises was proposed [32]. The framework consists of algorithms for dimensionality reduction, performance metrics (based on the Gaussian mixture model), scoring functions, and deep learning models. The authors demonstrated the capacity of the trained models by evaluating a data set of 10 rehabilitation exercises.

Similar techniques have also been employed in other domains, such as dance motion evaluation. Jang et al [33] employed DTW and Laban movement analysis to evaluate the correctness of dance movements in terms of being best, good, bad, and worst. In another work [34], the authors employed HMM for dance gesture recognition and evaluation, comparing the results with

those of domain experts in terms of being good, medium, or bad.

A common factor among all these efforts was that they focused on evaluating the incorrectness of the performance on the basis of subjective terms. In most cases, the method developed was used to sort multiple erratic performances with respect to a reference template. This approach motivated us to explore the use of DTW and HMM to generate a similarity score between a participant's performance and a reference.

Methods

Materials

MIRA

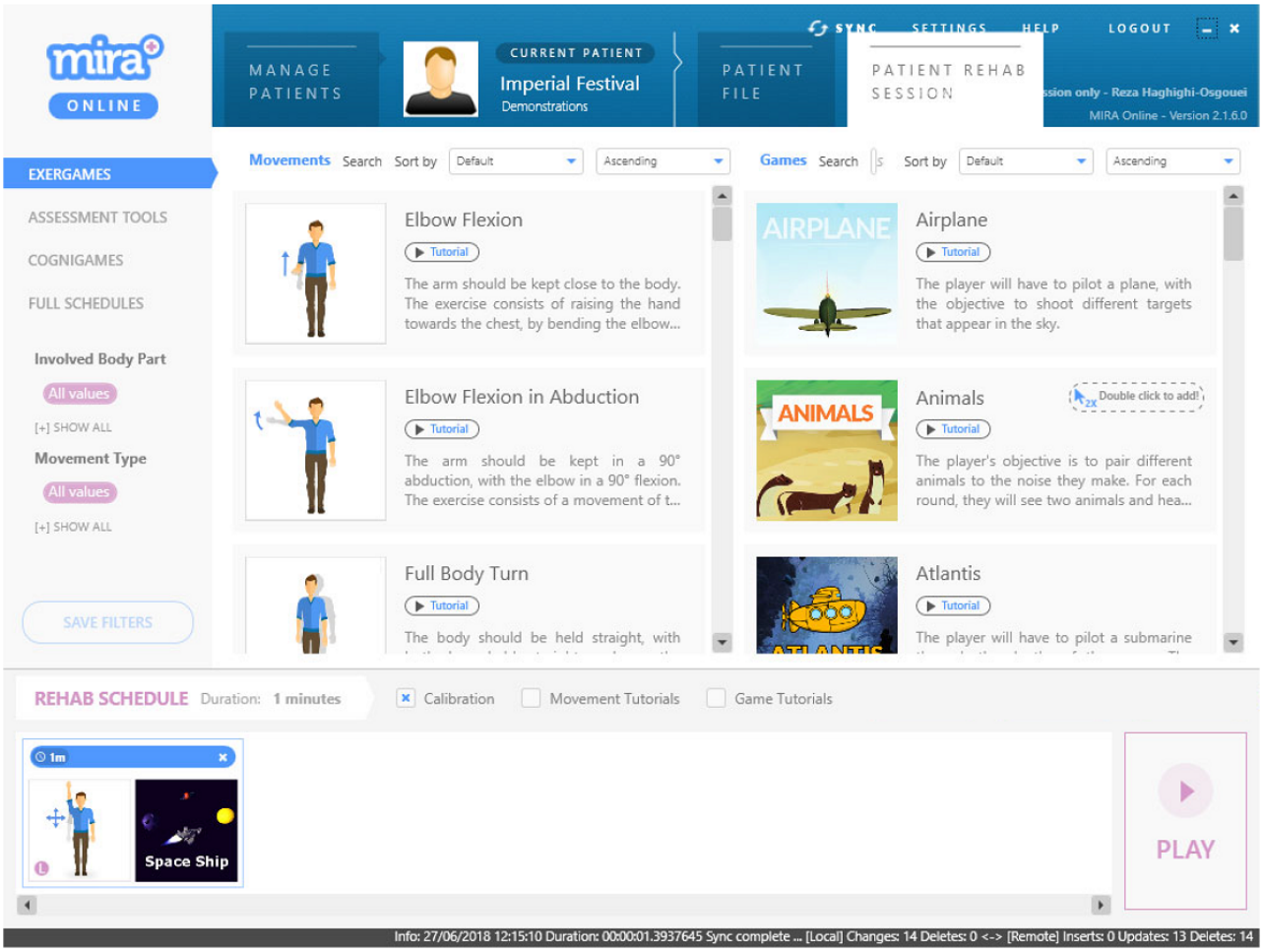
MIRA is a software platform that turns physiotherapy exercises into clinical exergames [35]. It aims to increase engagement levels and improve the uptake of exercises by converting the rehabilitation sessions into entertaining activities, making therapy more convenient and easier to follow, and offering greater accessibility. In turn, this has the potential for shorter recovery times as well as supporting physiotherapists, reducing workload, and waiting times at clinics. MIRA has been used in several clinical studies [36-39].

The MIRA system includes a Kinect V2 sensor (Microsoft Corp) connected to a computer running the MIRA program (Figure 1). Currently, 32 exercises and 25 games are supported by MIRA. Each rehabilitation session requires selecting an exercise and a suitable game (Figure 2). Exercises include shoulder abduction, elbow flexion, and side strides, and examples of games include Firefly, Fishing, and Football. Once an exercise has been selected, adequate game options are presented. The selected combination of exercise and game is then added to the session and can subsequently be executed. Each execution starts with a process of calibrating the patient's position in front of the Kinect. A short video tutorial explaining the exercise is followed by another video tutorial describing the game mechanics. As the game starts, the user must play it by moving the intended body part (ie, left arm, right leg, or neck) in the manner shown in the video.

At the end of each session, the MIRA system reports various scores. Depending on the game, it reflects on the extent to which the player follows the game's objectives. For example, the number of fish caught and taken to the boat or the number of times the spaceship is safely passed through the fire rings. Although the scores can be an indication of how well the user played the game, they do not have much value in a clinical context. The aim of this work is to introduce an objective evaluation method that is more meaningful and suitable for clinical evaluation.

Figure 1. Medical Interactive Recovery Assistant system including a Kinect motion sensor and software to match an exercise with a game. A child (left) and an elderly gentleman (right) playing the Atlantis game. The child is practicing an arm exercise, the gentleman a hip exercise.

Figure 2. A snapshot of the Medical Interactive Recovery Assistant program. Exercises are listed on the left and games are shown on the right. Multiple game options allow practicing the same exercise with different games, thus encouraging patients to cope with the prescribed exercise by discovering the various game scenarios.



Data Collection

We developed a program in the Unity 3D game engine (Unity Technologies) [40] to capture and store raw 3D position coordinates of the selected joints using the Kinect. This was needed as the MIRA program does not allow accessing joint data when playing an exergame because of regulations imposed on class I medical devices. There were no technical problems executing both programs in parallel as the Kinect SDK permits simultaneous access to the sensor from multiple sources. Using Kinect V2, the 3D position coordinates of 25 different human skeleton joints can be tracked with an update rate of 30 fps. However, it is not necessary to track all the joints but only those that are involved in the chosen exercise. For this study, 4 different types of exercises were selected in consultation with a physiotherapist (DS): shoulder abduction (both left and right arms), hip abduction (both left and right legs), lunge (both left and right legs), and sit-to-stand exercises. This resulted in a total of 7 exercises to be performed by participants. A brief description of each exercise is given in Textbox 1.

As 3D position coordinates are dependent on the user size and location in front of the Kinect camera, we decided to extract invariant features (joint angles) to describe each exercise optimally (Figure 3). These scalar features were discussed with the physiotherapist and confirmed to be sufficient for capturing the essence of each exercise. For example, in shoulder abduction, the shoulder angle (θ_1) reflects the range of motion and the arm angle (θ_2) indicates whether the arm is being stretched or not. Except the lunge exercise, which required 3 joint angles, all other exercises could be described with only 2 angles. A sample plot of the extracted features is shown in Figure 4.

A motion trajectory T(l) is formed by the sequence of feature values within the time frame $0 \leq t \leq l$, where l is the execution time. T(l) is a matrix of size $l \times 3$ for the lunge exercise and $l \times 2$ for rest.

Textbox 1. Correct execution of each exercise.

- Shoulder abduction: the arm should be kept close to the body. The exercise consists of raising the arm away from the side, keeping it in a straight line with the body.
- Hip abduction: the leg should be held straight and on the ground. The exercise involves raising the leg away from the side, keeping it in a straight line with the body.
- Lunge: stand straight facing forward with the spine and the pelvis in a neutral position. Take a step forward with a leg that is long enough so that when the knee bends, it does not go beyond the toes. Bend the back knee until it almost touches the floor, keeping both the torso and the spine in a neutral position. Return to the starting position.
- Sit-to-stand: sit on a chair. Without using the hands for support, stand up and sit back down. Make sure each movement is slow and controlled.

Figure 3. Extracted features (joint angles) from the joint 3D positions for each type of exercise. Both 2D side view and 3D perspective view are provided for clarity. 2D: 2-dimensional; 3D: 3-dimensional.

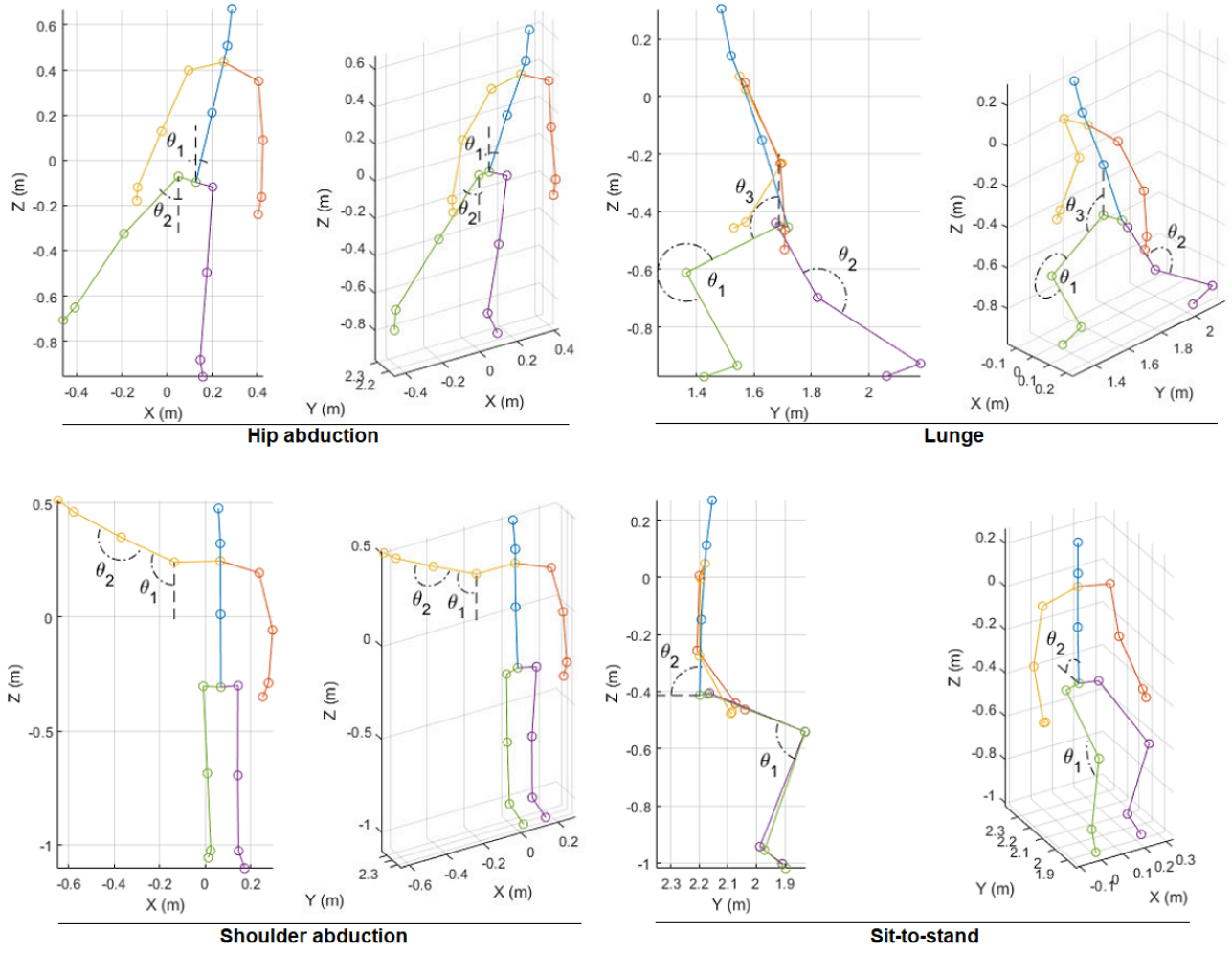
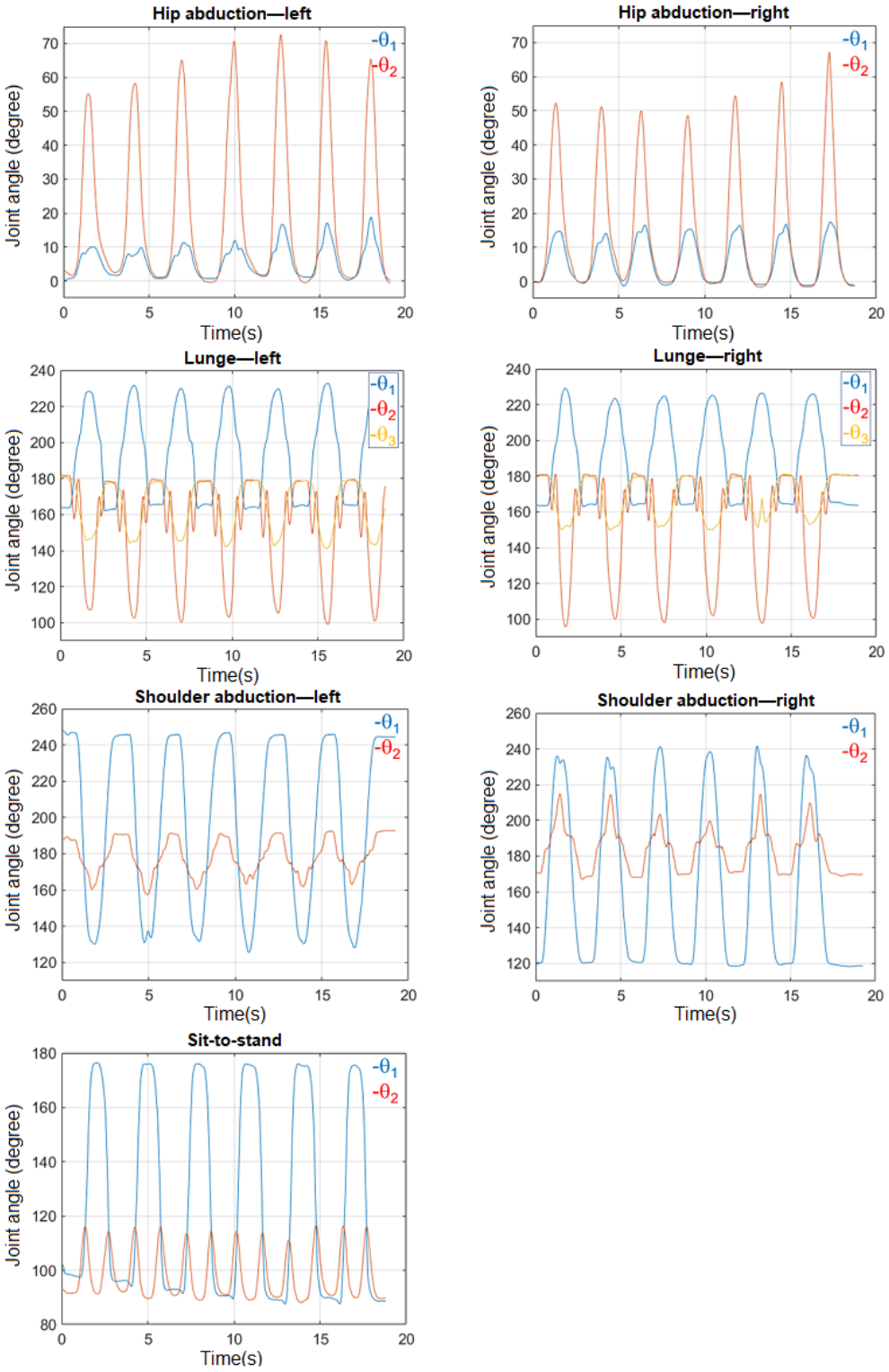


Figure 4. Sample extracted features obtained from 3D position for all seven exercises: hip abduction left (hpl) and right (hpr), lunge left (lul) and right (lur), shoulder abduction left (shl) and right (shr), and sit-to-stand (sit).



DTW

DTW [41] is a technique that aligns 2 time series and determines the minimum Euclidean distance between them. It is a frequently used approach in speech recognition to classify sound waves of the same word spoken in different accents and durations. DTW is sensitive to both the signal pattern and the amplitude. If 2 signals have the same patterns, for example, the same number of peaks but different amplitude, then the alignment cannot be perfect, thus yielding a large distance between them. If they have the same amplitude but different patterns, the alignment will also result in a large distance. Therefore, the output distance is a measure of the similarity between 2 time series. The higher the distance, the greater the deviation.

Although DTW was initially applied to speech recognition, it has also been widely used in gesture recognition [10,12,42]. In

these studies, the motion trajectories, each representing a gesture, are classified into the most similar gesture group (ie, the one with the smallest distance) by converting the distance between 2 trajectories into a similarity measure.

We define $D_{RP}=DTW(T_R,T_P)$ as a distance measure between the reference (T_R) and the participant (T_P) trajectories. The MATLAB function *dtw* was used for the implementation. Although the lower limit (D_l) of this distance is 0 (being perfectly similar), the upper limit is unknown and can take any large value. By estimating an upper limit, it is possible to convert the distance measure into a similarity score. By associating the upper bound with the worst possible performance, an upper limit can be approximated. For all the exercises, not moving would be the worst performance. We refer to this worst trajectory as T_W. Calculating $D_{RW}=DTW(T_R,T_W)$ allows us to establish the upper bound. Knowing both the lower and the upper bounds, a given distance $D_l=0\leq D\leq D_u$ can be transformed into a similarity measure or percentage score $0\leq S_D\leq 100$:

$$S_D=100\times(D-D_l)/(D_u-D_l)=100\times(D/D_u)$$

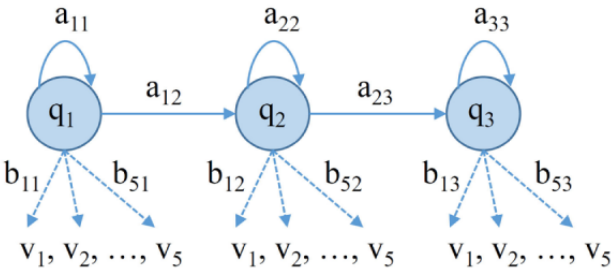
HMM

An HMM [43] is a stochastic model that considers an observed signal as the result of the transition of a system between several states, each of which has the probability that a particular symbol might be observed. HMMs are useful for the recognition of temporal patterns such as speech, handwriting, and gestures. An HMM with discrete observations is mainly specified by the state transition matrix A and the observation matrix B, assuming that the system goes through N different possible states S_1, S_2, ..., S_N and in each state, one of M different symbols v_1, v_2, ..., v_M can be observed (Figure 5).

For performance evaluation, a single HMM, λ_R, is trained based on the reference motion trajectory T_R. We then calculate the log likelihood of T_P given the trained model by $L_{RP}=\log(P(T_p|\lambda_R))/l_p$. Similar to DTW, the lower and upper limits of the log likelihood need to be calculated. The upper limit (L_u) is known and is equal to 0, as the highest probability is 1. However, the lower limit is unknown and can be any small value less than zero. Same as before, we assumed that this lower limit reflects the worst possible performance captured by T_W. Letting the lower limit be $L_{RW}=\log(P(T_w|\lambda_R))/l_w$, the similarity score $0\leq S_H\leq 100$ corresponding to log likelihood $L_l\leq L\leq L_u=0$ is obtained by:

$$S_H=100\times(L-L_l)/(L_u-L_l)=100\times(L_l-L/L_l$$

Figure 5. Hidden Markov model with three states (q1 to q3) and five observation symbols (v1 to v5). The relationship among states is described by transition matrix A=[aij]3x3, and between states and discreet symbols by observation matrix B=[bij]3x5. It is assumed the system evolves through certain states whose relationship is to be studied.



Experimentation

Setup

Standard hardware (computer, television, Kinect sensor) was used in combination with a Unity program to display the participant's live performance on the screen and store the 3D position data along with a time stamp. As mentioned above, 4 types of exercises were chosen to be performed by the participants: shoulder abduction, hip abduction, lunge, and sit-to-stand exercise. Except the sit-to-stand exercises, all other exercises were performed for both the left and the right sides, resulting in a total of 7 exercises.

Participants

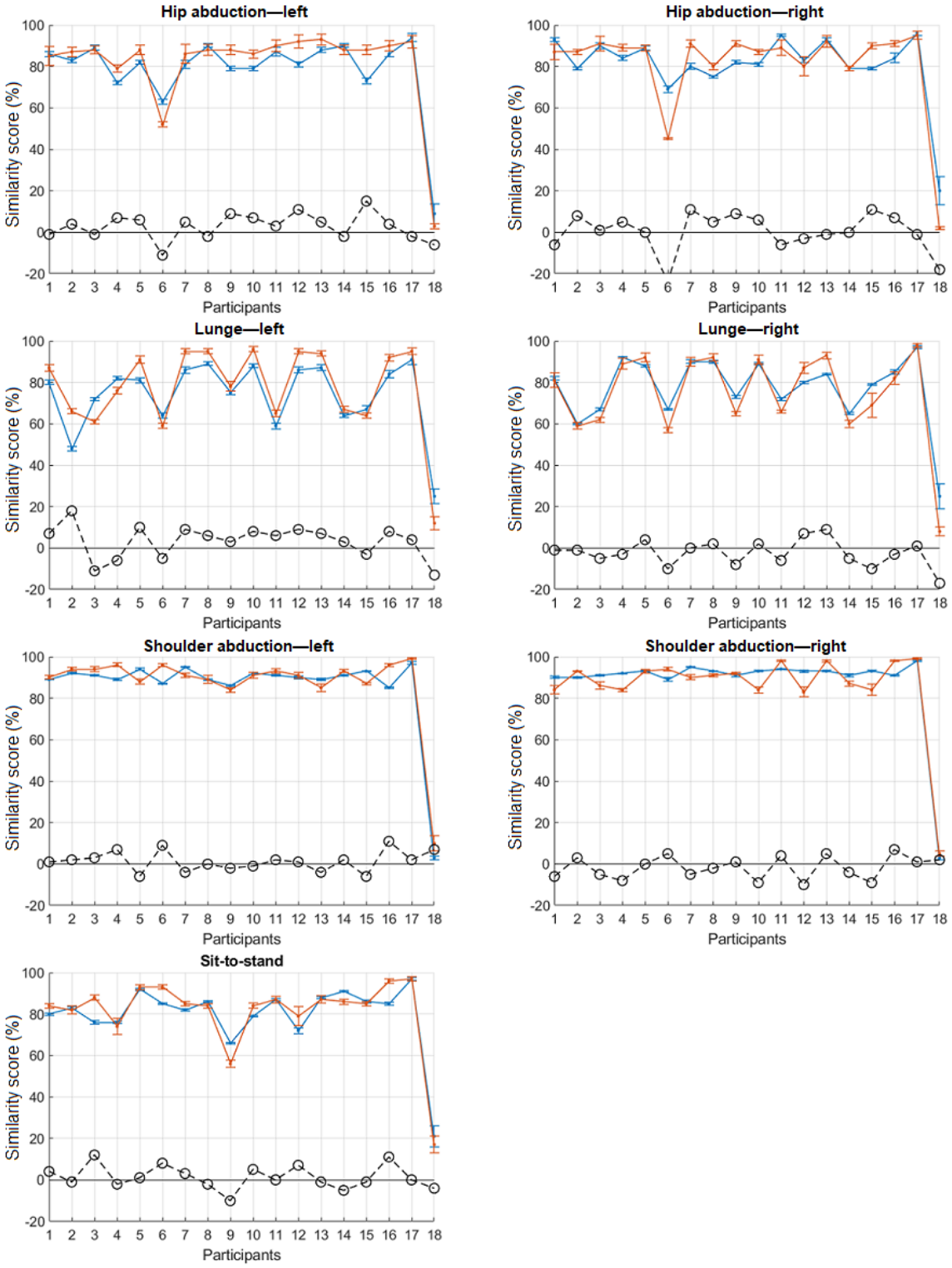
A total of 16 healthy participants, including 8 adult females (22 to 30 years), 6 adult males (22 to 40 years), and 2 school boys (12 and 17 years), were recruited for the study. Participants were asked to stand in front of the Kinect sensor and perform each of the 7 exercises for 20 seconds. They were told to repeat the chosen exercise at least five times with a short pause between each repetition. In addition to the 16 participants, the physiotherapist involved in the project (DS) was asked to perform the exercises as the reference performance. He repeated each of the 7 exercises at least five times during a period of 20 seconds each.

Results

Of the 5 repetitions, 3 were extracted (ignoring the first and the last) for each participant. For DTW scores, the distance between each repetition of a participant and each repetition of the physiotherapist was calculated, yielding a total of 9 values. The final DTW score (S_D) was obtained by taking the average of these values. For HMM scores, the likelihood of each repetition of a participant given the physiotherapist's model was calculated, yielding a total of 3 values. The final HMM score (S_H) was obtained by taking the average of these values. Figure 6 shows the similarity scores obtained by applying DTW (S_D, solid blue line) and HMM (S_H, solid red line) for each exercise. The difference between the 2 scores, S_D-S_H, is also indicated in the plots by a dashed black line. Participant 17 is the

physiotherapist and hence the reference. As expected, he obtained the maximum score in all cases. The worst performance, that is, making no movement, is included as participant 18, yielding very low scores in all exercises. Ideally, we would have expected to obtain a maximum score of 100% for the reference and a minimum score of 0% for the worst performance. However, these values were not obtained because of natural variability among the repetitions and cross-comparison between the repetitions.

Figure 6. Similarity scores obtained from applying dynamic time warping (SD, solid blue line) and hidden Markov model (SH, solid red line). Their difference, SH-SD, is shown by the black dashed line. Participant 17 is the physiotherapist and 18 is the worst performance, that is, making no movement. Error bars indicate standard error.



Discussion

Several observations can be made from these plots in Figure 6. Both scores showed similar trends. Whenever a participant did not perform well according to the DTW score (S_D), his/her HMM score (S_H) was low as well. Examples of this behavior are participant 6 in hip abduction (left and right) and participant 9 in sit-to-stand.

Regarding the difference, $S_H - S_D$, it is difficult to observe any obvious pattern. On some occasions, the difference was positive and on some others it was negative. There were also cases where the difference was negligible. The difference could be as large as +18% (participant 2, lunge—left) or as small as −24% (participant 6, hip abduction—right). For the reference participant 17, the difference was generally very low (−1%, −1%, 4%, 1%, 2%, 1%, and 0%). However, this was not the case for the worst performance, participant 18. In most exercises, the difference was negative and was not negligible, indicating that the S_D was usually larger than the S_H for the worst performance. In addition, in most plots, S_H was closer to 0% than S_D for the worst performance.

Among the exercises, shoulder abduction was less challenging and easy to perform, which is reflected by participants performing well and achieving high similarity scores. In contrast, lunge was the most difficult and demanding exercise to perform, which is also reflected in the obtained similarity values.

Time domain plots of the best and worst performances can be used to visually examine the correlation between the trajectories and the calculated scores. For each of the 7 exercises, the trajectories of the best and the worst performances were plotted against the reference (Figure 7). Each plot illustrates 3 repetitions of the chosen participant (solid red lines) and 3 repetitions of the physiotherapist (dashed blue lines). It should be noted that for hip/shoulder abduction and sit-to-stand, each repetition includes 2 features, and for lunge, each repetition includes 3 features (Figure 4). Evidently, whenever the participant's trajectories match those of the reference (in terms of both amplitude and duration), the obtained score is high. Conversely, when the patterns do not match, the score is low. For example, in hip abduction—left, participant 6 failed to achieve full range of motion (compare the peak amplitude, 40° versus 80°) and performed faster (compare the duration, 100 [1 second] versus 200 [2 seconds]). It is worth mentioning that both the DTW and the HMM algorithms are sensitive to amplitude than duration. They are both time-series algorithms that take into account the sequence of data (amplitudes) regardless of their frequency (duration). DTW does not allow time scaling of members within the sequence, and the HMM algorithm discards the time dependency of members by grouping them into clusters during the quantization preprocess. If two participants followed the required range of motion, but one performed slower (or faster) than the other, their score would be the same (see lunge—left, both participants 11 and 9).

Except the lunge exercise for which 3 features (joint angles) were extracted, 2 features were obtained for all the other exercises. However, not all the extracted features had the same weight and importance. For instance, in hip abduction, referring to Figures 4 and 7, θ_2 (hip angle) is the more relevant feature and θ_1 (torso angle) had lesser importance. This is contrary to the results for shoulder abduction and sit-to-stand. For lunge, θ_2 and θ_1 were both equally important, but θ_3 was lower. The main feature has a higher influence on the obtained similarity score. This is shown in Figure 8 for hip abduction—left as an example. Generally, the same trend was maintained for each measure (compare the same color solid and dashed lines). However, the effect of removing a minor feature $\theta(_1)$ was less influential on S_H than on S_D, as DTW is more sensitive to detail than HMM.

Figure 7. Time-domain plots of the best and worst trajectories (excluding participants 17 and 18). X-axis indicates the time in seconds and Y-axis indicates the joint angle in degree. The three repetitions of the reference trajectories are given in dashed blue lines and the chosen participant's trajectories in solid red lines. All plots include two features, except for lunge where three features are presented.

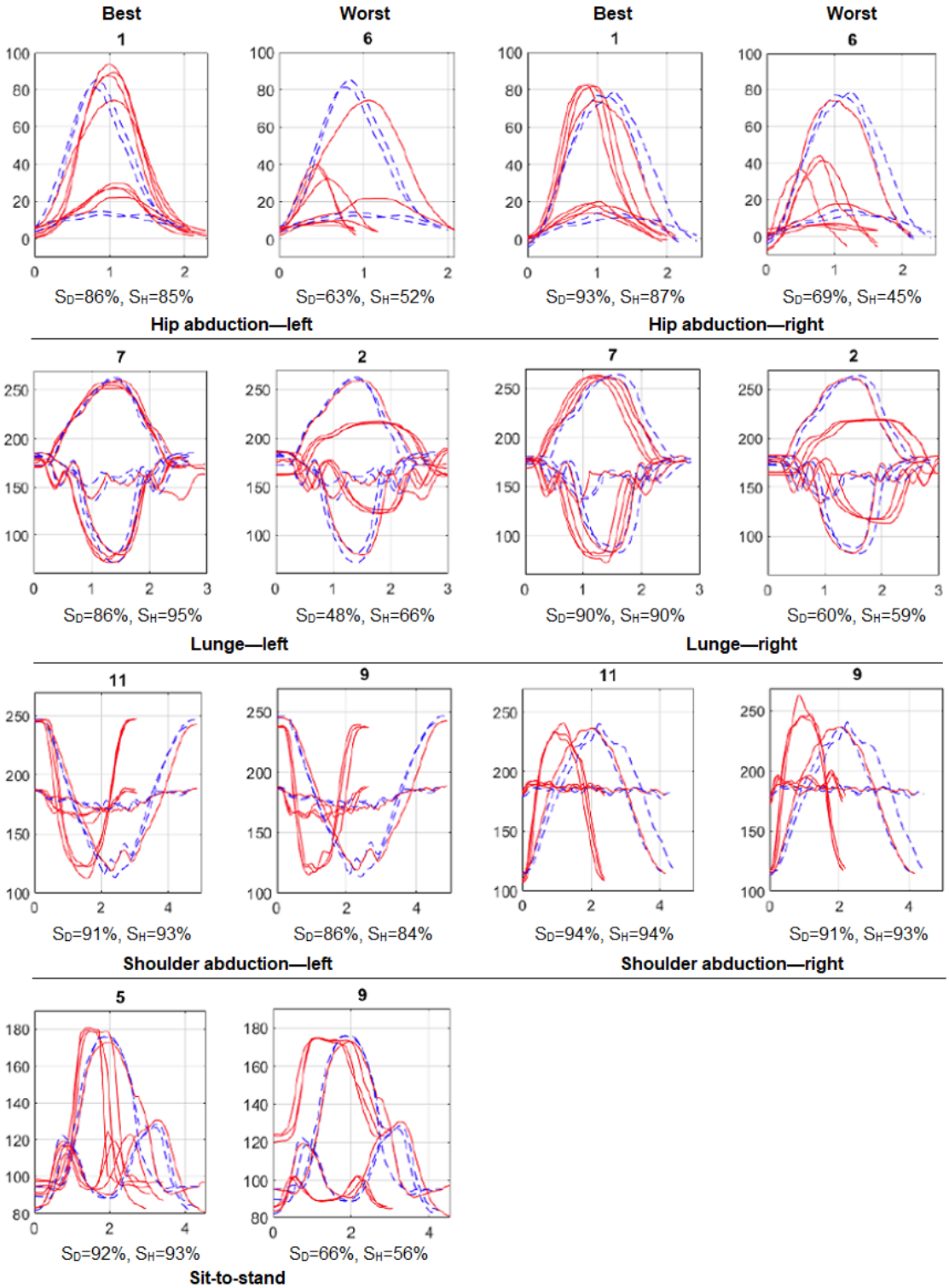
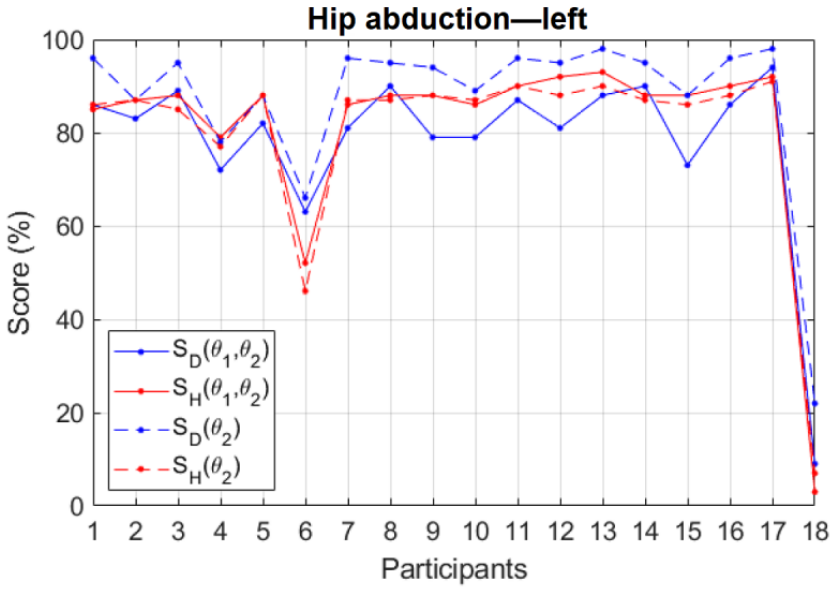


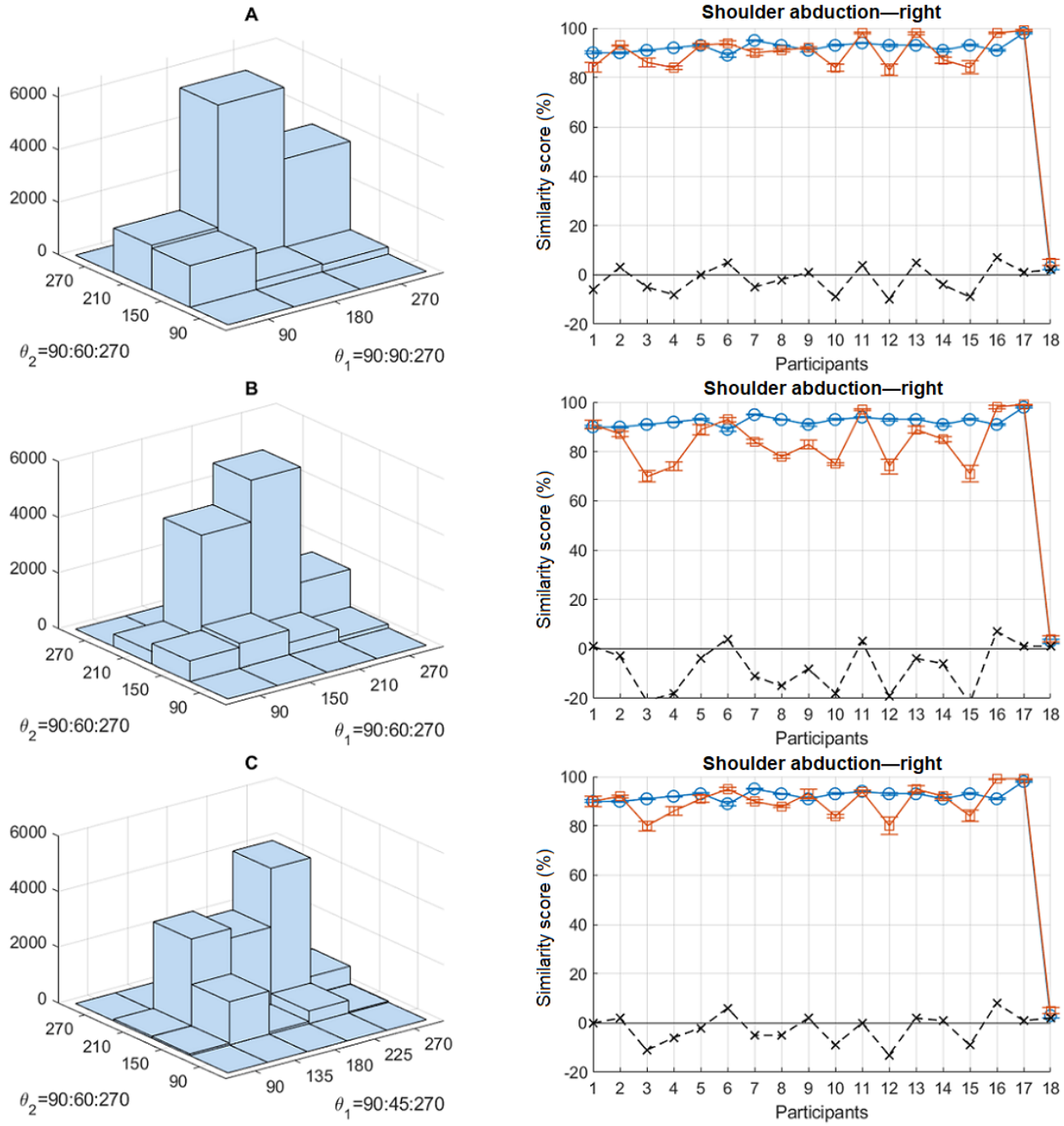
Figure 8. The effect on the scores of removing minor features.



Although single-feature S_D is clearly larger than full-feature S_D, single-feature S_H is almost the same as full-feature S_H. Adding more details, that is, presenting additional minor features, increases the distance values (and hence decreases the similarity scores) obtained by applying DTW.

Although DTW is more sensitive to detail, HMM is more sensitive to the way the feature space is quantized. Quantization is a preprocess applied over the extracted features to segment them into several clusters for the purpose of training a discrete HMM. The boundaries and the number of clusters have an obvious effect on the HMM scores. This can be seen in Figure 9 for shoulder abduction—right as an example. Bivariate histogram plots are used to visualize the clusters. Three cases were tested, changing θ_1 (main feature) boundaries and keeping θ_2 (minor feature) intact. θ_1 is divided into 3 clusters (90°, 180°, and 270°) in case A, 4 clusters (90°, 150°, 210°, and 270°) in case B, and 5 clusters (90°, 135°, 180°, 225°, and 270°) in case C. In all cases, θ_2 is divided into 4 clusters (90°, 150°, 210°, and 270°). A closer look reveals that the S_H scores in case B are clearly lower than those in cases A and C, which are more similar. The reason for this is that feature points are grouped into different clusters for the participant and the reference. This affects (reduces) the probability that a selected feature point of the participant is generated by the reference model. Most likely, the feature points of the participants and the reference in cases A and C are grouped into similar clusters; hence, their similarity scores are higher and more similar. In case B, however, they are grouped into different clusters, decreasing the probability values, thus lowering the similarity scores. One can take advantage of this behavior by adjusting the sensitivity of HMM similarity scores to smoothen or sharpen the differences.

Figure 9. The effect of quantization on the calculated hidden Markov model scores.



Worst performance is a key factor affecting the scores in both measures as it corresponds to the upper or lower boundary, as previously explained. This is evident from $S_D=100\times(D-D_l)/(D_u-D_l)=100\times(D/D_u)$ and $S_H=100\times(L-L_l)/(L_u-L_l)=100\times(L_l-L/L_l)$. Both unknown limits ($D_u$ for DTW and L_l for HMM) are used as denominators to normalize the distance $S_D=100\times(D-D_l)/(D_u-D_l)=100\times(D/D_u)$ and likelihood $S_H=100\times(L-L_l)/(L_u-L_l)=100\times(L_l-L/L_l)$ values. The larger the denominator, the smaller the deviations (fluctuations) in the scores. This value can also be intentionally altered to adjust the sensitivity of the scores. With a larger denominator, the scores are smoother and the differences between participants become smaller. With a smaller denominator, the scores become sharper and the differences between participants are highlighted. As explained previously, we chose no movement as the worst performance for all exercises. Seemingly, a different worst performance can yield different scores if it generates different denominators. For example, one might say that closing the elbow in shoulder abduction could be worse than keeping it stretched (the current situation). An example of altering limits (multiplying and dividing D_u and L_l by 2) for sit-to-stand is shown in Figure 10. When the limits are magnified (multiplied by 2), the scores are increased and smoothed (Figure 10, left). When the limits are shrunk (divided by 2), the scores are decreased and sharpened (Figure 10, right). Smoothed scores can be used to encourage patients performing prescribed exercises in the early stages, whereas sharpened scores could

be used in later stages to encourage further mastering of the skills involved in performing the exercises.

Several comparative tests were also conducted. Figure 11 shows the average scores across all 7 exercises. For each participant, the average score was obtained from 9×7=72 scores (9 values for each of the 7 exercises). As can be seen, the 2 plots show very similar trends. This was verified by applying the *t* test over the 2 measures (*P*=.49). Small error bars indicate high levels of consistency.

A comparison between the left and right performances, excluding sit-to-stand, is shown in Figure 12. No significant differences were observed between the left and the right scores. This was verified by applying a *t* test over the scores for each measure (*P* values are given in Table 1).

Furthermore, a comparison between female and male participants is shown in Multimedia Appendix 1. The scores were averaged across 8 female and 8 male participants (excluding reference). As it can be seen, there was no significant difference between the 2 genders. This was verified by applying a *t* test over S_D (*P*=.22) and S_H (*P*=.86).

Figure 10. Effect of altering limits (Du and Ll, obtained from the worst performance) on the scores: multiplied by 2 (left) and divided by 2 (right). Error bars indicate standard error.

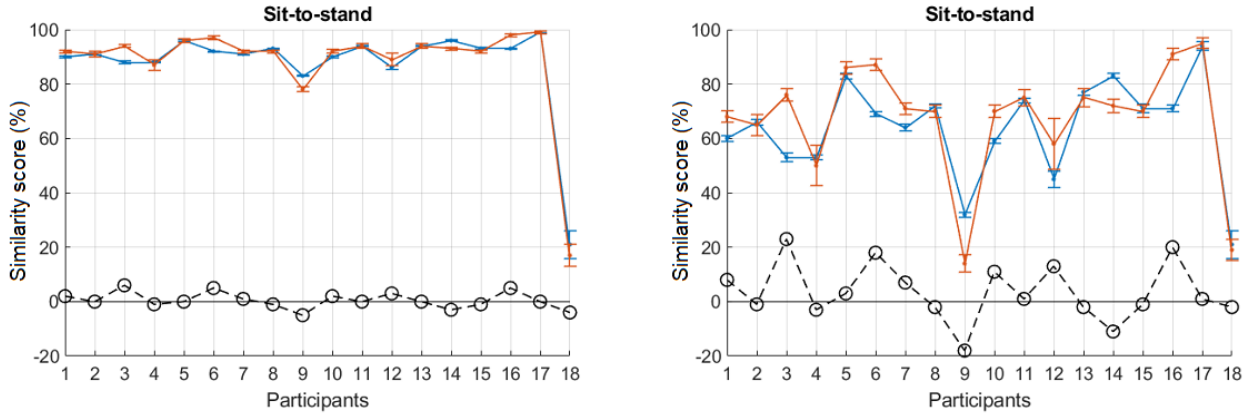


Figure 11. The combined and averaged scores (left: SD and right: SH) for all seven exercises. Error bars indicate the standard error.

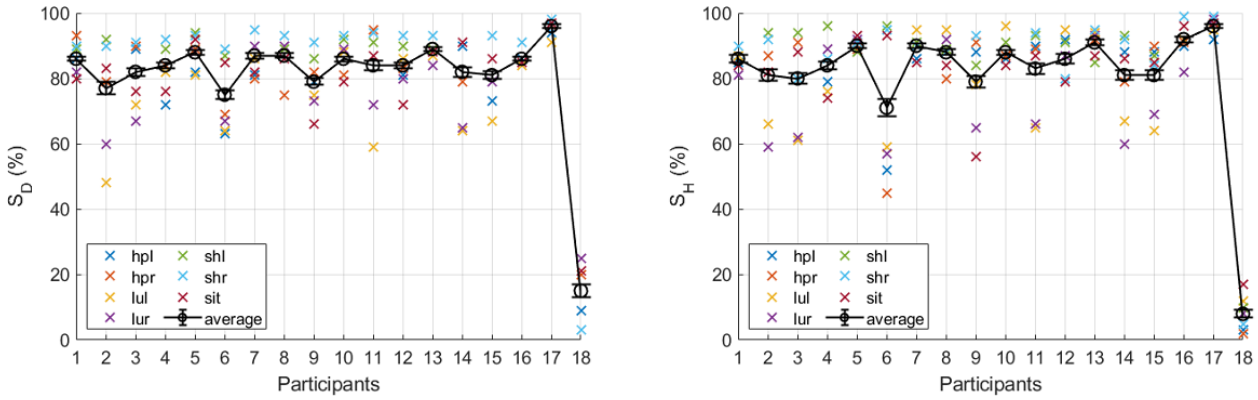


Figure 12. Comparison between left and right scores. Error bars indicate standard error.

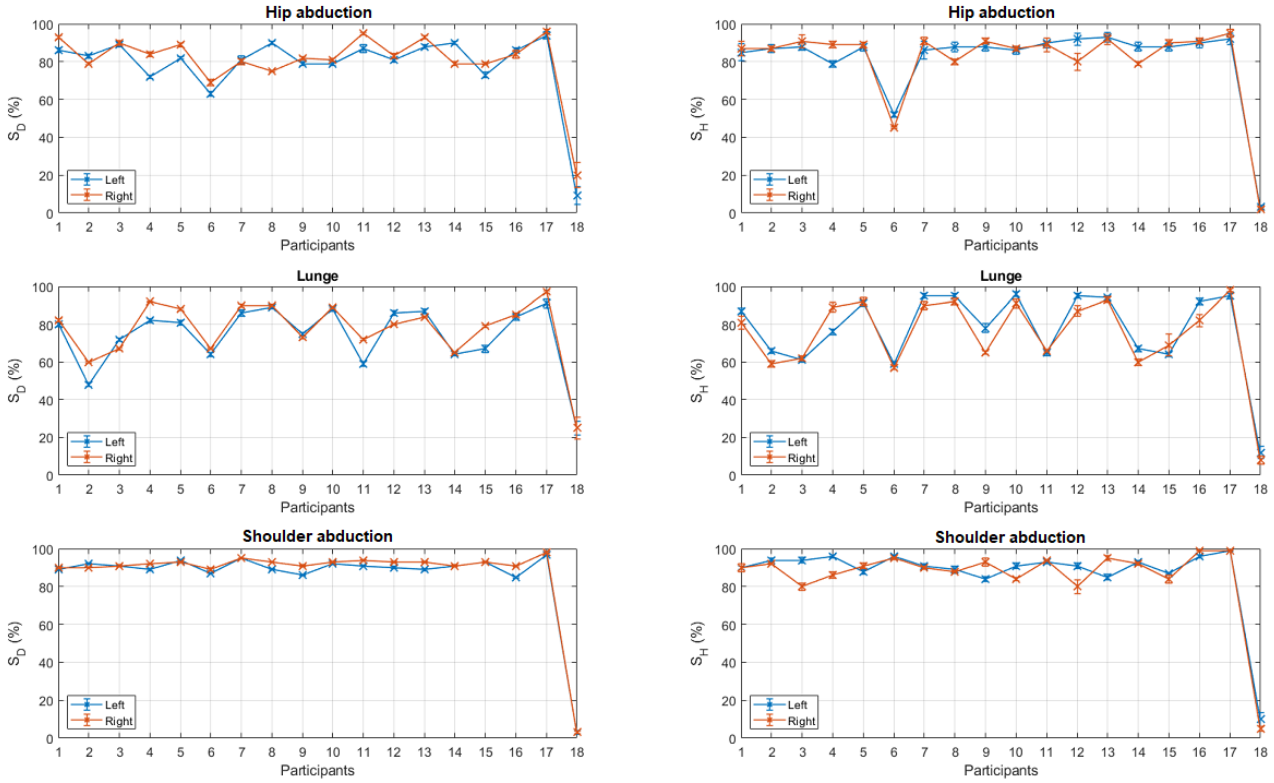


Table 1. *P* values obtained by applying the t test over the left and right scores.

Metrices	Exercises		
	Hip abduction	Lunge	Shoulder abduction
S_D[a]	.27	.09	.44
S_H[b]	.85	.25	.45

[a]S_D: dynamic time warping score.

[b]S_H: hidden Markov model score.

Conclusions and Future Remarks

We implemented and compared 2 commonly used machine learning algorithms, DTW and HMM, to objectively evaluate the performance of patients using a rehabilitation exergaming platform. 3D movement data were obtained using the Kinect depth camera, and invariant features (joint angles) describing each exercise were extracted. The extracted features are independent of body fit, size, and position and distance of the user to the Kinect. They are also independent of the hardware being used and can be adapted for any motion-sensing device capable of tracking human skeleton joints, such as those mentioned in the *Related Work* section.

Setting a physiotherapist performance as the *reference* and making no movement as the *worst performance*, we applied both DTW and HMM algorithms to compare participants' performance and report a similarity score. The idea of worst performance was the key to converting the distance measures (obtained from DTW) and likelihood values (obtained from HMM) to similarity scores between 0% and 100%. Overall, both algorithms showed similar trends but had different sensitivities. DTW was observed to be more sensitive to small changes, whereas HMM was more sensitive to the boundaries and clusters resulting from the quantization process. Both DTW and HMM are inherently more sensitive to range of motion than duration. In addition, both measures are sensitive to the worst performance. This suggests ways to use both algorithms to monitor patient progress at different stages: monitoring could start with HMM similarity scores in early stages for a more general comparison and switching to DTW similarity scores in later stages for finer comparison.

The application of these similarity scores is twofold. The scores can be used by the patients at home to encourage them to continue practicing the exergames to achieve higher similarity scores. In addition, the scores can be reported back to the physiotherapist to monitor patient progress and provide feedback. The exercise program can also be adjusted by the physiotherapist given the level of progress to better fit the patient's needs and progression.

Our proposed method has the potential for significant impact in the context of rehabilitation exergames by enabling remote

therapy home-based sessions where performance can still be adequately monitored. This can help better assess the quality of physical exercises performed by patients, fine-tune rehabilitation programs, and enhance the efficiency of home-based rehabilitation. In turn, cost reductions and freeing up of physiotherapy unit time may also be achieved.

Future work will include testing our proposed system on a public data set such as the University of Texas at Dallas-Multimodal Human Action Dataset [44]. In addition, we intend to recruit patients with reduced movement range or other constraints to participate in a study to validate our proposed performance metrics in a clinical setting. The study will also investigate the correlation between the objective scores used by our system and the subjective notes taken by physiotherapists when observing patients performing the exergames.

Acknowledgments

The project was funded through MedCity's Collaborate to Innovate program and received funding from the European Regional Development Fund and the Higher Education Funding Council for England. The authors acknowledge the support of MIRA Rehab Ltd as well as members of the Simulation and Modelling in Medicine and Surgery research group at the Imperial College London.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Comparison between female and male participants, left: DTW scores (SD) and right: HMM scores (SH). Error bars indicate standard error.
[PNG File , 73 KB - rehab_v7i2e17289_app1.png]

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Abbreviations

3D: 3-dimensional
DTW: dynamic time warping
HMM: hidden Markov model
KEHR: Kinect-enabled home-based rehabilitation system
MIRA: Medical Interactive Recovery Assistant

Edited by G Eysenbach; submitted 04.12.19; peer-reviewed by A Vakanski, E Nathan, J Moral-Munoz; comments to author 20.04.20; revised version received 01.06.20; accepted 14.06.20; published 18.08.20.

Please cite as:
Haghighi Osgouei R, Soulsby D, Bello F
Rehabilitation Exergames: Use of Motion Sensing and Machine Learning to Quantify Exercise Performance in Healthy Volunteers
JMIR Rehabil Assist Technol 2020;7(2):e17289
URL: http://rehab.jmir.org/2020/2/e17289/
doi:10.2196/17289
PMID:32808932

Original Paper

Exploring Attitudes and Experiences of People With Knee Osteoarthritis Toward a Self-Directed eHealth Intervention to Support Exercise: Qualitative Study

Rachel K Nelligan[1], BPhysio; Rana S Hinman[1], PhD; Pek Ling Teo[1], BPhysio, MHSc; Kim L Bennell[1], PhD

Centre for Health, Exercise and Sports Medicine, Department of Physiotherapy, School of Health Sciences, The University of Melbourne, Parkville, Australia

Corresponding Author:
Kim L Bennell, PhD
Centre for Health, Exercise and Sports Medicine
Department of Physiotherapy, School of Health Sciences
The University of Melbourne
161 Barry Street
Parkville, 3010
Australia
Phone: 61 3 8344 4135
Email: k.bennell@unimelb.edu.au

Abstract

Background: Knee osteoarthritis (OA) is a highly prevalent and debilitating condition. Exercise is a recommended treatment because of its effectiveness at improving pain and function. However, exercise is underutilized in OA management. Difficulty accessing health care has been identified as a key barrier to exercise uptake. Innovative and scalable methods of delivering exercise treatments to people with knee OA are needed. We developed a self-directed eHealth intervention to enable and encourage exercise participation. The effectiveness of this intervention on pain and function in people with knee OA is being evaluated in a randomized clinical trial.

Objective: This study aimed to explore the attitudes and experiences of people with knee OA who accessed the self-directed eHealth intervention and the features perceived as useful to facilitate self-directed exercise.

Methods: This was a qualitative study embedded within a randomized controlled trial. Individual, semistructured phone interviews were conducted with 16 people with knee OA who had accessed a 24-week eHealth intervention (website and behavior change SMS program) designed to support exercise participation. Interviews were audiorecorded, transcribed verbatim, and thematically analyzed using an inductive approach.

Results: Five themes arose: (1) technology easy to use and follow (website ease of use, SMS ease of use), (2) facilitators to exercise participation (credible OA and exercise information, website features, prescribed exercises simple to do unsupervised, freedom to adapt the exercise to suit needs, influence of other health care experiences), (3) sense of support and accountability (SMS good reminder and prompt, accountable, SMS tone and automation could trigger negative emotions [eg, guilt or shame], inability to contact someone when needed), (4) positive outcomes (knee symptom improvements, confidence to self-manage, encouraged active living), (5) suggestions for real-world application (provided by a health professional preferred, should be provided at subsidized or low out-of-pocket cost).

Conclusions: People with knee OA had mostly positive experiences with and attitudes towards the use of an eHealth intervention that supported exercise participation independent of a health professional. A human connection associated with the eHealth intervention appeared important.

(JMIR Rehabil Assist Technol 2020;7(2):e18860) doi:10.2196/18860

KEYWORDS

text messaging; mobile phone; knee osteoarthritis; exercise; qualitative; pain

Introduction

Knee osteoarthritis (OA) is a highly prevalent and debilitating condition [1]. Knee OA clinical guidelines advocate condition-specific information and exercise as first-line treatments [2-6]. Despite this, exercise is underutilized in preference for pharmacological, surgical, or "wait and see" management [7-10]. This is in part due to some patients having difficulty accessing health professionals trained in exercise prescription [11,12], particularly in remote areas [13]. Furthermore, in the absence of health professional input, people with knee OA can lack confidence navigating nonsurgical interventions [14] and motivation to adhere to exercise [11,15]. They may also hold negative exercise beliefs [11,16], which may prevent uptake of and adherence to self-directed exercise. The prevalence of knee OA is forecast to increase substantially due to an aging population and rising obesity. This is predicted to place even greater pressure on access to health care resources [17]. In light of this, innovative and scalable methods of delivering evidence-based, first-line treatments, such as exercise, are needed.

eHealth programs may be one solution to increase exercise participation in people with knee OA [18,19]. While qualitative studies demonstrate that, overall, self-directed, web-based programs designed to support exercise or physical activity are viewed positively by people with OA [20-22], engagement is low [23,24]. This may impede their successful implementation and subsequently their usefulness in facilitating improved health outcomes [25]. Identified facilitators of acceptance and engagement with these programs include content credibility and technology ease of use, while a key barrier is lack of health professional involvement [20,21]. Incorporating health professional input may be one solution to improve acceptance and engagement; however, this does not fully address the problem of health care accessibility.

SMS using mobile phones may be one strategy to improve engagement with OA eHealth self-management programs and support exercise behavior without the need for health professional input. SMS has been shown to effectively increase uptake of healthy behaviors including physical activity, smoking cessation [26], adherence to diabetes self-management, and medication adherence [27]. The combination of a self-directed, web-based intervention supported by SMS has not been evaluated in people with OA.

To explore this, we developed a "light-touch," self-directed, eHealth intervention that combines a website, "My Knee Exercise," and a 24-week behavior change SMS program. The effect of this intervention on knee pain and function is currently being evaluated in a randomized controlled trial (RCT) of 206 people with a clinical diagnosis of knee OA [28]. In addition, as patient acceptability is a key component to successful intervention implementation [29], qualitative enquiry is also needed to understand if the eHealth intervention is accepted by people with knee OA to facilitate self-directed exercise. Qualitative enquiry will also inform intervention modifications. The aim of this study was therefore to explore the experiences and attitudes of people with knee OA who accessed the eHealth intervention and identify which features were perceived as useful to facilitate self-directed exercise.

Methods

Design

A qualitative study based on an interpretivist paradigm [30] was nested within an RCT [28] evaluating the effectiveness of an eHealth intervention of web-based information and exercise prescription supported by behavior change mobile phone SMS (data collection completed and manuscript in preparation; Australian New Zealand Clinical Trials Registry ACTRN12618001167257). Reporting complies with The Consolidated Criteria for Reporting Qualitative Research checklist [31].

Participants

Participants in this study were a subsample of those allocated to the intervention arm of the RCT who had completed the 24-week intervention within the past 2 months. Participants were purposively sampled to participate in this qualitative study. Purposive sampling was used to ensure variation across sex, age, geographical location (eg, metropolitan, regional), and responses to 24-week measures of self-reported perceived change in symptoms and of website and SMS usefulness. The sample size was dictated by theoretical saturation, a concept where recruitment ceases when no new information emerges from the data [32]. Ethics approval was obtained from the Human Research Ethics Committee of University of Melbourne (HREC No. 1852367.1). Participants provided informed consent via online consent forms prior to the interview. Initial recruitment for the RCT was from the Australia-wide community via internet sources (social media and online newspapers) and a volunteer database. Eligibility criteria for the RCT included age ≥45 years and a clinical diagnosis of knee OA [5]. Full RCT eligibility criteria are reported elsewhere [28].

Table 1 describes the characteristics of the 16 participants interviewed. The mean age of participants was 63 years, and half (8/16, 50%) were female. Participants lived in locations across all states and territories within Australia, except for the Northern Territory; 9 (9/16, 56%) lived in regional Australia.

Table 1. Participant details (n=16).

Pseudonym	Sex	Age (years)	Level of education completed	Employment status	State	Geographical location[a]	Baseline knee pain[b]	Perceived change in knee condition (24 weeks)	Website usefulness[c] (24 weeks)	SMS usefulness[d] (24 weeks)
Olivia	F[e]	65	Tertiary	Part-time	NSW[f]	Metropolitan	6	Much better	7	7
Harry	M[g]	73	Tertiary	Retired	Qld[h]	Metropolitan	5	Moderately better	5	6
Charlotte	F	67	Secondary	Retired	WA[i]	Metropolitan	7	Much worse	1	4
James	M	67	Secondary	Retired	VIC[j]	Regional	5	Much better	6	7
William	M	58	Tertiary	Full-time	ACT[k]	Metropolitan	4	Slightly better	2	4
Amelia	F	75	Tertiary	Retired	SA[l]	Metropolitan	5	Slightly better	2	1
Charlie	M	48	Tertiary	Full-time	NSW	Regional	7	Much better	7	7
Liam	M	68	Tertiary	Retired	WA	Regional	5	Much better	6	6
Grace	F	73	Tertiary	Retired	SA	Regional	6	Moderately better	2	4
Joshua	M	62	Secondary	Retired	Qld	Regional	4	Much better	5	5
George	M	56	Secondary	Full-time	NSW	Regional	5	Moderately better	5	6
Lucy	F	59	Secondary	Part-time	NSW	Metropolitan	6	Moderately better	5	4
Oliver	M	53	Secondary	Full-time	WA	Regional	7	Slightly worse	5	2
Sophie	F	57	Tertiary	Part-time	SA	Metropolitan	6	Much better	5	6
Emily	F	55	Tertiary	Part-time	Tas[m]	Regional	7	Much better	6	6
Chloe	F	65	Secondary	Retired	WA	Regional	8	Slightly better	6	6

[a]Defined according to The Australian Statistical Geography Standard Remoteness Structure [33].

[b]Self-reported overall knee pain in the past week rated on a numeric rating scale, ranging from 0 to 10, where lower scores indicate less pain.

[c]Agreement with the statement "I thought the website I accessed as part of the study was useful in helping me manage my painful knee," rated on scale ranging from 1 to 7 (1= strongly disagree; 7=strongly agree).

[d]Agreement with the statement "I thought the mobile phone text messages I received were useful in helping me manage my painful knee," rated on a scale ranging from 1 to 7 (1= strongly disagree; 7=strongly agree).

[e]F: female.

[f]NSW: New South Wales.

[g]M: male.

[h]Qld: Queensland.

[i]WA: Western Australia.

[j]Vic: Victoria.

[k]ACT: Australian Capital Territory.

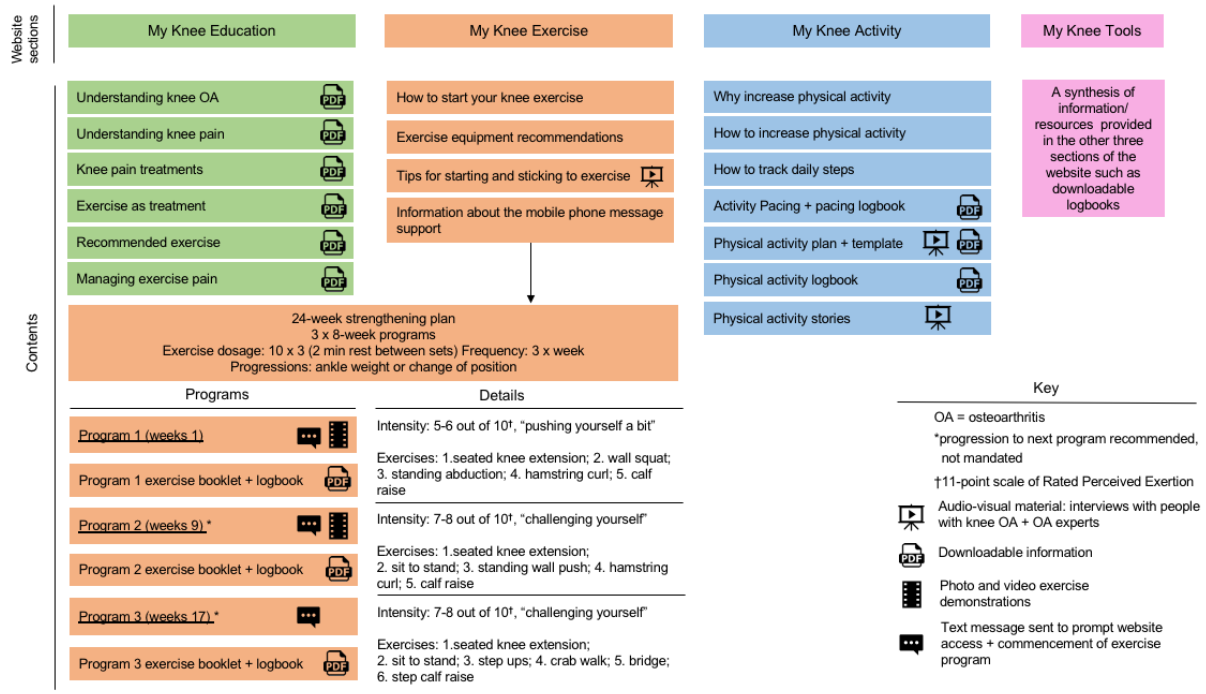
[l]SA: South Australia.

[m]Tas: Tasmania.

Intervention

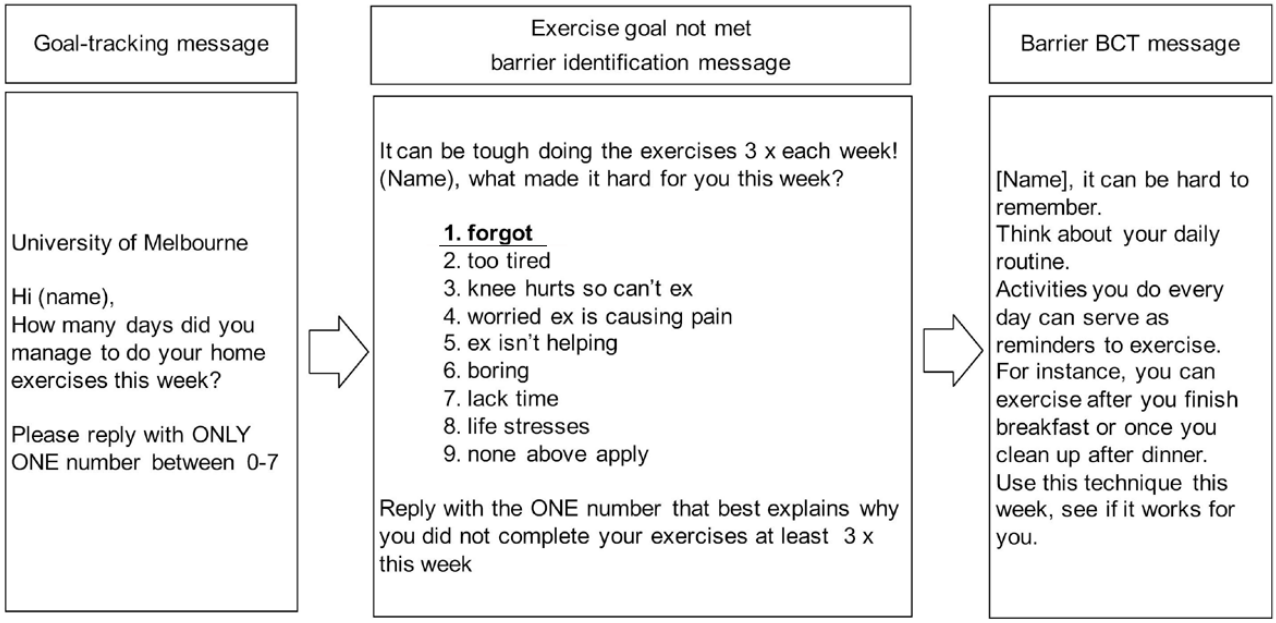
Full details of the digital intervention are described elsewhere [28]. In summary, the intervention included a website, "My Knee Exercise," and a 24-week mobile phone SMS behavior change program. The website contained information about knee OA, exercise, and general physical activity and prescribed a 24-week lower limb strengthening program to be completed 3 times per week. Figure 1 outlines the contents of the website. The website was developed by the researchers (RN, KB, RH), and 3 people with knee OA provided feedback on a prototype, which informed the final design. The strengthening exercises were based on those found to be effective at reducing pain and improving physical function in people with knee OA (when prescribed by a physiotherapist) in our prior clinical trials and were originally developed by the researchers, who are physiotherapists, in collaboration with a clinical physiotherapist [34-37]. Exercises focused on the hip, knee, and ankle such as sit-to-stand, seated knee extension, and calf raise. Exercise instructions were provided in text and visual formats (photo, video). Exercise equipment (eg, ankle weights) was recommended to progress the exercises, and information about where these could be purchased was provided. Exercise instructions and logbooks were available to download. Participants could access the website whenever they chose.

Figure 1. Description of the content in the 4 sections of the intervention website, "My Knee Exercise." OA: osteoarthritis.



The 3-times weekly strengthening exercise program was supported by an automated SMS program. The SMS program was rigorously developed using behavior change theory [38], with input into message tone and wording provided by 12 people (7 academics working in knee OA, 4 clinical physiotherapists, and 1 person with knee OA) in addition to the researchers who developed the program (RN, KB, RH, and a behavior change expert). In brief, the program functioned by prompting participants, on Mondays, to self-report how many strengthening exercise sessions they had completed in the previous week. Participants then received an SMS response based on their reported level of adherence. Adherent participants (≥3 exercise sessions/week) received a positive reinforcement SMS. Low-adherent participants (≤2 exercise sessions/week) received an SMS asking them to choose, from a prespecified list of exercise barriers, what made it challenging to complete their exercises 3 times as recommended. This triggered a response SMS containing a behavior change technique suggestion related to the selected barrier (see example in Figure 2). Irrespective of self-reported adherence, participants also received SMS (initially twice weekly and reducing to once a fortnight by week 24) containing behavior change technique suggestions to motivate and facilitate exercise participation. Participant responses not recognized by the program (eg, responses not using suggested keywords) triggered a "response not supported" message encouraging them to try again or contact program staff if needed. Participants received on average 2-5 SMS per week, dependent on weekly responses, with the frequency of contact declining over 24 weeks.

Figure 2. Example automated message sequence for a person with low exercise adherence (reporting <3 exercise sessions over the past week) and reporting their main barrier to exercise as "forgot." BCT: behavior change technique. [38] Reproduced under the terms of Creative Commons Attribution 4.0 license.



After randomization, participants in the intervention received a welcome email that provided website access (a URL and individualized username and password), asking them to login to the website within 7 days and were scheduled to receive their first SMS, after a period of at least 5 days beginning with Monday. The first SMS in the sequence was a prompt to self-report the number of prescribed exercise sessions completed in the previous week.

Interviews

Individual semistructured telephone interviews were conducted by RN (RCT coordinator, PhD candidate, and physiotherapist), who was also involved in intervention design and responsible for recruitment for the RCT. The interview guide was developed by the authors (RN, KB, RH) and aimed to explore experiences overall and with individual elements of the eHealth intervention (Multimedia Appendix 1). All interviews were audiorecorded, transcribed verbatim by an external service, and stored and de-identified in a password-protected, secure computer file on the university server. Pseudonyms were assigned to each participant to maintain confidentiality.

Data Analysis

An inductive thematic analytical approach was applied using the 6 phases outlined by Braun and Clarke [39,40]. Data were coded by 2 independent researchers, one who conducted the interviews (RN) and the second (PT) who had no prior involvement in design or evaluation of the eHealth intervention. Full details are provided in Table 2. Analysis occurred iteratively and reflectively with forward and backward movement within Phases 1-3. To present the data, pseudonyms were assigned to exemplary quotes.

Table 2. Thematic analysis process conducted based on the phases described by Braun and Clarke [39].

Phase	Description of the process
1. Familiarizing yourself with your data	Data were transcribed by an external company. All transcripts were read by RN for accuracy and to note initial ideas.
2. Generating initial codes	Two researchers experienced in qualitative analysis (RN, PT) independently coded all transcripts and collated data relevant to each code. The 2 researchers met after coding transcripts, in blocks of 4, to discuss and seek agreement of codes and their meaning before proceeding to the next 4 transcripts.
3. Searching for themes	RN and PT independently grouped codes into potential subthemes and themes, gathering all data relevant to each potential theme. They then met to compare, discuss, and seek agreement on themes. Agreement between the 2 researchers was strong; therefore, a third coder was not required.
4. Reviewing themes	KB read all transcripts. RN, PT, and KB checked that subthemes and themes truly represented the coded extracts and the entire data set.
5. Defining and naming themes	All authors discussed and refined subthemes and themes as well as definitions and names for each.
6. Producing the report	RN developed the draft of this manuscript. All authors provided input and approved the final version.

Results

Thematic Analysis

From the data, 5 themes were identified. Multimedia Appendix 2 outlines the themes, subthemes, and supporting quotes.

Theme 1: Technology Easy to Use and Follow

For the first subtheme of "website ease of use," participants found the website easy to get around, the navigation easy to follow, and the information provided easy to grasp regardless of technical abilities:

> *I'm not the smartest computer user in the world, but if I can do it, I reckon anybody can do it.* [George]

For the second subtheme of "SMS ease of use," participants mostly found the SMS program easy to use: "It's just simple" [Olivia]. However, one participant reported difficulty replying to messages in the recommended format:

> *Sometimes with the SMS, I'd put the letters and the things around the wrong way… it was very particular, you know, you had to do it in the right…But other than that, no worries at all.* [Lucy]

Theme 2: Facilitators to Exercise Participation

The first subtheme was "credible OA and exercise information." For many, the fact that the intervention was developed and delivered by a university, a credible source, was appreciated and gave them confidence to apply the eHealth program's information and recommendations. Participants felt they could trust the information, which reinforced and improved their understanding of OA and the role of exercise in managing their knee symptoms. This built their confidence to exercise despite discomfort and without health professional guidance.

The second subtheme was "website features." Participants appreciated certain features of the intervention that enabled exercise participation. Participants felt the website was comprehensive, and the information in the "My Knee Education" section of the website was easy to understand and helpful in supporting self-directed exercise being "more than what the doctor has given you" [Emily]. They found that the written exercise instructions, exercise pictures, and videos helped them master the exercises easily without needing supervision. Some participants valued being able to access the website frequently to view the exercises, while others only accessed the website once or twice, preferring to download and print exercise sheets and logbooks.

The third subtheme was "prescribed exercises simple to do unsupervised." Participants appreciated the simplicity of the recommended exercises. As they perceived the exercises as simple, they believed they did not need supervision:

> *An allied health (person) to actually monitor the exercises was not necessary.* [Harry]

The fourth subtheme was the "freedom to adapt the exercise to suit needs." Participants reported the freedom to use a flexible approach to execute and progress their exercise program over the 24 weeks to suit their needs. As a result, how each participant completed the recommended exercise regime varied greatly. For example, some completed all prescribed exercises at least 3 times a week, many chose not to add additional weight, and others replicated the exercises by doing similar activities in their daily routines. Some also chose their own exercise or physical activity program to complete at the recommended frequency, typically because they found the prescribed exercises too easy and boring. In addition, most participants expressed difficulty with at least one prescribed exercise (the wall squat most frequently reported). This, however, did not deter participants from completing the unsupervised program. If a recommended exercise caused pain, this was typically managed by leaving out the specific exercise and continuing with the remaining exercises or substituting with their own exercise.

The fifth subtheme was the "influence of other health care experiences." Many discussed their previous experiences with health professionals that influenced their willingness to undertake unsupervised exercise. This included already being familiar with exercise prescription due to prior health professional input and dissatisfaction with past face-to-face care received.

Theme 3: Sense of Support and Accountability

The first subtheme was "SMS good reminder and prompt." Participants felt the text messages were a good reminder and prompted them to continue exercising. Most participants appreciated the predictability of the messages, receiving them at the same time each week. This encouraged them to complete their exercise in anticipation of having to report their weekly exercise sessions each Monday.

The second subtheme was "accountable." Many of the participants reflected that the SMS program supported their weekly exercise by keeping them accountable to the research team or their commitment to the exercise program. Many described that the messages felt like someone was checking up on them:

> *You felt like you had to do it because you were going to get checked up…* [Chloe]
>
> *It was like a devil sitting on my shoulder going "have you done your exercises?" Oh, my God, I can only put two in for an answer this week; I've got to do better next week.* [Sophie]

The third subtheme was "SMS tone and automation could trigger negative emotions (eg, guilt/shame)." Participants frequently described feelings of guilt or shame when receiving an SMS particularly if they had not completed the recommended exercise frequency. Most believed this facilitated exercise participation. A few participants did, however, find the message response to exercise low-adherence demotivating: "it was a reminder of the bleeding obvious" [Amelia]. The automated and unsupervised nature of the SMS program was problematic for some, especially in extenuating circumstances:

> *When I got the planter fasciitis and the texts were coming through…they just kept coming, and it was kind of like a little shame thing.* [Charlotte]

The fourth subtheme was "inability to contact someone when needed." Many participants thought it would be beneficial if

the SMS program allowed them to provide more detail or converse with someone to better explain low adherence, particularly when the reason did not relate to the options provided. Some also wanted the ability to ask a question or contact someone about the exercise program or their condition if needed.

Theme 4: Positive Outcomes

The first subtheme was "knee symptom improvements." All participants felt the 24-week intervention had benefited them in some way. Many reported reductions in knee pain. This enabled them to walk more, rely less on pain medication, and delay or avoid knee surgery.

The second subtheme was "confidence to self-manage." Most participants expressed improved confidence in their ability to self-manage their condition. This included greater confidence to maintain their preferred lifestyle. For example:

> *…it's helped me not only with my mobility but my self-confidence to be able to go, yeah, I can get up there all right and come down there.* [Grace]

Several participants also reported the program helped motivate them to lose weight:

> *Not only has it changed the strength in my knees and reduced the amount of ongoing pain that I have with them, it's also inspired me to lose weight. I've actually lost at this stage — about 14 and a half kilos.* [George]

The third subtheme was "encouraged active living." Participants reported increases in physical activity and greater enjoyment in being physically active, which they attributed to their participation in the study. Except for one participant, all expressed a desire to continue to exercise and be physically active to maintain improvements in their condition.

Theme 5: Suggestions for Real-World Application

The first subtheme was "provided by a health professional preferred." All participants would recommend the program beyond the research environment. Relating to how participants could see the intervention being used outside the research environment, most suggested it could be provided by a health professional, particularly a general practitioner or a physiotherapist, to enhance or improve care. Some also believed promoting the intervention through social media was suitable.

The second subtheme was "should be provided at subsidized or low out-of-pocket cost." Most participants believed costs of participating in the intervention should be subsidized by private health insurers or government initiatives. A few felt strongly that themselves, the user, should pay "so long as it wasn't too expensive" [Grace], perceiving that this might support adherence.

Discussion

Principal Findings

This study explored the experiences and views of people with knee OA who participated in a self-directed, 24-week eHealth intervention designed to facilitate exercise participation. Overall, participants described positive experiences, valuing the simplicity and comprehensiveness of the resources (technical and content) and the regular SMS messages, both of which supported self-directed exercise. However, the SMS automation and tone were problematic for some people when weekly exercise was not completed. Human connection associated with the eHealth intervention also appeared important.

Our findings highlight that simple-to-use technology that conveys easy-to-understand information is well received by people with knee OA. This is in accordance with the findings of a qualitative study that investigated the preferences of people with chronic joint pain regarding the development of a web-based version of a face-to-face self-management program [20]. In order to engage with a web-based version of the program, participants believed it should be easy to understand and navigate, as well as be free from jargon. Participants also valued the eHealth intervention being developed and delivered by a credible source, a university. This influenced their confidence in and acceptability of the self-directed exercise program. Trustworthiness is a similar finding in other OA studies investigating eHealth interventions [20,21]. Furthermore, participants in our study believed the intervention should be provided by health professionals. Endorsement from a trusted health professional is a key facilitator to the adoption of eHealth programs [25]. Therefore, to facilitate implementation of the eHealth intervention, future studies could explore how health professionals might take an active role in dissemination.

In our study, participants valued the SMS messages as a predictable exercise prompt. However, for some people, the automation and tone of the messages were demotivating or evoked feelings of guilt when weekly exercise was not possible (particularly for reasons beyond their control such as an unrelated health problem). To our knowledge, there are no other studies exploring the views of people with knee OA toward the use of text messages to support exercise participation. People with diabetes who received twice weekly text messages to support physical activity participation valued the text messages as a functional reminder but many disliked receiving repetitive messages, describing them as "nagging" [41]. Another study explored the use of text messages to promote exercise in older adults and found participants valued the messages as encouraging and an important "push" to exercise [42]. However, similar to our findings, the messages could cause feelings of guilt when exercise was not completed. Overall, text messaging appears to be an accepted and valued way to remind or prompt people to complete regular exercise. However, such programs may also simultaneously evoke negative emotions. Possible strategies to address this issue, as described by participants, could include revising the tone and tenor of these messages and reducing the frequency of messages sent to people who are unable to exercise due to unrelated health concerns or personal circumstances.

Although the autonomy afforded by the eHealth intervention was valued, our findings also suggest a human connection was important to participants. Most participants felt that the regular SMS made them feel accountable to the people behind the program or research team, which facilitated regular exercise. Commitment to study researchers has been identified in other

qualitative evaluations of digital OA self-management programs [21,43]. This has implications for translation into real-world settings, as the perception that someone is "behind" the digital program appears vital. In addition, participants in our study suggested the intervention could be improved by having the ability to contact someone when needed, for example, to further explain reasons for low adherence or ask a clinical question. When using digital self-management programs, people with knee OA tend to prefer some form of support or therapist interaction [20]. Other studies have evaluated blended interventions where digital knee OA programs are supported by therapist input. One study explored the experiences of people with knee OA who had completed a 12-week digital physical activity program supported by up to 5 face-to-face physical therapy sessions [43]. Some participants described the physical therapist's involvement as positive, tailoring the digital program and monitoring their progress, while others felt it was restricting, particularly when the therapist did not know how the digital program worked. Another qualitative study evaluated the experiences of people with hip or knee OA who had participated in 6 weeks of "Joint Academy," a digital education and exercise program supported by 1:1 online written contact with a physical therapist [22]. Some participants in this study valued the interaction with their therapist, especially if they experienced pain during an exercise, while others felt the contact was unsatisfactory and that feedback and encouragement on their performance was lacking. These results, in combination with ours, may indicate that people have different preferences for the level of support that should be provided with eHealth self-management programs and highlights that a one-size -fits-all approach to implementation may be inappropriate. As the integration of eHealth interventions into usual care facilitates their successful implementation [25], one solution may be to integrate the eHealth intervention into a stepped model of OA care [44,45], where it is provided as the first "step" in the care plan. Stepped care is where support or interventions are provided in "steps," with input escalating based on an individual's outcomes or preferences for care [46]. This may better ensure the right level of input is provided to meet an individual's needs.

Strengths and Limitations

Our study had several strengths and limitations. Strengths include that this study was nested within an RCT, allowing for the comprehensive and robust evaluation of the eHealth intervention; use of purposive sampling to ensure a variety of participants was included (age, sex, geographical location, education level, and 24-week outcomes of self-reported perceived improvements and resource usefulness); conduct of all interviews within 2 months of completing the study to facilitate accurate recall; and independent data coding by 2 researchers (RN, PT) to formulate themes, which were reviewed for accuracy and completeness by a third researcher (KB) who also read all transcripts. There were several limitations. There was potential for bias as participants self-selected to volunteer for the overarching RCT advertised as investigating different electronic and digital resources to support knee OA management. Therefore, participants may have held more favorable views regarding the use of technology at the outset. Selection bias may also have occurred in the recruitment for this qualitative study, despite the use of purposive sampling, as participants with more favorable opinions of the eHealth intervention may have been more inclined to consent to be interviewed. However, we attempted to overcome this by deliberately recruiting people with low self-reported perceived usefulness of the resources and low self-reported perceived overall improvements in their knee condition (see Table 2). The researcher's (RN) perspectives and potential prior relationship with participants could have affected findings, as she was the interviewer for this study, the participant recruiter for the RCT this study is embedded within, and involved in developing the digital resources. We attempted to address this by selecting a second coder for analysis who had no prior involvement in the design or evaluation of the resources.

Conclusions

In summary, we found that people with knee OA had mostly positive experiences and perspectives of the eHealth intervention. Overall, participants valued the simplicity and comprehensiveness of the resources (technical and content) and the regular SMS prompts, which supported participation in self-directed exercise. Our findings demonstrate the intervention may be an acceptable resource for people with knee OA to encourage self-directed exercise participation. However, a human presence associated with the intervention appears important. Future modifications to the intervention could include adaptations to parts of the SMS program (tone and automation) to minimize inciting negative emotions when exercise is not possible. Further research should explore the real-world application of the intervention, including how the intervention could provide more personalized support for individuals wanting greater input and how it could be integrated into OA care or health professional consultations.

Acknowledgments

The trial was funded by the Australian National Health and Medical Research Council (NHMRC; program grant #1091302). RN is supported by a PhD stipend from the Australian Government Research Training Program Scholarship. RH is supported by an NHMRC Senior Research Fellowship (#1154217). PT is supported by a PhD stipend from the Australian Government Research Training Program Scholarship. KB is supported by an NHMRC Investigator Grant (#1174431).

Conflicts of Interest

RSH's institution receives grant funding from the NHMRC, ARC and Medibank Private/Better Health Foundation. KB receives royalties from Wolters Kluwer for UpToDate knee OA clinical guidelines. Her institution has received grant funding for OA

research from the National Health and Medical Research Council and Medibank Private. All other authors have no conflicts to declare.

Multimedia Appendix 1
Semi-structured interview guide.
[DOCX File , 23 KB - rehab_v7i2e18860_app1.docx]

Multimedia Appendix 2
Themes, sub-themes, and exemplary quotes. Pseudonyms used for participant names.
[DOCX File , 32 KB - rehab_v7i2e18860_app2.docx]

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Abbreviations

OA: osteoarthritis
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 24.03.20; peer-reviewed by A Janssen, M Keep; comments to author 12.06.20; revised version received 28.07.20; accepted 28.10.20; published 26.11.20.

Please cite as:
Nelligan RK, Hinman RS, Teo PL, Bennell KL
Exploring Attitudes and Experiences of People With Knee Osteoarthritis Toward a Self-Directed eHealth Intervention to Support Exercise: Qualitative Study
JMIR Rehabil Assist Technol 2020;7(2):e18860
URL: http://rehab.jmir.org/2020/2/e18860/
doi:10.2196/18860
PMID:33242021

Original Paper

Web-Based Health Coaching for Spinal Cord Injury: Results From a Mixed Methods Feasibility Evaluation

Sonya Allin[1], PhD; John Shepherd[1], MBA; Teri Thorson[2]; Jennifer Tomasone[3], BPHE, MSc, PhD; Sarah Munce[4], PhD; Gary Linassi[5], BSc, BMedSc, MB, FRCPC; Christopher B McBride[2], PhD; Tizneem Jiancaro[1], PhD; Susan Jaglal[1], PhD

[1]Department of Physical Therapy, University of Toronto, Toronto, ON, Canada

[2]Spinal Cord Injury BC, Vancouver, BC, Canada

[3]School of Kinesiology and Health Studies, Queens University, Kingston, ON, Canada

[4]Toronto Rehabilitation Institute, Toronto, ON, Canada

[5]Department of Physical Medicine and Rehabilitation, College of Medicine, University of Saskatchewan, Saskatoon, SK, Canada

Corresponding Author:
Sonya Allin, PhD
Department of Physical Therapy
University of Toronto
160-500 University Ave
Toronto, ON, M5G 1V7
Canada
Phone: 1 416 946 8641
Email: s.allin@utoronto.ca

Abstract

Background: Individuals with spinal cord injury (SCI) are at high risk of experiencing secondary conditions like pressure injuries. Self-management programs may reduce the risk of complications, but traditional programs have proven to be insufficiently tailored to the needs of people with SCI. To overcome barriers to self-management support, a web-based, self-management program was developed for Canadians with SCI called *SCI & U*.

Objective: This study aims to evaluate the feasibility and potential impact of the *SCI & U* program in the context of a mixed methods pilot study.

Methods: The study followed an explanatory, sequential mixed methods design. Participants (N=11) were Canadians with SCI who had been living in the community for more than 1 year. Each took part in a self-paced, six-session self-management program guided by a trained peer health coach. During sessions, participants could discuss a health topic with their coach from a predefined list (eg, skin or bowel management). Quantitative data were gathered before and after program participation to assess program feasibility and impact. Feasibility measures included attrition rates, frequency of topics selected, and recorded goals, whereas impact measures included measures of self-efficacy (University of Washington Self-Efficacy Scale [UW-SES]), mood (Personal Health Questionnaire Depression Scale [PHQ-8]), secondary conditions (Spinal Cord Injury Secondary Conditions Scale [SCI-SCS]), and resilience (Spinal Cord Injury Quality of Life Resilience Scale [SCI-QOL-R]). Qualitative measures were based on postintervention interviews; these were designed to confirm and expand on quantitative

Results: Of the 11 participants, 10 completed pre- and postassessments, and 6 coaching sessions. Sessions lasted between 31 and 81 min (average 55, SD 13), and the duration of the program ranged from 35 to 88 days (average 56, SD 23). Diet and exercise were selected as topics 40% (20/50 sessions with topics) of the time, whereas topics such as mental health, bladder management, pain, and bowel management were chosen less frequently. Results gathered before and after the pilot study demonstrated improvements with moderate effect sizes on the UW-SES and the electronic health literacy scale (ie, Hedges g>0.5). Effect sizes for measures of resilience (SCI-QOL-R), depression (PHQ-8), and secondary conditions (SCI-SCS) were small (ie, Hedges g>0.3). Qualitative results confirmed a common focus on diet and exercise, and defined coaches as sources of accountability, information, reassurance and affirmation, and emotional and technical support.

Conclusions: Results demonstrated that a web-based self-management program is feasible and acceptable by Canadians with SCI. Results also indicated a web-based, peer-led self-management program may impact resilience, self-efficacy, mood, and

secondary complications. Finally, results illuminated the role of the coach in facilitating behavior change. Future work seeks to validate results in the context of a randomized controlled trial.

(JMIR Rehabil Assist Technol 2020;7(2):e16351) doi:10.2196/16351

KEYWORDS

community-based participatory research; spinal cord injury; self-management; motivational interviewing; internet-based intervention

Introduction

Background

For individuals with spinal cord injury (SCI) who live in the community, the risk of experiencing secondary conditions such as pressure injuries or urinary tract infections is high. Even up to 20 years after the injury, rehospitalization rates for people with SCI remain over 30% [1]. To reduce the risk of secondary complications, people with SCI require knowledge about their injuries and strategies to mitigate risk. More specifically, knowledge and skills related to the management of "symptoms, treatment, physical, and psychosocial consequences and lifestyle changes inherent in living with a chronic condition" are required [2]. However, evidence suggests that knowledge and access to self-management tools are inadequate in the SCI community. For example, although some individuals with SCI report high levels of knowledge about bladder or pressure injury management on discharge from inpatient rehabilitation, studies indicate that less than half leave the hospital with clinically adequate knowledge [3]. Moreover, lack of knowledge is not the only barrier to self-care in the community; physical barriers, cost, lack of motivation, and pain also complicate the efforts to independently monitor and maintain health [4-6].

Self-management support programs are community-based tools designed to increase the knowledge and skills required to independently manage a chronic condition. As such, these programs carry the potential to fill some care gaps experienced by people with SCI in the community. Many existing programs, such as the Stanford Chronic Disease Self-Management Program [7] or the UK Expert Patient Programme [8], address a wide variety of chronic health conditions and are led by peers with the lived experience of a chronic condition. However, although peer-led programs have been associated with positive health outcomes (eg, improvements in self-efficacy, health-related quality of life [7,8], lower hospitalization rates [9], and reduced health care expenditures [10]), the typical formulation has shortcomings for community members with SCI. In one qualitative study of the CDSMP, for example, participants with SCI reported less program satisfaction than those with other conditions due to issues such as the lack of familiarity with SCI on the part of facilitators [11]. In this study and in another by Munce et al [12], individuals with SCI expressed a preference for web-based programming over in-person programming [11] and for content tailored to SCI management [11,12]. Tailored self-management programs delivered via the internet may therefore be met with higher satisfaction by individuals with SCI.

Community-based programs that deliver services to the SCI community via telephone or the internet have been both well received and are increasingly common in the literature [13-18]. Telephone-based self-management programs for people with SCI have proven to be safe and acceptable and to improve the participants' level of activation and awareness [13-16]. Examples of internet-based health interventions include a nurse-led telehealth intervention that focused on newly discharged people with SCI [17], a tele-exercise intervention led by remote exercise coaches [18], and programs to support consultations with specialists [19] or peer educators [20] via iPads. However, internet-based self-management support for SCI, although associated with promising usability and feasibility results [19-21], are a relatively new concept and require further evaluation. The internet may indeed have special affordances for people with SCI; in randomized trials comparing internet and phone-based nursing interventions following inpatient rehabilitation, for example, internet-based programming is associated with the least number of postdischarge hospital visits [17]. Internet programming has also been identified as preferable to phone-based programming by members of the SCI community in a qualitative study by Munce et al [12].

In response to the interest in and need for web-based self-management support, a web-based program for users with SCI was developed at the University of Toronto. This program called *SCI & U* was modeled after telephone-based support programs (eg, SCI Action Canada [13,14] and My Care My Call [15,16]) and is part of a growing family of web-based support interventions for SCI (eg, PHOENIX [18-20] and SCI Health Storylines [21]). Like telephone-based interventions [13-16], the program consists of highly structured interactions between participants and trained peers with SCI, or *health coaches*. This is because, in the context of telephone-based programs, peer coaches have been perceived by participants as powerful motivators for behavior change and relevant, credible mentors for skill development [22]. Structures have been created to support participation by members of the Canadian SCI community in the program's development [23]; these include a community advisory board and interdisciplinary design team. This kind of participatory approach reflects that of other research groups [13-16,20] and is intended to promote end user acceptance [24] and respect for guidelines for the creation of health programs serving individuals with disabilities [25].

Objectives

This study aims to evaluate the *SCI & U* web-based self-management program in the context of a pilot study. The specific objectives were to assess implementation feasibility and the potential impact on self-efficacy and experience of secondary conditions. Evaluations of feasibility and impact were based on an analysis of quantitative data gathered before and after program participation. Qualitative data from postintervention interviews with the pilot participants were analyzed to validate and expand upon the quantitative findings.

Methods

Study Design

The study followed an explanatory, sequential mixed methods design with a quantitative component followed by a qualitative component [26]. The quantitative data were the first focus of the analysis, and the qualitative approach used was postpositivist in that the qualitative data did not serve to test the hypotheses but to create an understanding of the intervention that could be shared between the research team and participants [27]. The integration of quantitative and qualitative results took place at the interpretation and reporting levels. A joint display was created to relate the quantitative data to the relevant and explanatory quotes [28].

Intervention

The *health coaching* intervention revolved around structured, web-based partnerships between participants and trained peer health coaches. In keeping with prior work [16], the intervention consisted of 2 principal components: trained peer health coaches and support materials.

A total of 5 peer health coaches were Canadians with SCI who acted as mentors and were trained in established health promotion techniques and paid as professional contractors. Peer mentoring after an SCI, on its own, has been associated with improved confidence in self-management skills and reduced hospital admissions [28]. However, trained peer health coaches have additional strengths as they have been educated in motivational interviewing (MI) [29] and brief action planning (BAP) [30]. Both MI and BAP dictate protocols that encourage health care recipients to actively participate in health care decisions [29,30]. Specifically, BAP helps health care recipients elicit, parameterize, and track realistic goals and plans for health behavior change [30]. It has been successfully embedded in many self-management programs [30], including *My Care My Call* [15,16].

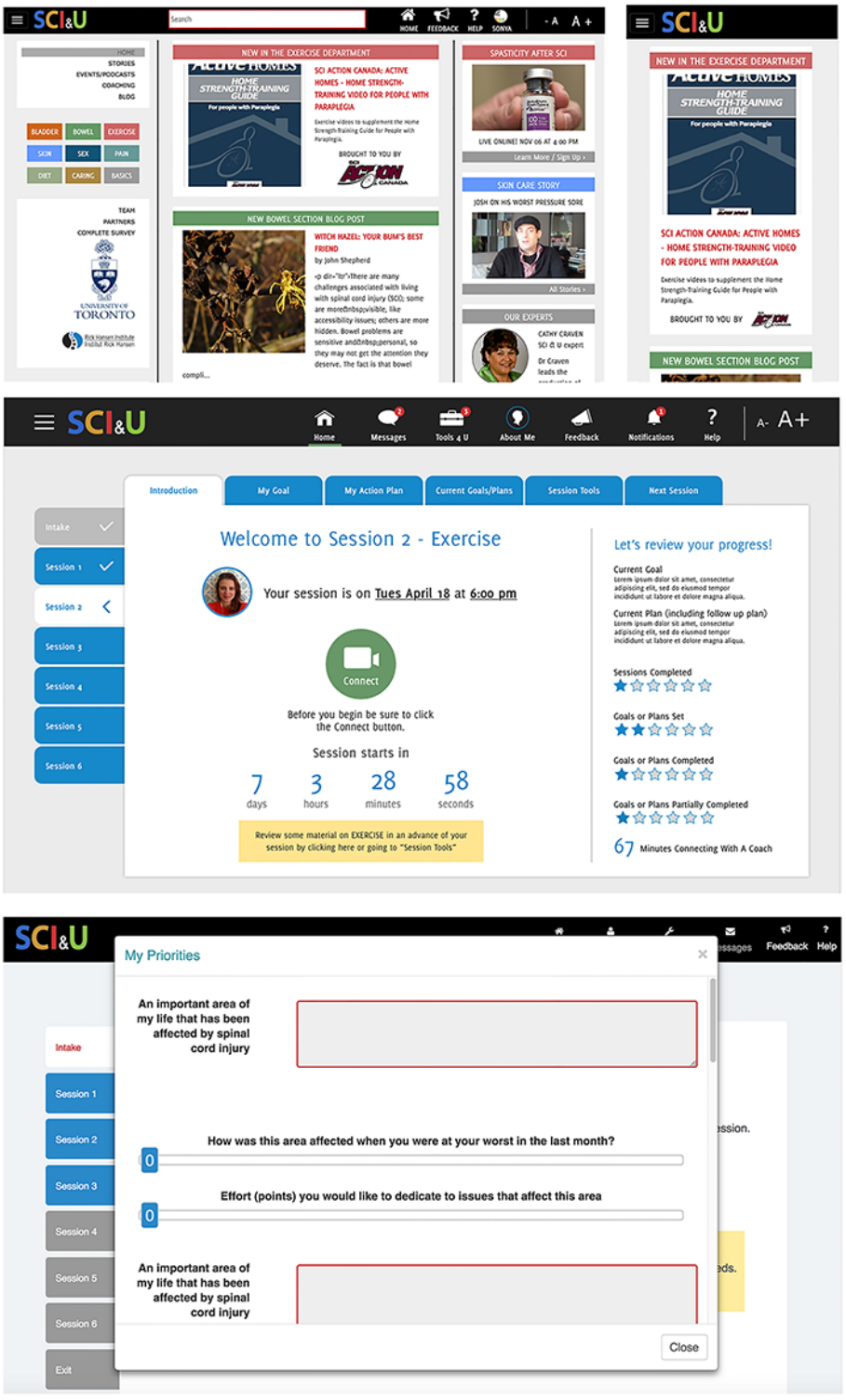
Web-based support materials were housed in a publicly accessible, curated information resource for SCI management [31], and a secure platform was designed to support confidential one-on-one interactions between the participants and web-based peer health coaches [32]. Both were developed using participatory processes [23]; the development of the coaching platform was additionally supported by an application program interface provided by a Toronto-based company called QoCHealth [33]. This allowed an in-house development team to create videoconferencing tools for Google Chrome browsers, tailored lists of topic-specific health information, and secure forms for goal setting and BAP (Figure 1). Of note, participants were not restricted in using alternative tools to communicate with coaches (eg, Skype) if Google Chrome was unavailable or these tools were familiar and comfortable to the participants. No conversations between the participants and coaches were recorded.

The consenting participants were recruited via community organizations and matched with the coaches based on their availability and the participants' review of web-based coaching profiles and coach availability. The participants were matched with coaches with whom they had no relationship before the study. For the most part, the coaches worked with 2 participants at a time. Once partnerships were established, the participants engaged in up to 6 web-based self-management sessions with their coaches, using the coaching platform. The sessions were designed to last between 45 min and 1 hour, and pacing was flexible; however, the participants were asked to schedule sessions within a span of 2 weeks to complete all sessions within 12 weeks. The coaches were asked to dedicate as much as 1 hour of their time to prepare for each hour of interaction with their clients. The length of the sessions, flexible pacing, and program duration were informed by research detailing the relationship of these factors to the effectiveness of a telephone-based exercise intervention [14].

During the first *SCI & U* session, the participants worked with coaches to identify health priorities; these were recorded using a web-based version of the Patient Generated Index (PGI; Figure 1) [34]. The PGI allows individuals to formulate personalized goals and expectations for health care interventions; it has been used as an outcome measure in studies of chronic conditions and to articulate patient-centered treatment objectives [35,36]. At the end of each session, the participants were invited to select a single topic from a predefined list of health management *topics* for the subsequent session. The list of topics was informed by a prior survey of the Canadian SCI community [12]; these included management of pain, diet, exercise, mental health, bowel, bladder, skin, and sexuality.

During sessions, coaches discussed topics with participants and shared stories, listened, worked through issues, or helped formulate goals or plans according to the BAP process. Coaches were given scripts to guide conversations, but the precise content and structure of each session was directed by the participants. The scripts contained information standards for the MI and BAP processes, as well as topic-specific information drawn from a web-based educational website for the SCI community called SCI-U [37]. These educational materials were codeveloped and validated in the context of user studies by an author (JS) working alongside a team of Canadian SCI researchers and members of community organizations [38].

Figure 1. Top: the publicly accessible informational website that was designed to support the SCI & U program. In the middle, designs for the coaching dashboard of the secure platform. Bottom: a customized Patient Generated Index form, as implemented in the secure platform.



Quantitative Component

Recruitment

The participants were restricted to English-speaking adults with traumatic, congenital, or nontraumatic SCI who had internet access and had been living independently in the community for at least a year. They were recruited by means of advertisements (tweets, flyers, and brochures) sent to members of organizations serving the Canadian SCI community. Additional recruitment efforts were led by a patient educator at the GF Strong Rehabilitation Centre in Vancouver, who introduced the study to the participants in outpatient programs. The study protocol was approved by both the University of Toronto (research ethics board [REB] #34808) and the University of British Columbia (REB #H17-01841). All participants provided oral consent and received an honorarium of Can $200 (US $150, Can $1 [US

$1.33]) as compensation for the time required of them to complete the assessments.

Data Collection

Only participants, coaches, and the research team had access to the web-based coaching platform during the study. The quantitative data related to feasibility were derived from the participants' attendance and usage of the coaching platform (ie, their completion of web-based activities). These measures included attrition rates for participants, the length of sessions, range of health management topics selected for discussion, and counts of goals and action plans established. In keeping with a related study directed at supporting self-management among inpatients with a mobile app, it was decided that the intervention would be considered feasible if more than 80% of the participants were retained for the duration of the study and if the same percentage adhered to the intervention [21]. For this prior study, however, adherence was related to usage of an app, whereas in this study, adherence was defined as having attended every web-based session with a coach. In addition, the number of goals and action plans established by participants and the variety of health topics they covered were considered indications of engagement, with more goals/plans and greater variety considered as markers of increased engagement.

The quantitative data to assess potential impact were derived from the participants' independent completion of web-based assessments before and after participation. The assessment surveys were built into the platform and included measures of health-related self-efficacy, emotional and physical health status, and health literacy. In addition, the participants were asked to provide basic demographic information (eg, age, level of injury) via web-based surveys and before the commencement of coaching sessions. Initial surveys were completed within 1 week of each participant's first session in the program; exit surveys were completed within 2 weeks of each participant's last session.

Health-related self-efficacy is defined as the belief in one's ability to meet, and overcome, health-related challenges to achieve the desired outcomes [39]. In this study, self-efficacy was measured using the short (6-item) form of the University of Washington Self-Efficacy Scale (UW-SES), a reliable measure validated in populations with SCI [40]. The responses were made on a 5-point Likert scale; higher scores indicate higher self-efficacy. In addition, resilience, or the ability to flexibly cope with challenges to independent health management, was measured using the short form of the Spinal Cord Injury Quality of Life Resilience Scale (SCI-QOL-R). This is an 8-item scale that has also been validated in SCI populations and that correlates with measures of depression, positive affect, and life satisfaction [41]. Similar to the UW-SES, responses on the SCI-QOL-R were made on a 5-point Likert scale; higher scores indicate greater resilience.

Physical health status was measured using self-reports on the Spinal Cord Injury Secondary Conditions Scale (SCI-SCS). This is a 16-item scale detailing secondary conditions associated with SCI, which impact health and functioning [42]; higher scores indicate more problems related to secondary conditions. The participants' overall emotional status was measured using the Personal Health Questionnaire Depression Scale (PHQ-8), an 8-item scale commonly used to assess self-management interventions [43] and validated for use in the SCI population [44]. Scores on the PHQ-8 range from 0 to 24 and reflect recent experiences of depression; higher scores indicate more recent depressive symptoms [43].

Finally, to measure health literacy, the electronic health literacy scale (eHEALS) was used. This is a validated 8-item scale with questions related to skills at finding, evaluating, and using information found on the web to improve or maintain health [45]. In the SCI community, it has been used to evaluate the health information–seeking behavior of veterans with SCI [46].

Analysis

For all quantitative measures, we reported averages, SDs, and medians. The survey responses collected before participation in the program were compared with responses gathered after participation. To compare the pre- and postintervention scores in the surveys, we reported the results of two tailed, paired *t* tests. A significant change in scores was defined by *P* values under a Bonferroni-adjusted alpha level of .01 for each of the 5 outcome surveys (eg, .05/5) and power (ie, 1 minus the probability of failing to reject a false hypothesis) was set at 0.8. In addition, and because the sample sizes were small, we reported Hedges g statistics as estimates of effect size [47].

Qualitative Component

Recruitment

In addition to the demographic and assessment surveys, the participants who completed the study were asked to complete semistructured one-on-one interviews following completion of the program. The purpose of these interviews was to validate the quantitative measures and expand upon them wherever possible, that is, shed light on the program mechanisms related to change in quantitative measures.

Data Collection

The consenting participants took part in the interviews, along with a member of the research team (either SM or JS). The interviews took place after the participants exited the program and via videoconferencing or phone. The interviews were recorded, transcribed, and deidentified; the analysis focused on the deidentified transcripts. To facilitate the organization and analysis of the deidentified data, NVivo software (QSR International) was used.

Analysis

The analysis followed an inductive thematic methodology, as described by Braun and Clarke [48]. The paradigm guiding the analysis was pragmatic and focused on the description of coaching experiences. It has been argued that approaches centering on descriptions of specific phenomena are suited to health services research, as they cater to both qualitative and quantitative analyses [49].

Overall, 4 authors (SA, TT, JS, and SM) met several times to discuss and assign codes to the transcript data. The group then proposed a coding framework. This was iteratively refined and, once finalized, was applied to a subset of interview transcripts by 2 team members (SA and TT). The coders worked together

to guarantee reliable intercoder agreement on the subset and suggest new themes or refine existing themes. A total of 4 members of the research team (SA, TT, JS, and SM) reviewed all the proposed refinements. After a consensus was reached, the final coding framework was applied to all transcripts by the lead author (SA).

After coding, the relationships between the codes were discussed and analyzed using Jaccard similarity coefficients [50]. The Jaccard coefficients required each code to be presented as a vector of ones and zeros, where each element in the vector reflected the presence or absence of a specific transcript. It was suggested that pairs of codes with high coefficients were relatively likely to co-occur in transcripts. However, all quantitative suggestions of coding associations were manually reviewed to guarantee validity.

Results

Participant Demographics

Table 1 provides details of the demographics of participants. A total of 11 participants took part in the pilot, including 7 women and 4 men. Of the 11, 7 were from relatively rural Ontario (ie, municipalities with populations under 100,000); others were from the Vancouver area in British Columbia. Traumatic SCI was reported by 8 participants. Of these, 3 reported nontraumatic SCI, and 1 reported spina bifida. The participants who took part in the pilot reflected a mix of gender, level of injury, injury type, and use of mobility aids. All had been living with SCI for >5 years, with an average of 20 years and a median of 22 years. Most reported that they were regular users of both the internet and had access to email; several additionally reported regular use of social apps (eg, Facebook) and YouTube or games.

Of the 11 consenting participants, 10 completed web-based baseline assessments, and 9 completed both baseline and follow-up assessments. One participant was not comfortable using the web-based coaching platform, so the research team deferred to telephone delivery of the coaching service for this person. Although she completed her initial visit via videoconferencing software, this required the involvement of a personal support worker, and the telephone was therefore seen as preferable. This participant did not complete any web-based activities or assessments, so her data were excluded from the quantitative analysis of impact and feasibility.

Table 1. Demographics of participants (N=11).

Characteristics	Values
Age[a] (years), mean (SD)	43 (8)
Years since injury[b], mean (SD)	20 (12)
Gender, n (%)	
Male	4 (36)
Female	7 (64)
Province of residence, n (%)	
Ontario	7 (64)
British Columbia	4 (36)
Mobility, n (%)	
Powered wheelchair	6 (55)
Manual wheelchair	3 (27)
Walker	1 (9)
Not reported	1 (9)
Injury etiology, n (%)	
Traumatic	8 (73)
Nontraumatic	3 (27)
Injury level, n (%)	
Paraplegia	5 (46)
Tetraplegia	3 (27)
Not reported	3 (27)

[a]Median age was 46 years.

[b]Median number of years since injury was 22 years.

Quantitative Results

Feasibility

One participant completed baseline assessments only to later withdraw from the study due to the birth of her child. All remaining participants (n=10) completed 6 sessions with their coach; 9 used the web-based platform, and 1 used the telephone. However, the participant who used the telephone did not complete the web-based intake or exit surveys. The resulting retention rate for the pilot was 10 of 11 (81%), and the adherence rate was 100%, but substantial data were missing for 1 of 10 (10%) remaining participants. The participants who accessed the web-based surveys were able to successfully complete these most of the time; complete data for ≤7 out of the 9 participants were recorded for every study measure. All sessions were conducted between December 2017 and April 2018.

Across the 10 participants who completed the program, the median session duration with a coach was 55 min (range 31-81 min). Most participants completed the sessions within 14 days of each other (the average interval between the sessions was 11 days; range 3-45 days). There was variation in the overall duration of the program for participants: the average program duration was 56 days with a range of 35 to 88 days. The coaches reported frequent rescheduling of sessions due to participant illness or issues coordinating across time zones, but the exact number of rescheduled sessions was not captured during the pilot. The coaches were asked to initiate the rescheduling of the missed sessions, wherever possible.

Although the participants were invited to use the coaching platform's built-in videoconferencing software, most defaulted to communication tools with which they were familiar with. A total of 2 participants used the built-in videoconferencing tool initially, later defaulting to the use of the Zoom videoconferencing platform [51]. There were 5 others using the Zoom platform exclusively, 1 participant used Skype [52], and 1 used Facebook Messenger [53]. This occurred because the built-in tool was relatively limited; it was optimized for Google Chrome specifically and would not work on some devices (eg, iPads). The one participant who did not use the web-based platform initially met her coach via Skype because technical support (a personal support worker) was available at her home at that time. Thereafter, she defaulted to communicating with her coach by telephone.

The participants elected to discuss a health management topic with their coach most of the time; only 7 sessions (or 14% of the 50 sessions following the first) were left open ended or without a *topic* from the list of predefined choices. Many participants selected a different topic for every session; however, 1 participant elected to focus on *diet* and another on *exercise* for 3 sessions in sequence. Goals or action plans were established during 30% of the sessions, but there was significant variation in the participants' goal-setting behavior. Some elected to establish new goals or action plans at every session, whereas others never set a goal. Established goals and plans were also frequently unrelated to the health management *topic*, chosen for a given session. The topics selected by the participants and the examples of goals/action plans are provided in Table 2.

Table 2. Health management topics chosen by participants for coaching sessions and related goals.

Session topics	Total sessions, n (%)	Total participants, n (%)	Example goals [participant ID]
Diet	11 (22)	9 (90)	• "To plan, prepare and cook more nutritious meals myself." [Number 6] • "Healthy Food/fruits and vegetables/stay away from carbs." [Number 5]
Exercise	9 (18)	7 (70)	• "Go in to [a community recreation facility] and get set up for family plan." [Number 3] • "You will do your exercises [arm bike] and stretches that your occupational therapist has suggested." [Number 4]
Mental health	8 (16)	8 (80)	• "To find someone to talk to about frustration & depression." [Number 1] • "To talk with my husband and son about my frustration and need for them to contribute more." [Number 2]
Other	7 (14)	5 (50)	• "To buy a handicap accessible van." [Number 2] • "Study material for direct funding 45 minutes daily, 7 days/week." [Number 7] • "Take a rest/nap for at least an hour every other day." [Number 8] • "Getting the wheelchair done/be in touch OT and seating specialist." [Number 5]
Bladder	6 (12)	6 (60)	• "Maintain the status quo with my bladder until I see the surgeon and the urologist." [Number 2] • "Drink more than 8 glasses a day [of water]." [Number 5]
Pain	5 (10)	5 (50)	• No goals related to pain management were recorded
Bowel	4 (8)	3 (30)	• "More fiber intake." [Number 5]
Skin	1 (2)	1 (10)	• No goals related to skin management were recorded

Impact

Baseline assessment data are shown in Table 3. It may be noted that 2 participants reported PHQ-8 scores consistent with major depression at the outset of the pilot (ie, their scores were >10), and on the SCI-SCS, more than two-thirds reported that they had moderate or significant recent problems with urinary tract infections, circulation, spasticity, or pain. Recent moderate or significant bowel, bladder, and sexual dysfunction were also reported by more than half of the participants.

The quantitative results related to changes in measures before and after the pilot are also given in Table 3. The graphs detailing baseline scores by changes in scores for each outcome measure have been provided in Multimedia Appendix 1. Positive postintervention changes were associated with all outcome measures, and effect sizes for the UW-SES and eHEALS were moderate (ie, >0.5). Effect sizes for the measures of resilience (SCI-QOL-R), depression (PHQ-8), and secondary conditions (SCI-SCS) were small (ie, >0.3). No changes were found to be significant, although changes in SCI-QOL-R scores neared significance (P=.08).

A closer inspection of the scores on the SCI-SCS subscales indicated larger effects related to bowel dysfunction and pain subscales of the SCI-SCS. The estimate of effect size for self-reports on the pain subscale based on Hedges g was moderate at 0.52 (95% CI 0.01 to 1.04), whereas that of the bowel dysfunction subscale was large at 1.04 (95% CI 0.04 to 2.11).

Table 3. Pretest and posttest measures.

Scale	Maximum value	Values, n (%)	Pretest		Posttest		Paired *t* test *P* values (adjusted)	Hedges g (95% CI)
			Mean (SD)	Median	Mean (SD)	Median		
UW-SES[a]	30	9 (90%)	19.2 (6.3)	21.3	23.2 (2.9)	24.0	.33	–0.52 (–1.08 to 0.03)
SCI-QOL-R[b]	40	9 (90%)	29.3 (5.7)	27.0	31.7 (4.6)	31.0	.08	–0.36 (–0.61 to –0.10)
SCI-SCS[c]	48	7 (70%)	21.7 (7.2)	22.0	17.9 (6.4)	18.0	.71	0.48 (0.02 to 0.94)
PHQ-8[d]	24	8 (80%)	7.75 (5.2)	5.0	6.0 (3.5)	4.5	.27	0.30 (–0.11 to 0.71)
eHEALS[e]	50	8 (80%)	37.1 (4.7)	37.5	40.8 (6.2)	41.5	.43	–0.59 (–1.29 to 0.10)

[a]UW-SES: University of Washington Self-Efficacy Scale.

[b]SCI-QOL-R: Spinal Cord Injury Quality of Life Resilience Scale.

[c]SCI-SCS: Spinal Cord Injury Secondary Conditions Scale.

[d]PHQ-8: Personal Health Questionnaire Depression Scale.

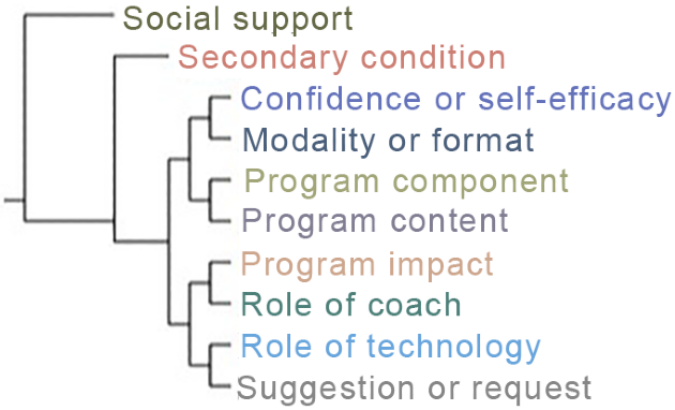
[e]eHEALS: electronic health literacy scales.

Qualitative Results

The coding dictionary that was agreed upon by the 4 authors (SA, JS, TT, and SM) is presented in Multimedia Appendix 2. A tree map illustrating codes as they were applied to transcripts is shown in Figure 2.

The following results focused on the theme of "Program Impact," as the statements related to this theme were able to directly validate and expand upon the quantitative data. In addition, we focused on the "Role of Coach" as this theme was frequently colocated in the transcripts alongside the participants' statements about program impact.

Figure 2. Tree Map of codes as generated by NVivo software. Codes that are close together are those with high Jaccard coefficients.



Program Impact

Similar to the quantitative data related to the frequency of the selected health topics, the qualitative data confirmed diet and exercise as having been discussed with the coaches by many participants. Descriptions of program-related dietary changes were common; the examples documented in the interviews included experimentation with gluten-free and fiber-rich diets.

Changes in fluid intake were also recorded; this was specifically related to bladder health during the interviews. It may be noted that although some diets influenced the experience of bowel dysfunction related to SCI [53], bowel management was relatively infrequently selected by participants as a guiding topic for the discussions.

Along with the changes in diet, changes related to exercise were also frequently described by the participants. This confirms that quantitative data indicating exercise was a popular topic. Examples of exercise-related changes drawn from the interviews included speaking to physicians about exercise routines, joining a gymnasium, and contacting a personal trainer. The participants described the impact of these changes as having a wide range. Participant number 3, for example, related the fact that she was "moving more" to her experience of pain and decrease in opioid use. This participant also noted that her family relationships had improved because they "all benefitted" from a membership to a local community center. Others indicated changes in exercise routines improved mood. Changes to exercise routines may therefore be related to changes in other quantitative measures, such as, the SCI-SCS and PHQ-8.

Some participants reflected on their discussions with the coaches about mental health. This reflects that quantitative data indicating mental health was selected as a topic about 16% of the time. Overall, 2 participants specifically referenced the impact of weather on their mental health and described their interactions with the coaches as particularly meaningful during the winter months. It may be noted that the program was conducted during the winter for all participants.

A joint display relating the participants' impact statements to the quantitative findings is presented in Table 4.

Table 4. Joint display of impact statements made by participants alongside quantitative results.

Topics	Quantitative measures	Selected quotes from interviews [participant ID]	Meta-inference
Bowel and bladder management	SCI-SCS[a] bowel subscale (Hedges g=1.04): 18% of the sessions on diet, 10% on bladder, and 8% on bowel	• "Part of the conversation got me to go to my doctor and ask about gluten free diets." [Number 5]) • "[The program] certainly improved my eating habits." [Number 3]) • "I'm always having a hard time digesting … [my coach and I] would talk about that." [Number 5]) • "When we were doing … kidney and bladder, I really sort of upped my fluid intake." [Number 1]	Several participants described dietary changes resulting from the program; the impact on bowel dysfunction may be indirectly related to these changes
Exercise	SCI-SCS (Hedges g=0.48): 11% of the sessions on exercise	• "I had been meaning to contact a trainer at a gym here …. I texted during [my coaching] session and she messaged me back right away." [Number 2] • "I have a real hard time sleeping. We thought, you know, maybe exercise [could help]." [Number 1]) • "[The program] pushed me to do exercises more." [Number 7]	Many participants described changes to exercise routines resulting from the program; the changes were designed to influence diverse health issues, such as sleep. The overall changes on the SCS may be related to both changes in diet and exercise
Pain	SCI-SCS pain subscale (Hedges g=0.52): 10% of sessions on pain	• "I'm moving more. I've reduced my opioids right down to nothing and I'm at a two-week point there." [Number 6]	One participant specifically reported exercise as having impacted pain and the use of pain medication
Mental health	PHQ-8[b] (Hedges g=0.30): 16% of sessions focused on mental health	• "[We discussed] depression. You know, in the winter, obviously, we all get a little bleak, not being able to get outside, so that was a good [topic] at that time." [Number 8] • "I've stayed stable … I'm in a better place. I feel good mentally." [Number 6]	Mental health was a frequent topic of discussion; some participants specifically related changes in mood to changes in exercise

[a]SCI-SCS: Spinal Cord Injury Secondary Conditions Scale.

[b]PHQ-8: Personal Health Questionnaire Depression Scale.

Role of the Health Coach

Alongside the discussions regarding program impact, the participants made frequently mentioned the supportive roles played by their coaches. The coaches were credited as being sources of accountability, inspiration and encouragement, social support, and health management information. In addition, the coaches were frequently credited as being sources of technical support. These roles are described in greater detail in the following sessions.

Source of Accountability

The participants frequently mentioned the fact that the program had increased their accountability to plans for behavior change, and that their coach had played a critical role in fostering this accountability. Being available to listen and check in on plans

motivated many participants to take action. The coaches were also described as affirming and bolstering the participants, even when plans did not go as expected:

> *He [said] "what are your goals this week" and "I'll check up on you in the next week or in two weeks and we'll talk about it". So, every conversation was like, "hey, I did this and I accomplished this", which made it that much more interesting to get back to each other and talk.* [Number 2]

Source of Inspiration and Encouragement

Coaches were often described as acting like "cheerleaders" [Number 1] and as valuing the participants' efforts, regardless of the outcome. In addition, many participants described the coaches as role models. Some specifically related their self-management behaviors to those of their coaches:

> *My coach… has low-level quadriplegia and here I am with paraplegia. I felt if anything, my gosh, why am I being so whiny about being active when … [my coach] would have a more difficult time being active?* [Number 3]

Source of Information

The coaches were often credited as sources of health information. Several times, the participants described working with the coaches to search for web-based information or receive useful links in their email from the coaches after a session. Sometimes, information flow was described as going both from coach to participant and vice versa:

> *We had some good conversations each week for each [self-management] topic. [My coach] made some recommendations on the last session that I haven't had a chance to look at and do yet, but I will.*" [Number 7]

> *[My coach] was always really good at sending me things to read. Whatever we talked about there was always a follow-up to read.* [Number 6]

Source of Social Support

Interactions with coaches were often valued as social support. Many described the support of peer coaches as particularly meaningful during the winter and due to a perceived level of mutual understanding:

> *I get feeling stuck a lot or like I'm alone. I have a service dog, but he only does so much. So, yeah, [it helps] just to know that I'm not alone.* [Number 1]

> *[My coach] was good, because …. there are some similarities in his life … so he could relate on the same level as me.* [Number 5]

Source of Technical Support

Finally, although the coaches were primarily focused on supporting the participants' self-management efforts, they were frequently asked to troubleshoot technical issues for participants. The commonly encountered technical issues related to videoconferencing software (either built into the platform or from a third party) and web-based forms for action planning or assessment:

> *When I did the intake, [my data] didn't save … so I had to go through with my coach.* [Number 3]

> *My coach… had to spend a bit of time guiding me as to where [to enter my goal] … I think once she may have even entered in the goals for me because I couldn't figure out where I was supposed to.* [Number 1]

Discussion

Principal Findings

The results indicated that the delivery of a web-based self-management program tailored for the Canadian SCI community is feasible, and that its use may be associated with positive changes in terms of self-efficacy, mood, resilience, and experience of secondary conditions. The qualitative and quantitative results illustrated the wide variety of self-management topics touched upon by the intervention and the range of self-reported behavior changes adopted as a result. In addition, the qualitative results shed light on the specific mechanisms used by the coaches to promote behavior change; these included provision of encouragement, information, social support, and accountability.

Comparison With Prior Work

The feasibility results, in terms of adherence and retention, reflected the preliminary work related to the development of other web-based self-management programs for the SCI community, such as PHOENIX [20] and SCI Health Storylines [21]. A feasibility study evaluating the use of SCI Health Storylines by 20 individuals with SCI found that 85% were retained as inpatients and 70% were retained at 3 months post-discharge [21]. Our results were similar, as 81% of the participants remained throughout the pilot. However, the adherence measures for the two studies were not directly comparable, as SCI storylines did not require attendance at the scheduled web-based sessions with a coach. Instead, our adherence measures better reflected those from a tele-exercise intervention for the SCI community, which, like ours, reported 100% adherence [18]. This same study reported that 85% of the exercise data were successfully recorded by the developed technology; in this pilot, the data were successfully collected from 9 of 10 participants, and each study measure was completed by at least 7 of the 9 participants.

In terms of technology usability and acceptance, the results reflected those of the PHOENIX study, which demonstrated iPads and iTunes U to be acceptable for peer-led education and self-management support among users with SCI [20]. A related study exploring the use of iPads to facilitate periodic web-based medical consultations between users with SCI and health professionals revealed similarly high user acceptance of tablets and an overall preference by participants for the web-based, rather than in-person or telephone-based meetings [19]. Our results echoed the same in the context of an intervention spanning multiple sessions. In addition, most participants in this study were able to satisfactorily complete web-based activities; only one deferred to use of the telephone to complete activities such as goal setting. Both this study and the PHOENIX study illustrate participants' relative comfort with mainstream,

community-based videoconferencing tools (eg, Skype, Face Time, and Zoom) [20]. Although this study provided custom videoconferencing tools, most deferred to tools with which they were familiar, even despite potential failure to comply with Canadian Health Information Privacy Policies (eg, Personal Health Information Protection Act).

The topic of the use of videoconferencing software in the context of community-based research projects like this one is an increasingly controversial topic, particularly in the light of revelations regarding potential security loopholes [54]. Given that videoconferencing data were not collected by the research team and security risks were not well understood, research partners in this study permitted deferral to communication tools to promote accessibility. The built-in tool was, as mentioned previously, limited in that it was optimized for Google Chrome and would not work on other devices such as iPads. The issue has since been discussed with the University of Toronto REB, which is now indicating that it will explicitly recommend the use of institutionally sanctioned software (eg, Skype for Business [52]) for research communication and will ask research teams for justification to use alternatives (eg, Zoom [51]) in future studies. Moreover, these policies are actively changing as new risks are exposed. Moving forward, the SCI & U team has chosen to focus on informing the participants about potential security risks related to web-based communication, and our protocol is being amended to reflect this change in practice. The practices will likely continue to change as the situation evolves and policy comes to light.

The feasibility results also demonstrated user engagement and highlighted the variety of ways in which participants chose to tailor the SCI & U program. Although diet and exercise were the most popular topics of discussion during the coaching sessions, the participants also chose to discuss issues such as pain, bowel dysfunction, and sex. Flexibility was found to be similarly valuable in the context of the *Get in Motion* intervention. Participants in this study were found to have very different needs in terms of program pacing and duration based on their baseline levels of activation, for example [14]. In addition, the users in this study elected to set goals 30% of the time, indicating engagement with program activities.

In addition, both this intervention and others [15,16,20] illustrate the feasibility of participatory approaches to program development. For the PHOENIX program [20], a community-based *task force*, including members of the SCI community, worked to identify the needs, develop digital content for, and provide feedback on the program as it was developed. In this study, a similar task force was asked to iteratively comment on program content and design [23].

Perhaps, the impact results might best be related to those from a recent randomized controlled trial (RCT) of the *My Care My Call* program [15]. This was a peer-led, self-management support intervention targeting the management of secondary conditions delivered to 84 participants with SCI over 6 months. As with SCI & U, peer health coaches were trained in the use of both the MI and BAP techniques. The results showed that program participation was associated with a significant increase in measures of activation, resource awareness, social participation, and quality of life. In this study, program participation was associated with similar improvements in the measures of self-efficacy and resilience and in the ability to navigate electronic health resources.

Fewer studies have measured the health outcomes resulting from self-management interventions in the SCI population, and none that we know of are built around web-based interactions with trained peers and associated activities. However, for newly discharged people with SCI, peer mentoring has been associated with a reduced number of return hospital visits after 6 months [55]. The participation by individuals with SCI in peer-led exercise programs has been associated with improved self-reported physical activity 6 months after program participation [13]. Similar exercise outcomes, in turn, have been associated with decreased pain and improved mental health [56,57]. This study focused on relatively short-term outcomes (<12 weeks) and measured the experience of secondary health complications based exclusively on self-reports on the SCI-SCS. Nevertheless, the results pointed to potential moderate effect sizes on this scale, with larger effects on specific subscales of the SCI-SCS (eg, bowel dysfunction and pain). Some effects might have been incidental to the changes in diet or exercise as such changes were widely reported by the participants during the interviews.

The qualitative results illustrated the variety of ways in which coaches supported the participants' health-related behavior change. The specific roles taken up by the coaches echoed those taken up by the coaches of the *My Care My Call* program. A content analysis of more than 500 *My Care My Call* telephone calls found the coaches to have fostered behavior change by acting as *role models*, *advisors*, and *supporters* [22]. The same study found the role of *advisor* as reflecting the coaches' training and expertise in the MI and BAP techniques. The coaches in this study also acted as *role models* or *supporters* and served as *advisors* when they walked the participants through the BAP protocol or provided information. However, the coaches of SCI & U were additionally asked to act as *advisors* when they provided technical support. Technical requests might indicate a somewhat expanded role of *advisor* in the context of programs like SCI & U.

Limitations

The results were based on a limited sample. This was a small feasibility study with a convenience sample of 11 participants from two Canadian provinces. The individuals who responded to the recruitment calls might have been people with both motivation and internet access a priori and therefore biased. Moreover, the majority of the participants experienced injuries more than 10 years before commencement of the study.

The quantitative outcome measures were based on self-reports and were only collected at baseline and as participants exited the program. It remains unclear whether the changes reported by the participants were or will be robust to time.

In addition, this study lacked a control group. Confounding factors, such as the weather, were not controlled and might have influenced outcome measures. The impact of the weather on

the participants' mood was, in fact, referenced during the interviews.

Moreover, the results presented in this study omitted the perspective of the coaches in the study on issues such as program feasibility (eg, its demands on their time and their experience of the technology). However, the perspectives of coaches were collected through postintervention interviews that are currently being analyzed. We expect a future study to touch upon the impact and feasibility of the program as perceived by these individuals. To validate the results and ensure that they are robust to both time and confounding factors, the intervention is currently being tested in the context of a longer RCT.

Conclusions

A web-based self-management program that has individuals with SCI partnering with trained peers has been demonstrated to be feasible. Moreover, the program is a promising means to develop self-efficacy, health literacy, and resilience in a population at high risk of health complications while living in the community. These results indicate the potential of web-based tools to bolster existing community-based support for people with SCI, particularly for those in small or rural communities.

Future work seeks to validate the results of this pilot study. An RCT is currently underway for this purpose; this will compare the effects of the SCI & U intervention over the span of a year on an experimental group and relative to wait-listed controls.

Acknowledgments

The authors would like to thank the members of the Client Advisory Group and Barry Arana, Virginia Guo, Shawn Farrugia, Eric Wan, Joel Desamero (and QoCHealth in Toronto), Marla Rogers, Lindsay Sleeth, and Spero Ginis. The authors also acknowledge the Ontario Neurotrauma Foundation and the Rick Hansen Institute for their support of this work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Baseline scores by change in scores (ie, follow up score minus baseline) for measures on the PHQ-8, SCI-SCS, eHEALS, UW-SES and SCI-QOL-R.
[PNG File , 139 KB - rehab_v7i2e16351_app1.png]

Multimedia Appendix 2
The coding dictionary agreed upon by authors for coding of transcripts.
[DOCX File , 13 KB - rehab_v7i2e16351_app2.docx]

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Abbreviations

BAP: Brief Action Planning
eHEALS: electronic health literacy scale
MI: motivational interviewing
PGI: Patient Generated Index
PHQ-8: Personal Health Questionnaire Depression Scale
RCT: randomized controlled trial
REB: research ethics board
SCI: spinal cord injury
SCI-QOL-R: Spinal Cord Injury Quality of Life Resilience Scale
SCI-SCS: Spinal Cord Injury Secondary Conditions Scale
UW-SES: University of Washington Self-Efficacy Scale

Edited by G Eysenbach; submitted 25.09.19; peer-reviewed by S Newman, X Li, J Amann, B Lai; comments to author 05.03.20; revised version received 10.06.20; accepted 14.06.20; published 31.07.20.

Please cite as:
Allin S, Shepherd J, Thorson T, Tomasone J, Munce S, Linassi G, McBride CB, Jiancaro T, Jaglal S
Web-Based Health Coaching for Spinal Cord Injury: Results From a Mixed Methods Feasibility Evaluation
JMIR Rehabil Assist Technol 2020;7(2):e16351
URL: http://rehab.jmir.org/2020/2/e16351/
doi:10.2196/16351
PMID:32589148

Viewpoint

Stroke and Telerehabilitation: A Brief Communication

Ayisha Bashir[1], MSc, MBBS

Department of Biomechanics, University of Nebraska, Omaha, NE, United States

Corresponding Author:
Ayisha Bashir, MSc, MBBS
Department of Biomechanics
University of Nebraska
6160 University Dr S
Omaha, NE, 68182
United States
Phone: 1 402 554 3228
Email: abashir@unomaha.edu

Abstract

This rapid communication highlights stroke telerehabilitation, a health care service that provides daily monitoring of the care of patients recovering from stroke, delivering convenient and immediate feedback for patients, family, and caregivers. The delivery, management, and coordination of nursing care services, provided via telecommunications technology, is a convenient method of delivering health care to patients recovering from stroke. It is important to assess the service quality of the telehealth process and to establish the role of telehealth nursing and related technologies in the care of patients recovering from stroke. Studies show that even though both health professionals and participants have reported high levels of satisfaction and acceptance of telerehabilitation interventions, the quality of the evidence on telerehabilitation in poststroke care remains low. Conducting a quality study of telehealth rehabilitation for patients recovering from stroke will help assess if home health agencies with telehealth capabilities caring for patients recovering from stroke and patients with chronic diseases can provide quality care to patients in their home and fill this health care gap. Patients that are severely handicapped and impaired and unable to reside in their home environment are not included in telerehabilitation services provided by the home care agency. It would be informative to study the benefits of telerehabilitation and the care provided to patients recovering from stroke within nursing homes, given the need for social distancing to reduce disease transmission during the current coronavirus disease (COVID-19) global health pandemic. Using telerehabilitation would mean that patients have a lower risk of exposure to infectious agents. Further research into telehealth interventions and stroke management in home care is crucial.

(JMIR Rehabil Assist Technol 2020;7(2):e18919) doi:10.2196/18919

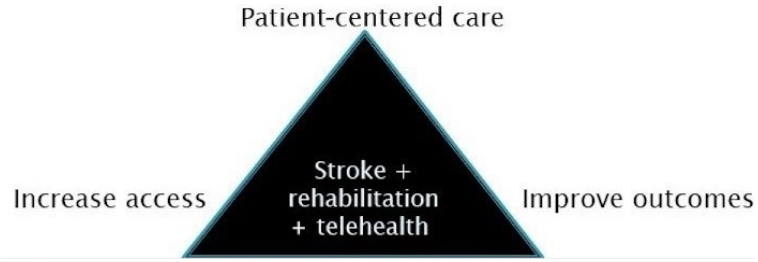
KEYWORDS

telerehabilitation; rehabilitation; nursing; stroke; telehealth

Background

Telerehabilitation is an emerging method of health care delivery through which medical rehabilitation care can be provided from a distance, using telehealth to provide remote health care [1,2]. In stroke care, immediate assessment and treatment are essential to reduce the risk of death and disability [3]. However, many patients do not receive adequate treatment due to a lack of specialist services. Technological development, telehealth techniques, and telehealth stroke rehabilitation may facilitate future telehealth projects, improve care team satisfaction, and allow patient management to continue at home [2,3]. The use of telehealth and telecommunications technologies promotes self-care and well-being and enhances positive health outcomes in people with stroke, peripheral artery disease, and severe disabilities and is favored by their family caregivers [3,4]. In addition, telerehabilitation aims to provide more patient-centered care and greater access (Figure 1). The importance of matching technology to the needs of this population and the lessons learned from these investigations should be addressed. This viewpoint highlights findings from a pilot study related to telehealth nursing effectiveness for patients with chronic diseases [4] and applies these notions toward future investigations related to stroke telerehabilitation. Numerous studies have assessed the cost-effectiveness and patient acceptance of telehealth methods of service delivery, yet the perspectives of service providers and caregivers delivering stroke care have not been studied [5,6].

Figure 1. Goals for telerehabilitation for poststroke care.



Discussion

Overview

Research findings indicate that even though health professionals and participants have reported high levels of satisfaction and acceptance of telerehabilitation interventions, the overall quality of the evidence on telerehabilitation in poststroke care remains low [2,7].

In the article "Perspectives of Nurses Toward Telehealth Efficacy and Quality of Health Care: Pilot Study," the authors examined whether telehealth technology impacts the perceived level of internal service quality delivered by the nurses of the relevant telehealth organization, the Visiting Nurse Association (VNA). A similar study of telehealth rehabilitation for patients recovering from stroke aimed to assess if home health agencies with telehealth capabilities caring for patients with chronic diseases and those receiving stroke rehabilitation can take care of patients in their home setting, thereby filling this gap [3]. Telerehabilitation for patients recovering from stroke is perceived as providing convenience and a sense of security to the patient, caregivers, and family members, allowing timely nursing interventions under supervised physician care [2,7]. Caring for the needs of the patients recovering from stroke represents a significant financial and emotional burden. Telehealth interventions can improve self-management, communication, and the engagement of caregivers involved in the long-term care of these patients [3].

Patients with chronic disease and patients recovering from stroke are generally provided with services including companion care, infusion pharmacy, home care, home health technology, hospice, and palliative care. Organizations using telehealth nursing services monitor the patient through assessment and the collection of data, including heart rate, blood pressure, weight, oxygen saturation, and temperature. Other members of the household or caregivers may monitor the health care process. The patients are triaged according to their vitals. The central station clinician is responsible for the initial interpretation of the data and contacts the patient with any health care concerns, including blood pressure changes, weight gain, or oxygen level fluctuations [3,4] (Table 1).

Table 1. Telemedicine services for chronic diseases and telerehabilitation at the Visiting Nurse Association.

Type of disease	Types of patient telehealth technology and interventions
Stroke rehabilitation and chronic heart disease	• Devices for monitoring blood pressure, heart rate, oxygen saturation, and weight • Tablet and wireless gateway for data transmission • Web-based portal transmitting data from the patient blood pressure monitor and other devices to health care professionals • Health care personnel include regional center operator, family practitioner, cardiologist, neurologist, and other health care professionals if needed
Chronic obstructive pulmonary disease	• Pulse oximeter, weighing machine • Tablet and wireless gateway for data transmission • Web-based portal transmitting data from the pulse oximeter to health care professionals • Data capturing readings and patient-selected questions • Follow-up in person or by telephone • Health care personnel include respiratory nurse, family practitioner, pulmonologist, and other health care professionals if needed

Conclusion and Future Directions

Some patients recovering from stroke are stable; however, others have urgent needs. It is largely older adults with chronic diseases, especially stroke and heart disease, that benefit from telehealth interventions [3,8]. Nationwide telehealth service quality studies related to the care of patients recovering from stroke would have a more significant impact on research and the perceptions of rehabilitation and telehealth quality service [9,10]. Patients that are handicapped and impaired and unable to reside in their home environment are not included in telerehabilitation services provided by home care agencies [3,9]. It would be informative to study the benefits of telerehabilitation and the care of patients recovering from stroke within nursing homes. Feedback from health care professionals and physician specialists will help to refine the collaborative care efforts for this vulnerable patient population. Future studies of telehealth interventions and stroke management in home care will be important, given the need for social distancing during the current global health pandemic [11,12]. Due to the rapid spread of coronavirus disease (COVID-19), the provision of rehabilitation and stroke care may place health care workers in a position of

vulnerability as they may acquire the virus and spread it [13,14]. Telehealth management of patients would reduce their risk of exposure to any infectious agent, whether during a pandemic or community outbreak [13,14]. Therefore, future strategies should consider expanding telerehabilitation services for patients while addressing barriers and solutions with medical staff, caregivers, and patients [14,15]. This may shed light on whether telerehabilitation can have a supportive role alongside standard rehabilitation care in patients poststroke and uncover the barriers and facilitators of this method of health care delivery.

Acknowledgments

The research was made possible thanks to the valuable insight and guidance of Dr Sara Myers from the Department of Biomechanics and Dr Dhundy Bastola from the School of Interdisciplinary Informatics at the University of Nebraska at Omaha. The author would like to thank the VNA of Omaha for their help and for sharing their knowledge of the telehealth nursing process.

Conflicts of Interest

None declared.

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Abbreviations

COVID-19: coronavirus disease
VNA: Visiting Nurse Association

Edited by G Eysenbach; submitted 26.03.20; peer-reviewed by S Chen, M Castellon; comments to author 20.04.20; revised version received 21.04.20; accepted 14.06.20; published 17.07.20.

Please cite as:
Bashir A
Stroke and Telerehabilitation: A Brief Communication
JMIR Rehabil Assist Technol 2020;7(2):e18919
URL: https://rehab.jmir.org/2020/2/e18919
doi:10.2196/18919
PMID:32706739

Original Paper

Optimizing Telehealth Experience Design Through Usability Testing in Hispanic American and African American Patient Populations: Observational Study

D'Arcy King[1], PhD; Sundas Khan[1], MD; Jennifer Polo[1], BA; Jeffrey Solomon[1], BFA; Renee Pekmezaris[1], PhD; Negin Hajizadeh[1], MPH, MD

Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Manhasset, NY, United States

Corresponding Author:
Sundas Khan, MD
Donald and Barbara Zucker School of Medicine at Hofstra/Northwell
600 Community Drive
Suite 403
Manhasset, NY, 11030
United States
Phone: 1 516 600 1419
Email: skhan31@northwell.edu

Abstract

Background: Telehealth-delivered pulmonary rehabilitation (telePR) has been shown to be as effective as standard pulmonary rehabilitation (PR) at improving the quality of life in patients living with chronic obstructive pulmonary disease (COPD). However, it is not known how effective telePR may prove to be among low-income, urban Hispanic American and African American patient populations. To address this question, a collaborative team at Northwell Health developed a telePR intervention and assessed its efficacy among low-income Hispanic American and African American patient populations. The telePR intervention system components included an ergonomic recumbent bike, a tablet with a built-in camera, and wireless monitoring devices.

Objective: The objective of the study was to assess patient adoption and diminish barriers to use by initiating a user-centered design approach, which included usability testing to refine the telePR intervention prior to enrolling patients with COPD into a larger telePR study.

Methods: Usability testing was conducted in two phases to identify opportunities to streamline and improve the patient experience. The first phase included a prefield usability testing phase to evaluate technical, patient safety, and environmental factors comprising the system architecture. This was followed by an ergonomic evaluation of user interactions with the bicycle, telehealth tablets, and connected wearable devices to ensure optimal placement and practical support for all components of the intervention. The second phase of research included feasibility testing to observe and further optimize the system based on iterative rounds of telePR sessions.

Results: During usability and feasibility research, we identified and addressed multiple opportunities for system improvements. These included physical and environmental changes, modifications to accommodate individual patient factors, safety improvements, and technology upgrades. Each enrolled patient was subsequently identified and classified into one of the following 3 categories: (1) independent, (2) intermediate, or (3) dependent. This categorization was used to predict the level of training and support needed for successful participation in the telePR sessions. Feasibility results revealed that patients in the dependent category were unable to perform the rehab sessions without in-person support due to low technical acumen and difficulty with certain features of the system, even after modifications had been made. Intermediate and independent users, however, did exhibit increased independent utilization of telePR due to iterative improvements.

Conclusions: Usability testing helped reduce barriers to use for two subsets of our population, the intermediate and independent users. In addition, it identified a third subset, dependent users, for whom the telePR solution was deemed unsuitable without in-person support. The study established the need for the development of standard operating procedures, and guides were created for both patients and remote respiratory therapists to facilitate the appropriate use of the telePR system intervention. Observational research also led to the development of standard protocols for the first and all subsequent telePR sessions. The primary goals in developing standardization protocols were to establish trust, ensure a positive experience, and encourage future patient engagement with telePR sessions.

(JMIR Rehabil Assist Technol 2020;7(2):e16004) doi:10.2196/16004

KEYWORDS

chronic obstructive pulmonary disease; usability testing; telehealth; telerehabilitation; vulnerable populations

Introduction

Chronic obstructive pulmonary disease (COPD) is a disease that occurs when airflow to the lungs is obstructed, and it is classified as chronic inflammatory lung disease caused by exposure to irritating gases or particulate matter (most commonly cigarette smoke). If the disease is not treated, symptoms often get worse due to excessive inhalation of irritating gases, and by the time these symptoms appear, significant lung damage has already occurred [1]. Acute COPD exacerbations lead to further loss of lung function, are associated with decreased quality of life (QoL) and increased morbidity and mortality, and generate a significant cost to the health care system [2-4]. Current data suggests that COPD mortality is increasing, and COPD is presently the third leading cause of death in the United States, claiming 134,676 lives in 2010 [5]. In addition, an estimated 715,000 hospital discharges related to COPD were reported in 2010, which is a discharge rate of 23.2 individuals per 100,000 population; of these discharges, 65% were 65 years or older [6].

Health and healthcare disparities have been observed among ethnic minority populations, with African American and Latin American populations showing more rapidly rising death rates than the non-Latin white American population. Both African American and Hispanic American patients bear a high burden of illness and death due to COPD and are twice as likely to visit the emergency room for COPD-associated conditions as compared to non-Hispanic American white patients [7,8]. Higher rates of smoking, reduced healthcare access, and lower socioeconomic status all contribute to this high disease burden in both African American and Hispanic American patients [9]. Patients admitted for COPD exacerbation have a 23% risk of 30-day readmission and a 50% risk of 12-month readmission, and both African American and Hispanic American race/ethnicity are associated with an almost twofold increase in hospitalization risk [10,11].

Early pulmonary rehabilitation following hospital admission has been shown to improve QoL and to decrease readmissions [12]. Telehealth-delivered pulmonary rehabilitation (telePR) has been shown to be as effective as standard pulmonary rehabilitation (PR) at improving QoL [12,13]. However, it is not known how effective telePR will be among low-income, urban Hispanic American and African American populations [14]. To assess outcomes in these populations, we developed a telePR intervention that included an ergonomic recumbent bike with graded exercise levels, a tablet with a built-in camera, and wireless monitoring devices designed for use in patients' homes and local community centers, as illustrated in Figure 1. The goal of the initiative was to improve the management of patients with COPD in disparity populations by providing point-of-care services accessible through telePR in the community and patients' homes.

The primary goal of the study was to compare the effectiveness of a referral to telePR versus standard PR for patients hospitalized for COPD exacerbation. Although there are data on standard PR improving outcomes in Hispanic American and African American patients, patients from these populations are not included in studies exploring the efficacy of telePR, despite evidence that underserved Hispanic American and African American patients have positive perceptions of telehealth interventions in general [15,16]. Barriers to access that disproportionately affect disparity patients include lack of referral to PR due to perceived ineffectiveness; lack of insurance coverage or high copayments; and difficulty accessing PR due to transportation costs, distance, and lack of caregiver support. This study aimed to overcome many of these major barriers by providing PR outside of the standard PR setting, via telehealth settings. Participants had the option of choosing to receive telePR either within the patient's home or in a community center.

We sought to identify opportunities to streamline and improve the patient experience in different settings (either in a community center or in a patient's home) prior to recruiting and enrolling patients with COPD into a larger study. In the larger study, patients participated in telePR for 1-hour sessions that occurred 2 times a week for 8 weeks, and who were subsequently followed for 1 year. The objective was to encourage patient adoption and to remove barriers to use by adopting a user-centered design approach to refine the telePR intervention system during prefield testing, as well as to conduct usability testing for select patients who were having difficulty with the telePR technology.

Figure 1. Telehealth-delivered pulmonary rehabilitation (telePR) model of care.

Methods

Study Design

Usability testing was conducted in two phases to identify opportunities to streamline and improve the patient experience by evaluating technical, safety, and environmental factors. Phase 1 included a prefield usability testing assessment that consisted of (1) design ergonomics for optimal placement of the bicycle, telehealth tablets, and connected wearable devices; (2) user-centered design optimizations based on real-world observations of users; and (3) development and documentation of standards of operation (SOPs) for all subsequent sessions. Phase 2 included in situ observation of patients during telePR sessions and assessment of their level of engagement with the remote respiratory therapist. Prior to the commencement of research activities, approval was obtained from Northwell Health's Institutional Review Board. Patients who agreed to enroll in the usability and feasibility testing were invited to complete the Northwell Health audiovisual recording authorization form prior to fielding.

Recruitment Methods

Participants recruited for the usability testing included patients hospitalized for COPD exacerbation at Northwell Health and Wyckoff Heights Medical Center. The patients recruited from Northwell Health were drawn from one of 7 Northwell hospital locations: Long Island Jewish Medical Center, North Shore University Hospital, Long Island Jewish Forest Hills, Southside Hospital, Glen Cove Hospital, Huntington Hospital, or Long Island Jewish Valley Stream. The source of referrals was inpatient admissions to the targeted hospitals. Patients were also recruited from their homes or outpatient doctors' offices immediately after discharge (up to 2-3 weeks post-hospital discharge). Feasibility was assessed by querying databases at all 8 hospitals for COPD and stratifying by race/ethnicity. Race/ethnicity was classified according to participants' self-identification. Based on the responses from a needs assessment, all of the Hispanic American and African American patients with severe COPD who were asked whether they would participate in the telePR system expressed interest.

Eligible patients were approached for consent to participate in the usability session. A session included the following activities: two brief usability questionnaires to collect information about attitudes and experiences with the rehab session, a postinterview to inquire about experiences during the usability session, and audio recordings of the session. Informed consent included a detailed description, in English and Spanish, of the risks and benefits of the study with user-friendly images of the equipment.

For Phase 2 (the feasibility phase), 4 participants were enrolled. This is a typical sample size for usability studies, as prior studies have elicited a sufficient response of usability issues [17-19]. The demographics of the participants are outlined in Table 1.

Table 1. Participant demographics (N=4).

Participants	Hospital	Age	Race/Ethnicity	Gender
1	Long Island Jewish Forest Hills[a]	81	Hispanic American	Male
2	Long Island Jewish Medical Center[b]	87	African American	Male
3	Long Island Jewish Forest Hills[a]	63	African American	Male
4	Long Island Jewish Medical Center[b]	71	Hispanic American	Female

[a]Community hospital.

[b]Large academic center.

Statistical Analysis

To ensure the acceptability and usability of the telePR, we used a mixed methods approach to look at indicators of usability and acceptability in two stages. First, we analyzed usability testing sessions using qualitative analytic methods. All usability testing sessions were audio-recorded and professionally transcribed. Structural coding was used to mark responses to topical questions in the usability questionnaires. The data were categorized to develop a codebook and independently coded by 3 coders. The main themes that emerged indicated necessary adaptation to increase the usability and acceptability of the telePR system. Second, we measured whether participants were able to complete the usability sessions, using quantitative methods (eg, system usability scale) and qualitative measures (eg, identification of any technical or logistical barriers encountered).

The usability questionnaire assessed the following elements:

1. Comfort level with physical elements such as the seat, screens, blood pressure monitor, and pulse oximetry
2. Experience and interaction with the respiratory therapist throughout the session
3. Ability to see the rehabilitation video during the session
4. Effective visualization of co-participants during the session
5. Overall experience with the bike and all of its components

Phase 1: Prefield Testing Assessment

Phase 1 included a prefield testing assessment of the telePR system consisting of technical, safety, and environmental factors. This was followed by an ergonomic evaluation of user-interaction with the bicycle, telehealth tablets, and connected wearable devices to ensure optimal placement and practical support for all components of the intervention. A key output of the prefield testing assessment was the development of a user manual based on the user-centered design and ergonomics assessment. Protocols were developed to ensure personalized requirements were met prior to the start of each telePR session (see Figure 2). These included adjusting the seat height of the bicycle and tablet screen; changing of gears; setting the best audio levels; and placement of weights and bands, rescue inhaler, water, food for patients with diabetes, or other items needed in case of an emergency (such as a mobile phone). At the start of each telePR session, the remote respiratory therapist was required to record baseline measurements including blood pressure, pulse rate, pulse oximetry, and glucose (in patients with diabetes), which were assessed through connected wearable devices. Part of the ergonomics assessment was to ensure these wearable devices were placed in areas easily accessible to patients throughout the session. Usability testing was conducted face-to-face with the patient and remotely with the respiratory therapist to best understand the patient experience.

The remote respiratory therapist was a key player in the telePR session and set the tone of the experience. As part of the output from the initial prefield testing assessment, an SOP manual was developed for the therapist. The guide included instructions for the therapist to review with the patient prior to each session. These included an equipment checklist, instructions for how and when to check the patient's vital signs, prompts for transitioning from one activity to another, recommendations for a personalized script used at the opening and close of each session, and guidance for wrapping up each session with the patient. A quick-access checklist was also developed for the respiratory therapist as a reminder to adjust monitor screens to patient eye level prior to the session; to constantly observe the patient throughout the session; to adjust volumes for the patient during specific parts of the session (eg, for the educational video); and to prompt time considerations for specific tasks. Safety protocols were also developed to assess for issues and to troubleshoot situations in which loss of video or wireless connection occurred, patients had trouble using the bike or other equipment, specific tablet-related issues (eg, pop-up on the screen) occurred, or any emergencies arose (eg, the patient falls during the session). Usability testing was conducted through mock-session simulations with the respiratory therapist before the implementation of the feasibility testing.

Figure 2. Telehealth-delivered pulmonary rehabilitation (telePR) session outline.

Phase 2: Feasibility Testing

Feasibility testing was performed to assess ease of use and usefulness of each telePR component, including the bicycle, tablet, and wearables during a 90-minute telePR session. Real-world usability testing sessions were conducted with patients to uncover obstacles in workflow that were unable to be identified during simulated usability testing sessions. With the support of a research study member, 4 encounters were observed between a single patient and a remote respiratory therapist. Of these 4 observed encounters, 1 encounter took place at a community center and the other 3 encounters took place within patient homes. We began each session by scanning the different types of locations to assess possible issues with the environment and physical space. Audio recordings of the participant and respiratory therapist were made during each session. Following the telePR session, patients were asked to complete two surveys: (1) a set of usability questions for a thorough review of their experience and opinions regarding the telePR session, and (2) the widely validated 10-question System Usability Scale (SUS) [20].

Results

Phase 1: Prefield Testing Assessment

A fundamental assessment prioritization scale (see Figure 3) was configured based on the initial observations of the telePR sessions to account for technical issues, physical and environmental obstacles, and potentially problematic patient factors. Technical issues were assessed and quickly modified at the start of each session, as bandwidth and other issues caused considerable delays and confusion on the part of the patient, leading to demotivation and frustration. If a strong internet connection could not be established, the session could not be completed. With regard to the ergonomics of the tablet, many patients experienced difficulty with interface issues, such as trouble with double-clicking icons that were deemed too small (especially for those with arthritis and those with visual impairment). Tablet placement needed to be assessed based on patient mobility, vision needs, and auditory needs—this was a critical step that required a research study team member to make requisite device adjustments between the different patient visits to the community center.

When considering environmental and physical issues, we found through usability testing that it was vital for the remote respiratory therapist to review a checklist with the patient to ensure the following items were present prior to the session: water, oxygen (if necessary), weights, and a phone in case of an emergency, in order to facilitate participant independence during subsequent sessions. Prior to the encounter, the SOP manual also called for the therapist to advise patients to adjust the angle of the tablet and position the seat for the most advantageous level of comfort. During this phase of usability testing, the need to modify the tablet mounting was identified as a priority optimization to prevent patient neck strain when viewing the tablet, riding the bike, and completing other exercises during the session. Over the course of the study, additional opportunities for system improvements were found and implemented, which included physical and environmental changes, individual patient factor accommodations, safety improvements, and technology modifications (Table 2).

Figure 3. Fundamental assessment prioritization scale.

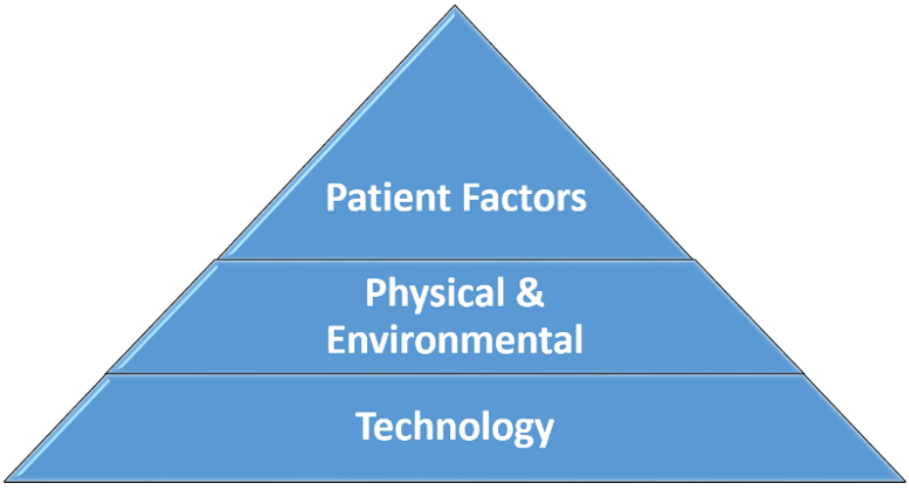

Table 2. Summary of system improvements.

Issue	Modification
Physical/environmental	
Patients that have low motor and upper body strength have trouble adjusting the bike seat to a level of comfort and the tablet to eye level.	Prior to the encounter, the respiratory therapist will need to advise patients to adjust the angle of the tablet and the seat position to the most advantageous comfort level. In certain patients, the study team member will need to be present to adjust the seat.
Tablet mounting arm is too short and may cause neck strain for certain patients.	Tablet mounting should be on a longer arm stand to prevent patient neck strain when viewing the tablet, riding the bike, and completing other exercises during the session.
The lack of a standardized approach to each telePR[a] session leads to patient dependency.	The respiratory therapist should present a checklist to the patient prior to the encounter to check items (such as the seat, tablet, water, oxygen, weights, phone, etc) so that the patients may become independent during subsequent sessions.
Safety	
Emergencies that occur during the encounter must be addressed.	Develop a standard of operations for patient emergencies that may occur during the telehealth visit.
Wi-Fi may be lost during the telePR session.	Handouts should be available with directions for patients to answer the phone or to call the respiratory therapist if Wi-Fi is lost.
Patients that have knee problems may have trouble completing the telePR session.	Consider mobility criteria prior to a patient's enrollment in the study (eg, patients who have had a recent knee surgery may encounter difficulties riding a bike).
Technology	
Bandwidth issues cause considerable interruptions throughout the session.	An initial technical assessment is needed at each site to ensure that Wi-Fi is sufficient to support telehealth technology. If issues continue to arise, then a research study member should be present at a particular site to address them.
Audio problems may occur during a telePR session.	In case of audio problems during teleconferencing, the patient's cell phone number should be provided to the respiratory therapist to call if the teleconference goes down.
The Windows software has small close (X) icons that are not ideal for patients with large fingers, arthritis, or visual impairment to exit screens.	For users in the Dependent category, the technical demands required to configure and use the tablet hardware, software, and the associated devices are too tedious for a successful experience; these patients require a study team member to be present at the telePR session.

[a]telePR: telehealth-delivered pulmonary rehabilitation.

Phase 2: Feasibility Testing

After the implementation of the usability recommendations, two rounds of feasibility testing were conducted with 4 patients (2 in the community center setting and 2 in the patients' homes). Upon completion of the telePR session, each patient completed one SUS inventory for the bike and one SUS inventory for the technology. Patients were asked to answer questions on a Likert scale from 1-5, with 1 coded for "Strongly disagree" and 5 coded for "Strongly agree." Answers were converted, added, and multiplied by 2.5 to convert scores from a 0-40 scale to a 0-100 scale. Scores of 70 and above were considered acceptable while scores of 85 and above were considered excellent. Of the 4 patients, 3 completed the SUS. For the bike SUS, patient 1 scored 95% (38), patient 2 scored 50% (20), and patient 3 scored 25% (10). For the technology SUS, patient 1 scored 90% (36) and patient 2 scored 52.5% (21); patient 3 did not complete the technology SUS.

After completing two rounds of feasibility testing, 3 different categories of patients were classified as follows: independent, intermediate, and dependent (Table 3). This categorization was assessed and applied for each patient for all subsequent telePR sessions, used to predict the level of training and support needed for successful participation in all future sessions. Results revealed that those in the independent category could manage the telePR sessions by themselves. We determined that patients in the intermediate category required assistance during their initial sessions but were able to complete subsequent rehab sessions without support. Respondents in the dependent category were unable to perform the rehab sessions without in-person support due to low technical acumen and difficulty with certain features of the system, such as not being able to locate the icon to start the session, connect the tablet to the Wi-Fi, turn on the tablet, etc. The intermediate and independent users, however, did exhibit increased independent utilization due to iterative improvements to the system architecture and greater technical acumen.

Table 3. Telehealth-delivered pulmonary rehabilitation (telePR) participant categorization.

Category	Characterization
Independent	Most likely to be able to complete the telehealth rehab session without in-person support (other than initial set-up instructions).
Intermediate	Requires in-person support for the initial 2-3 telehealth rehab sessions but is able to independently complete the remaining sessions.
Dependent	Unable to perform the telehealth rehab sessions without in-person support.

Discussion

The goal of usability testing is to identify potential barriers and develop recommendations for optimizing applications like the telePR program. The primary technical recommendation derived from our usability testing was to assess Wi-Fi bandwidth as part of the set-up protocol and installation process. Following this recommendation, we developed patient-friendly troubleshooting guidelines, including audio-only communication options to be used in cases where Wi-Fi issues occurred during the session.

Safety recommendations included the development of SOPs for patient emergencies that may occur during the telePR visit. Usability testing and user-centered design practices helped to identify a need for remote respiratory therapist guidelines and a readiness checklist for patients to review prior to commencing each telePR rehab session. This process also highlighted the necessity of developing protocols and operating standards to address technical, safety, and environmental issues. Protocols and SOPs included a diagram with seat, tablet, water, oxygen, weights, and phone placements; a sticker to remind patients to answer a phone call from the respiratory therapist in case of lost Wi-Fi; and a checklist for patients with mobility issues. Physical and environmental recommendations included the creation of markers (with the use of colored tape) at the initial visit that indicate personalized settings for the tablet angle, seat placement, and audio levels appropriate for the environment. The study team was also prompted to ensure the provision of power strips with each bike in case more than one electrical cord was needed (for the bike and tablet).

We further identified the need to assess for technical acumen at the first telePR session in order to categorize patients into Independent, Intermediate, and Dependent segments. This assessment allowed for appropriate study personnel to be deployed to the telePR visits and for specific, tailored instructions to be used. For users in the Dependent category, the technical demands required to configure and use the tablet hardware, software, and the associated devices made it impossible to conduct sessions successfully without the presence and aid of a research study team member. It was also important to interpret the results of the SUS to effectively place patients into the Telehealth-delivered pulmonary rehabilitation (telePR) participant categorization (Table 3), as patients in the Dependent category rated the bike and technology with scores of 50 and below. The primary goals in developing standardization protocols were to establish trust, ensure a positive experience, and encourage future patient engagement with telePR sessions. Our usability testing allowed us to achieve our primary goal and create a feasible protocol to support and guide current and future telePR session participants.

Acknowledgments

The research reported in this work was funded by a Patient-Centered Outcomes Research Institute (PCORI) award (1511-33066). The authors of this work are solely responsible for the statements presented herein, which do not necessarily represent the views of the PCORI, its Board of Governors, or its Methodology Committee.

Conflicts of Interest

None declared.

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Abbreviations

COPD: chronic obstructive pulmonary disease
PR: standard pulmonary rehabilitation
QoL: quality of life
SOPs: standards of operation
SUS: System Usability Scale
telePR: telehealth-delivered pulmonary rehabilitation

Edited by G Eysenbach; submitted 26.08.19; peer-reviewed by M Nitsch, S Sarbadhikari, T Abdulai; comments to author 06.01.20; revised version received 01.03.20; accepted 28.03.20; published 04.08.20.

Please cite as:
King D, Khan S, Polo J, Solomon J, Pekmezaris R, Hajizadeh N
Optimizing Telehealth Experience Design Through Usability Testing in Hispanic American and African American Patient Populations: Observational Study
JMIR Rehabil Assist Technol 2020;7(2):e16004
URL: http://rehab.jmir.org/2020/2/e16004/
doi:10.2196/16004
PMID:32749229

Original Paper

An Affordable, User-friendly Telerehabilitation System Assembled Using Existing Technologies for Individuals Isolated With COVID-19: Development and Feasibility Study

Masahiko Mukaino[1*], MD, PhD; Tsuyoshi Tatemoto[2*], PT, PhD; Nobuhiro Kumazawa[2], PT, MSc; Shigeo Tanabe[2], PT, PhD; Masaki Katoh[3], PT; Eiichi Saitoh[1], MD, PhD; Yohei Otaka[1], MD, PhD

[1]Department of Rehabilitation Medicine I, School of Medicine, Fujita Health University, Toyoake, Japan

[2]Faculty of Rehabilitation, School of Health Sciences, Fujita Health University, Toyoake, Japan

[3]Department of Rehabilitation, Fujita Health University Hospital, Toyoake, Japan

[*]these authors contributed equally

Corresponding Author:
Yohei Otaka, MD, PhD
Department of Rehabilitation Medicine I
School of Medicine
Fujita Health University
1-98 Dengakugakubo, Kutsukake-cho
Toyoake, 4701192
Japan
Phone: 81 562 93 2167
Email: otaka119@mac.com

Abstract

Background: Isolation due to a COVID-19 infection can limit activities and cause physical and mental decline, especially in older adults and people with disabilities. However, due to limited contact, adequate rehabilitation is difficult to provide for quarantined patients. Telerehabilitation technology could be a solution; however, issues specific to COVID-19 should be taken into consideration, such as strict quarantine and respiratory symptoms, as well as accessibility to deal with rapid increases in need due to the pandemic.

Objective: This study aims to develop and to investigate the feasibility of a telerehabilitation system for patients who are quarantined due to COVID-19 by combining existing commercial devices and computer applications.

Methods: A multidisciplinary team has identified the requirements for a telerehabilitation system for COVID-19 and developed the system to satisfy those requirements. In the subsequent feasibility study, patients diagnosed with COVID-19 (N=10; mean age 60 years, SD 18 years) were included. A single session of telerehabilitation consisted of stretching exercises, a 15-minute exercise program, and a video exercise program conducted under real-time guidance by a physical therapist through a video call. The system included a tablet computer, a pulse oximeter, videoconferencing software, and remote control software. The feasibility of the system was evaluated using the Telemedicine Satisfaction Questionnaire (TSQ; 14 items) and an additional questionnaire on the telerehabilitation system (5 items). Each item was rated from "1 = strongly disagree" to "5 = strongly agree."

Results: The telerehabilitation system was developed by combining existing devices and applications, including a pulse oximeter and remote control mechanism, to achieve user-friendliness, affordability, and safety, which were determined as the system requirements. In the feasibility study, 9 out of 10 patients were able to use the telerehabilitation system without any on-site help. On the TSQ, the mean score for each item was 4.7 (SD 0.7), and in the additional items regarding telerehabilitation, the mean score for each item was 4.3 (SD 1.0).

Conclusions: These findings support the feasibility of this simple telerehabilitation system in quarantined patients with COVID-19, encouraging further investigation on the merit of the system's use in clinical practice.

(JMIR Rehabil Assist Technol 2020;7(2):e24960) doi:10.2196/24960

KEYWORDS

telerehabilitation; COVID-19; telemedicine; isolation; user-friendly; feasibility; rehabilitation; eHealth

Introduction

Despite global efforts to mitigate the spread of COVID-19, which was declared a global pandemic by the World Health Organization on March 12, 2020 [1], the virus is showing no signs of slowing down. To counteract the rapidly spreading infection, many individuals, including those already infected by the virus as well as older adults and people with disabilities who are at high risk of severe pneumonia due to COVID-19, are quarantined to avoid contact. However, isolation limits activities and may cause physical and mental decline, particularly among older adults and people with disabilities [2].

Providing rehabilitation by alleviating the functional decline experienced by individuals in isolation due to COVID-19 should be a solution to this issue [3]. However, there have been concerns that rehabilitation typically involves human interaction at close proximity and physical contact, and therefore increases the risk of infection transmission [4].

Telerehabilitation may potentially address this problem. Recent developments in digital technology have made it possible to conduct telerehabilitation using real-time communication technology [5]. However, there are several issues in applying telerehabilitation for patients with COVID-19. For example, there is an issue around operation of the systems by the patients who are quarantined. In applying telerehabilitation to patients, proficiency in the operation of videoconferencing systems, monitoring devices, and applications is necessary because the patients have to operate them alone when using the system in their own room. In many previous studies in telerehabilitation, patients were given an opportunity to practice the exercise and operation under the supervision of therapists prior to the start of telerehabilitation [6-8]. However, this method cannot be applied to patients with COVID-19 because they are already quarantined when they start the telerehabilitation program.

Another issue may be the cost for the system. Previous studies have shown the feasibility and effectiveness of telerehabilitation with older adult patients and patients with disabilities using dedicated videoconferencing systems prepared for telerehabilitation [6-8]. Although those dedicated telerehabilitation systems have been shown to be effective, the initial investment for such systems may not be prioritized because of the rapid expansion in demand for medical resources caused by the COVID-19 pandemic. Therefore, there may be demand for a system that is affordable and accessible for immediate response to this pandemic.

With the aim of solving these problems and providing exercise opportunities for patients who are isolated, we developed and tested the feasibility of a simple telerehabilitation system using common, commercially available devices and applications.

Methods

Participants

Patients who were diagnosed with COVID-19 and admitted to a university hospital, and who agreed to participate in this study were included. The exclusion criteria were as follows: requirement of oxygen therapy, existence of hearing loss, existence of severe orthopedic or neurologic disease, and inability to understand instructions. The patients' demographics, including the days after onset, the severity of the pneumonia at its worst (severe: requiring incubation; moderate: requiring oxygen; mild: presenting signs of pneumonia but do not require oxygen; and asymptomatic), and comorbidities, were collected from the medical record. The levels of functioning of the patients were evaluated using the Functional Independence Measure (FIM) [9]. This study is approved by the institutional review board. All patients provided written informed consent prior to study participation.

Telerehabilitation System

The telerehabilitation system was prepared in private rooms where the patients were quarantined in the university hospital. The telerehabilitation system was designed and built by a team consisting of two physicians, an engineer, and two physical therapists. The preliminary version of the system was introduced previously [10]. The team first discussed and defined the requirements for the telerehabilitation system for COVID-19 and then developed the system to satisfy the requirements. The hardware of the system consists of a desktop computer for the health professionals who are providing the service, a tablet computer for patients, and a pulse oximeter to monitor vital signs. The pulse oximeter is a commercially available product (RingO2, Neuroceutical Inc) that can be connected to a tablet via Bluetooth. On the tablet, the remote-controlled software TeamViewer (TeamViewer GmbH), conferencing softwares Zoom (Zoom Video Communications Inc) and Skype (Microsoft Corp), and a pulse oximeter control application were installed. A video file of an exercise program was also preinstalled on the tablet computer in the patients' rooms in case of an unstable internet connection. The cost for implementation is the price in Japan, with the value converted into US dollars (US $) and Euros (€) at the exchange rate on May 8, 2020, when the study started.

Procedure

The exercise program was performed in the following manner (Figure 1). A physical therapist with 12 years of professional experience provided the service. First, at a prescheduled time, the physical therapist called the patient via Skype and instructed them to start the TeamViewer software to enable remote control of the tablet from the therapist's side. The therapist then launched the apps (Zoom and the app for controlling the pulse oximeter) to start the exercise. The vital signs and basic motor ability were checked, and then, a video exercise program was performed. After ending the program, the vital signs were checked again. The total length of the session was 20 minutes including preparation. The patients received the survey on the feasibility of the program after a single session.

Figure 1. Exercise program delivered using the telerehabilitation system. Upper panel: A physical therapist instructs the patient about an exercise program using the telerehabilitation system. Lower panel: Screen of the tablet computer installed in the participant's room.

A Survey for Feasibility of the Program

A survey using the Telemedicine Satisfaction Questionnaire (TSQ) [11] was administered after the end of the program. The TSQ was developed by Yip et al [11] to assess satisfaction with telemedicine, and it consists of 14 items and a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree).

In this study, the following five questions were added to further assess satisfaction with the delivery of exercise programs using the system: "I can easily understand how to move," "I feel safe performing the exercise," "The room environment is appropriate for performing the exercise programs," "The devices used are appropriate for performing the exercise programs," and "Telecommunication with medical experts during exercise is helpful." The changes in SpO_2 levels before and after the exercise were also evaluated.

Results

Development of the System

As a result of the discussion on system requirements by a multidisciplinary team, three requirements were set for the system: (1) user-friendliness, to be used without prior practice because patients with COVID-19 are isolated from the beginning; (2) affordability, to be quickly implemented in response to the rapid spread of COVID-19 infection; and (3) safety, achieved through the real-time monitoring of vital signs to be able to respond to a possible rapid deterioration in respiratory function during exercise. The system specifications were determined and developed as follows to satisfy each of the predefined requirements:

1. User-friendliness: The lack of practicing in advance was expected to cause significant problems in operating the devices in patients with low digital literacy. Therefore, the system was developed to let the service provider operate most of the functions on behalf of the patient using a remote control application (TeamViewer). Since the content of the exercises could not be practiced in advance, we prepared a video for a 15-minute exercise program as a tool to assist in teaching the exercises. The video of the exercise program was preinstalled on the patient's tablet PC to avoid the quality of playback being affected by the quality of the internet connection. During the exercise, the video was started remotely by the service provider, and the exercises were performed along with the video, with real-time advice by the therapists.
2. Affordability: In this regard, the system was created using existing devices and applications, with an emphasis on being inexpensive and readily available. The hardware was simple, consisting of a PC on the service provider's side and a tablet PC on the patient's side. Zoom and Skype, which are common videoconferencing applications, and

TeamViewer, a remote control application, were installed on the tablet. As a monitoring device of vital signs, a pulse oximeter (RingO2), which can be connected to the tablet PC via Bluetooth, was prepared. The initial cost for preparation of the system for a single set of hardware and software was ¥287,800 (US $2705.90; €2489.41) for the service provider and ¥39,800 (US $383.41; €344.27) for a single patient. The details of the cost are shown in Table 1.

3. Safety: To address this point, a pulse oximeter was prepared for real-time monitoring during the exercise to respond to possible difficulty in respiratory function. A pulse oximeter (RingO2) that can be connected to a tablet PC via Bluetooth was used. The service provider could check the blood oxygen saturation and heart rate of the patients through the screen during the session.

Table 1. Detailed initial costs for the devices and applications.

Items and products	Provider	Cost (¥)	Cost (US $)[a]	Cost (€)[b]
Service provider kit				
Laptop PC				
MacBook Pro 13 inches	Apple Inc	188,800	1775.10	1633.08
Remote control software				
TeamViewer Business license	TeamViewer GmbH	59,400 (per year)	558.48	513.80
TeamViewer mobile devise support option	TeamViewer GmbH	39,600 (per year)	372.32	342.53
Conferencing software				
Zoom Meetings (Basic license)	Zoom Video Communications Inc	Free	Free	Free
Skype	Microsoft Corporation	Free	Free	Free
Total (service provider kit)	N/A[c]	287,800	2705.90	2489.41
Patient kit				
Tablet PC				
LAVIE tablet PC	NEC Corporation	20,000	188.04	173.00
Pulse oximeter				
RingO2 (with viewer application)	Neuroceuticals Inc	19,800	186.16	171.27
Total (patient kit)	N/A	39,800	374.20	344.27

[a]US $ was calculated from ¥ at the market price as of May 8, 2020: 106.36 ¥/US $

[b]€ was calculated from ¥ at the market price as of May 8, 2020: 115.61 ¥/€

[c]N/A: not applicable.

Feasibility Study

A total of 10 patients with COVID-19 participated in this study. The demographic variables of the patients are summarized in Table 2. The mean age of the patients was 60 (SD 18) years; 4 patients were men, and 6 were women. The average SpO_2 levels at the start and end of the study were 94.4 (SD 2.6) and 95.1 (SD 2.0), respectively. There were 3 patients that experienced moderate pneumonia, 5 had mild signs of pneumonia, and the others were asymptomatic. The average FIM of the patients was 122.4 (SD 4.5; mean motor score 87.7, SD 4.3; mean cognitive score 34.4, SD 1.1). Out of the 10 patients, 4 had no experience using a tablet PC or smartphone.

Table 2. Patient demographics.

Demographic	Patients (N=10)
Age (years), mean (SD)	60 (18)
Gender, n	
Male	4
Female	6
Pneumonia at its worst, n	
Moderate	3
Mild	5
Asymptomatic	2
Days after diagnosis, mean (SD)	9.9 (8.0)
Comorbidities, n	
Hypertension	4
Diabetes	2
Stroke	1
Mild cognitive impairment	1
Depression	1
Lumbar compression fracture	1
Functional Independence Measure, mean (SD)	
Total score[a]	122.4 (4.5)
Motor score[b]	87.7 (4.3)
Cognitive score[c]	34.4 (1.1)
Experience in using tablet PC or smartphone, n	
Yes	6
No	4

[a]Range of total score was 18-126.

[b]Range of motor score was 13-91.

[c]Range of cognitive score was 5-35.

All the patients successfully completed the session. The average time required for preparation after the first Skype call to the start of the exercise was 3.0 (SD 1.1) minutes. In 1 case out of 10, on-site support for handling tablet computers was required at the start of the session. The patient had no cognitive disorder, had been treated for depression, and had no experience using a tablet PC. The patient asked for on-site help because of an unexpected movement of the application at the start of the session. After the initial set up, the patient required no further on-site help.

The results of the TSQ and the additional questions are shown in Figure 2. On the TSQ, the mean score for each item was 4.7 (SD 0.7), and the mean total score of the TSQ (maximum score of 70) was 65.2 (SD 6.9; mean 93.1%, SD 9.8%). In the additional items regarding telerehabilitation, the mean score for each item was 4.3 (SD 1.0). Additionally, there were several feedbacks from the participants regarding difficulty experienced while handling tablets and the limited visibility of video calls and video exercise programs. The TSQ was also administered to physical therapists who were service providers, with a total score of 61 (87.1%) and a mean score of 4.4 (SD 0.6).

Figure 2. Telemedicine Satisfaction Questionnaire and additional questionnaire for the telerehabilitation system. The percentage of response options for each question is shown.

Discussion

Principal Findings

In this preliminary study, a telerehabilitation system for patients isolated due to COVID-19 was developed by combining commercially available devices and applications, and its feasibility was tested in 10 patients with COVID-19. The exercise program was safely conducted, with no significant decrease in SpO_2. Patients' satisfaction with the telerehabilitation system was generally high.

Various telerehabilitation programs have been used in patients with orthopedic, neurological, respiratory, and cardiovascular diseases, and have been shown to be effective [12-15]. Telerehabilitation is considered to have potential benefits for patients, such as better accessibility, reduced time burden, and cost effectiveness [16-18]. It has also been shown that it may be as effective as on-site rehabilitation [6-8]. The use of telerehabilitation systems in isolated patients due to infection has rarely been reported, but the rapid spread of COVID-19 infections has increased interest in this area. The capabilities required for a telerehabilitation system for patients in isolation due to infection may differ from those of previous telerehabilitation systems.

In this study, we first identified three prerequisites (user-friendliness, affordability, and safety) as necessary for the establishment of a telerehabilitation system for patients in isolation due to infection, and then, we developed a system based on those prerequisites. User-friendliness is an important point in telerehabilitation [19], but it is particularly important in the case of telerehabilitation for infectious diseases. Many previous studies of telerehabilitation have consisted of prior practice and subsequent tele-sessions [6-8]. However, when practice is initiated in isolation from the beginning, the user needs to handle the device and applications, and perform exercise without any on-site assistance. Therefore, a high level of user-friendliness is necessary to successfully conduct the exercise sessions with patients that have variations in their levels of digital literacy.

Affordability and safety were also important, although they may conflict with user-friendliness. For example, the surest way to make the telerehabilitation system user-friendly is to create a customized system for the target patients. However, the development of customized systems may reduce affordability. In addition, monitoring is necessary for patient safety, which would complicate the system. To satisfy all these requirements, a new approach was taken in this study to combine existing devices and applications, including monitoring devices, and to minimize patient manipulation by the use of remote control.

The results of our study support the main assumed benefit of the system: user-friendliness. Out of the 10 patients in this study, 9 were able to complete the session without on-site assistance, and 7 patients agreed or strongly agreed with the item "no assistance is required while using the system." Overall, a high level of satisfaction was observed, with the TSQ scores averaging 93.1% (65.2/70), which is comparable to previous studies [20-22]. However, there was some feedback from patients about usability issues, and further improvement in the

user-friendliness of the system would help for widespread clinical implementation in the future. The effectiveness of the system should also be tested to see if this telerehabilitation system can contribute to the maintenance of function in isolated patients.

Another advantage of the system demonstrated in this study is that it was built using existing commercial resources and requires minimal initial cost. In fact, the initial costs required in this study were less than in previous studies [23,24], with a total of US $2781.12 for the service provider kit (including annual license of the applications) and US $383.41 for the patient kit. Many of the commercialized devices and applications such as PCs, tablet PCs, pulse oximeters, videoconferencing applications, and remote control applications used in this study already exist and can be prepared inexpensively. In addition, these resources are easily accessible, and therefore, the system can be easily replicated and deployed. Such an approach also eliminates the need to spend time and cost on developing the dedicated devices or apps, supporting the rapid social response to changes in the rehabilitation practice due to the COVID-19 pandemic.

Limitations

There are several limitations. This study was conducted as a feasibility study with a small sample. The merit of conducting the telerehabilitation with this system on the patients' functioning should be further investigated with a larger sample and a longer-term intervention.

Although the results of the TSQ support the good feasibility of this telerehabilitation system, it can be affected by the environment due to internet connection; these results were, in fact, obtained in a stable internet environment with a Wi-Fi connection. However, the system is designed to reduce the influence of unstable internet connection by preinstalling the video program on the tablet, so a level of internet speed that is stable enough to make video calls should be sufficient to provide the same quality of intervention as in this study.

A survey of service providers was also conducted, but only 1 person provided the service in this study, and there was insufficient information on the user-friendliness for the service side. In particular, because the service provider took over all operations on the patient's side, the service provider's operations have become more complicated, and there is room for improvement of the operation method and consideration of how to operate the system, such as the development of robotic process automation software.

Conclusions

The telerehabilitation system developed in this study may be applicable to individuals experiencing isolation related to the COVID-19 pandemic. The results of this study should prompt further investigation of the usefulness of telerehabilitation in clinical settings.

Conflicts of Interest

None declared.

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Abbreviations

FIM: Functional Independence Measure
TSQ: Telemedicine Satisfaction Questionnaire

Edited by G Eysenbach; submitted 13.10.20; peer-reviewed by B Smith; comments to author 04.11.20; revised version received 17.11.20; accepted 05.12.20; published 10.12.20.

Please cite as:
Mukaino M, Tatemoto T, Kumazawa N, Tanabe S, Katoh M, Saitoh E, Otaka Y
An Affordable, User-friendly Telerehabilitation System Assembled Using Existing Technologies for Individuals Isolated With COVID-19: Development and Feasibility Study
JMIR Rehabil Assist Technol 2020;7(2):e24960
URL: http://rehab.jmir.org/2020/2/e24960/
doi:10.2196/24960
PMID:33279877

Original Paper

Usability and Acceptability of an App (SELFBACK) to Support Self-Management of Low Back Pain: Mixed Methods Study

Anne Lovise Nordstoga[1*], PhD; Kerstin Bach[2*], PhD; Sadiq Sani[3*], PhD; Nirmalie Wiratunga[3*], PhD; Paul Jarle Mork[1*], DPhil; Morten Villumsen[1*], PhD; Kay Cooper[4*], PhD

[1]Department of Public Health and Nursing, Norwegian University of Science and Technology, Trondheim, Norway

[2]Department of Computer Science, Norwegian University of Science and Technology, Trondheim, Norway

[3]School of Computing Science and Digital Media, Robert Gordon University, Aberdeen, United Kingdom

[4]School of Health Sciences, Robert Gordon University, Aberdeen, United Kingdom

[*]all authors contributed equally

Corresponding Author:
Anne Lovise Nordstoga, PhD
Department of Public Health and Nursing
Norwegian University of Science and Technology
Håkon Jarls gate 11
Trondheim, 7030
Norway
Phone: 47 99268260
Email: anne.l.nordstoga@ntnu.no

Abstract

Background: Self-management is the key recommendation for managing nonspecific low back pain (LBP). However, there are well-documented barriers to self-management; therefore, methods of facilitating adherence are required. Smartphone apps are increasingly being used to support self-management of long-term conditions such as LBP.

Objective: The aim of this study was to assess the usability and acceptability of the SELFBACK smartphone app, designed to support and facilitate self-management of non-specific LBP. The app provides weekly self-management plans, comprising physical activity, strength and flexibility exercises, and patient education. The plans are tailored to the patient's characteristics and symptom progress by using case-based reasoning methodology.

Methods: The study was carried out in 2 stages using a mixed-methods approach. All participants undertook surveys, and semistructured telephone interviews were conducted with a subgroup of participants. Stage 1 assessed an app version with only the physical activity component and a web questionnaire that collects information necessary for tailoring the self-management plans. The physical activity component included monitoring of steps recorded by a wristband, goal setting, and a scheme for sending personalized, timely, and motivational notifications to the user's smartphone. Findings from Stage 1 were used to refine the app and inform further development. Stage 2 investigated an app version that incorporated 3 self-management components (physical activity, exercises, and education). A total of 16 participants (age range 23-71 years) with ongoing or chronic nonspecific LBP were included in Stage 1, and 11 participants (age range 32-56 years) were included in Stage 2.

Results: In Stage 1, 15 of 16 participants reported that the baseline questionnaire was easy to answer, and 84% (13/16) found the completion time to be acceptable. Overall, participants were positive about the usability of the physical activity component but only 31% (5/16) found the app functions to be well integrated. Of the participants, 90% (14/16) were satisfied with the notifications, and they were perceived as being personalized (12/16, 80%). In Stage 2, all participants reported that the web questionnaire was easy to answer and the completion time acceptable. The physical activity and exercise components were rated useful by 80% (8/10), while 60% (6/10) rated the educational component useful. Overall, participants were satisfied with the usability of the app; however, only 50% (5/10) found the functions to be well integrated, and 20% (2/10) found them to be inconsistent. Overall, 80% (8/10) of participants reported it to be useful for self-management. The interviews largely reinforced the survey findings in both stages.

Conclusions: This study has demonstrated that participants considered the SELFBACK app to be acceptable and usable and that they thought it would be useful for supporting self-management of LBP. However, we identified some limitations and suggestions useful to guide further development of the SELFBACK app and other mobile health interventions.

(JMIR Rehabil Assist Technol 2020;7(2):e18729) doi:10.2196/18729

KEYWORDS

low back pain; self-management; physical activity; exercise; patient education; smartphone; mHealth; eHealth; digital health; case-based reasoning

Introduction

Low back pain (LBP) is a common and costly condition, peaking in midlife but affecting all age groups [1,2]. Further, LBP is the leading cause of years lived with disability worldwide [3] and is associated with substantial direct (health care) and indirect (eg, work absenteeism, loss of productivity, disability pensions) costs [4-6]. Most LBP does not have a known pathoanatomical cause and is known as nonspecific LBP [3,7,8]. Clinical guidelines encourage active treatment and self-management [9], with physical activity, patient education, and strength and flexibility exercises being some of the key components [10-12].

Adherence to self-management of LBP is challenging, with several reported barriers, in keeping with other chronic conditions [13,14]. Evidence suggests that individually tailored exercise programs for patients with nonspecific LBP are more effective on pain and functioning than nontailored programs [15]. Mobile health (mHealth) technologies such as mobile apps are increasing in popularity and offer the potential for supporting people with LBP and providing them with individually tailored (personalized) recommendations. Although many mobile apps for self-management of LBP are available, most are not personalized and provide the user with generic recommendations only, which may not be relevant to everyone using the app. Moreover, their effectiveness on pain and functional outcomes has not commonly been documented [16,17].

The selfBACK project aims to improve self-management of nonspecific LBP by developing an evidence-based decision support system (DSS) that is made available for end users via the selfBACK app. The protocol for designing and implementing the selfBACK DSS has been published elsewhere [18]. In brief, the selfBACK app is underpinned by behavior change [19] and normalization process theories [20] and aims to achieve improved clinical outcomes for people with nonspecific LBP of any duration. It does this by promoting behavioral change to address factors such as fear avoidance and low pain self-efficacy. The selfBACK app provides the patient with weekly self-management plans, tailored to their individual characteristics, achieved by gathering data on physical activity (measured by a wrist-worn monitor) and other personal and LBP-related factors (measured by a weekly questionnaire in the app) such as pain, function, sleep, mood, fear avoidance, self-efficacy, barriers, and exercise adherence in the last week [21]. Creating and tailoring of the self-management plans are achieved by using a case-based reasoning methodology to capture and reuse information from previous similar and successful LBP patients (ie, favorable progression of symptoms, measured via the weekly questionnaire) available in the selfBACK case base [21]. In keeping with recent evidence-based guidelines for LBP [10], the weekly self-management plans comprise physical activity recommendations, strength and flexibility exercises, and patient education. Patients can adjust recommended physical activity goals, and exercise prescription is by co-decision, where the app recommends a plan which the patient can adjust if they wish. As there is insufficient evidence on the effectiveness of a specific type of exercise for treatment and prevention of LBP [22], selfBACK incorporates a suite of flexibility and strengthening exercises commonly utilized in the management of LBP. The patient education is also tailored to the individual, depending on their response to the weekly questionnaire. Several behavior change techniques [23] are incorporated in the app, including goal setting, problem solving, feedback and monitoring, commitment, information about health consequences, and prompts and cues.

Following the Medical Research Council guidance for the development and evaluation of complex interventions [24], we took a systematic approach to developing the selfBACK DSS, involving usability and acceptability testing prior to piloting a randomized controlled trial (RCT) [25]. In this paper, we present the results of the usability and acceptability study. Due to the complexity of the selfBACK DSS and the iterative design process employed in its development, we employed a 2-stage approach. In the first stage, we explored the feasibility and acceptability of data collection of patient characteristics and symptoms using a web questionnaire and usability and acceptability of the physical activity component of selfBACK using a wrist-worn monitor and prototype app, Traxivity [26]. In the second stage, we explored the usability and acceptability of a further developed app version with 3 self-management components (ie, physical activity, exercises, and patient education). This manuscript presents summary findings from Stage 1 to demonstrate the iterative design process. Because Stage 2 used a more developed app with all 3 selfBACK components, we present more detailed analysis of this stage.

Methods

Study Design

A sequential exploratory mixed-methods design was applied in this study [27] with participants using the selfBACK app for 4 weeks in both stages. In Stage 1, the following data were collected: completion times for the web questionnaire, user activity from the app, and usability and acceptability (via self-report questionnaire). Semistructured telephone interviews with a subgroup of participants were conducted to explain and interpret quantitative findings. In Stage 2, the following data were collected: usability and acceptability of the app version with 3 self-management components. Semistructured interviews were conducted to further explore usability and acceptability.

Setting and Participants

Stage 1 took place in Aberdeen, Scotland (November 2017 through February 2018). We recruited 16 adults (aged ≥18 years) with nonspecific LBP of any duration or severity from a university physiotherapy clinic, the university staff and student

population by email, and the wider public by media release. Interested participants were referred to the study team and screened for inclusion and exclusion criteria either face-to-face or by telephone by a research assistant trained for the study. Suitable participants attended the university to complete baseline measures and be provided with access to the app. In Stage 1, selfBACK was only available as an Android app, and some participants' phones would not support the app. In these cases, we loaned smartphones to participants for the 4-week study duration.

Stage 2 took place in Trondheim, Norway (April 2018 to May 2018). We recruited 11 adults (aged ≥18 years) with nonspecific LBP of any duration or severity from a hospital back and neck outpatient clinic and the wider public. Interested participants were referred to the study team and screened for inclusion and exclusion criteria by telephone by a research assistant trained for the study. Suitable participants were asked to complete the baseline web questionnaire before they attended the university to be provided with access to the app. Exclusion criteria for both stages were self-reported serious pathology; terminal illness; serious depression; unable to read, speak, or understand English (the selfBACK app was only available in English); leg pain worse than LBP; unable to perform physical activity or exercises; pregnancy; fibromyalgia; and previous spinal surgery. Because selfBACK is intended for self-management of nonspecific LBP of any duration or severity, the participants in both locations were suitable candidates. All participants provided written, informed consent, and ethical approval was granted by the Robert Gordon University School of Health Sciences (SHS/17/14) and the Regional Committee for Ethics in Medical Research, Mid-Norway (2018/31).

Questionnaires

Information collected by the web questionnaire forms the basis for creating the self-management plans in selfBACK. The information collected included gender, age, weight and height to calculate BMI, education, employment status, LBP intensity, LBP duration, pain-related disability, activity limitation, pain mannequin, pain self-efficacy, leisure-time physical activity, insomnia symptoms, health-related quality of life, and mental health (Table 1). The web questionnaire was completed before the participants were given access to the app. A web questionnaire was carried out at the end of the 4-week test period, including the 10-item System Usability Scale (SUS) [28] and a 29-item design questionnaire [29]. The SUS has a mix of positive and negative questions scored on a 5-point Likert scale (strongly disagree to strongly agree): We adapted each question to say "selfBACK system" in place of "system" (Textbox 1). The design questionnaire was adapted from that used in a previous study of pain self-management apps [29]. It included items on the design and content of the selfBACK system and incorporated a mix of closed and open questions (Multimedia Appendix 1). In Stage 2, only the participants that volunteered for the interviews completed the SUS and design questionnaire.

Table 1. Participant characteristics collected with the web questionnaire.

Characteristics	Stage 1 (n=16)	Stage 2 (n=11)
Age (years), mean (SD, range)	51.1 (13.9, 23-71)	43.0 (7.5, 32-56)
Male/female	10/6	5/6
BMI (kg/m^2), mean (SD, range)	26.2 (4.2, 18.8-32.8)	25.2 (3.2, 18.8-29.5)
Education ≥13 years, n (%)	7 (47)	10 (91)
Employment, n (%)		
Full-time	7 (44)	10 (91)
Part-time	4 (25)	0
Retired	4 (25)	0
Other	1 (6)	1 (9)
LBP[a] intensity past week (0-10), [30]		
Average LBP, mean (SD, range)	3.8 (2.0, 1-7)	4.5 (2.3, 1-8)
Worst LBP, mean (SD, range)	5.3 (2.8, 1-10)	5.7 (2.5, 1-9)
LBP duration, current episode, n (%)		
1 week	1 (6)	0
4 weeks	3 (19)	1 (9)
12 weeks	5 (31)	0
>12 weeks	7 (44)	10 (91)
RMDQ[b] (0-24), median (range) [31]	5.0 (1-17)	9.0 (1-14)
Activity limitation, n (%)		
Not at work/not at leisure	4 (25)	3 (27)
Not at work/yes at leisure	4 (25)	3 (27)
Yes, at work/not at leisure	0	0
Yes, at work/yes, at leisure	8 (50)	5 (46)
Leisure-time physical activity [32], n (%)		
Sedentary	1 (6)	2 (18)
Some physical activity	10 (62)	5 (46)
Regular physical activity	5 (32)	4 (36)
Regular hard physical activity	0	0
PSFS[c] (0-10), median (range) [33]	6 (4-9)	4 (1-8)
Number of pain sites (0-9), median (range)	3 (1-5)	2 (1-5)
EQ-5D[d] (0-100), mean (SD, range) [34]	75.1 (14.1, 40-95)	64.5 (22.7, 20-90)
Insomnia symptoms, n (%) [35]	4 (27)	6 (55)
PSEQ[e] (0-60), median (range) [36]	49 (14-58)	49 (36-60)
PSS[f] (0-40), median (range) [37]	12 (3-25)	14.0 (10-23)
PHQ-8[g] (0-24), median (range) [38]	3 (0-13)	7.0 (0-12)

[a]LBP: low back pain.
[b]RMDQ: Roland-Morris Disability Questionnaire.
[c]PSFS: Patient-Specific Functional Scale.
[d]EQ-5D: Euroqol 5-D (health-related quality of life).
[e]PSEQ: Pain Self-Efficacy Questionnaire (2-item).
[f]PSS: Perceived Stress Scale.

[g]PHQ-8: Patient Health Questionnaire.

Textbox 1. System Usability Scale.

1. I think that I would like to use the selfBACK system frequently.
2. I found the selfBACK system unnecessarily complex.
3. I thought the selfBACK system was easy to use.
4. I think that I would need the support of a technical person to be able to use the selfBACK system.
5. I found the various functions in the selfBACK system were well integrated.
6. I thought there was too much inconsistency in the selfBACK system.
7. I would imagine that most people would learn to use the selfBACK system very quickly.
8. I found the selfBACK system very cumbersome to use.
9. I felt very confident using the selfBACK system.
10. I needed to learn a lot of things before I could get going with the selfBACK system.

Interviews

The semistructured interviews in both stages explored participants' perceptions of and experiences with using selfBACK and their suggestions for improving it. The interviews covered the following topics: perceived usefulness and appeal of the app; barriers and facilitators to using the app; technical difficulties; app features that were liked or disliked; usability and interactions required from the user; ease of using the wrist-worn physical activity monitor; usefulness of the physical activity, exercise, and educational components; appropriateness of the feedback feature (motivational notifications); general ease of use and navigation; and suggestions for improvement.

In Stage 1, 10 of the 16 participants volunteered for the interviews, which were conducted by 2 research assistants trained by KC. In Stage 2, 10 of the 11 participants volunteered for the interviews, which were conducted by ALN. Stage 2 interviews were conducted in Norwegian and translated to English for analysis.

Data Analysis

Descriptive statistics are reported for demographics, completion rates for the web questionnaire (Stage 1), app user activity (Stage 1), and the design questionnaire. An overall SUS score was computed for each participant in keeping with previous research [39], such that the final scores ranged from 0 to 100, with higher scores indicating better usability. Interviews were transcribed and then analyzed by ALN and KC using framework analysis [40], which is increasingly used in health research as a systematic tool for thematically analyzing interview data [41]. This involved familiarization with the data (reading and rereading transcripts), coding the data (using both predefined and open coding using Microsoft Word), developing an analytical framework (grouping codes into categories in an iterative manner), applying the analytical framework to the whole data set, charting the data in Microsoft Excel (arranging summaries of the data in matric-based charts according to key themes and subthemes), and finally interpreting the data, within and between participants [41]. At each stage, the researchers worked independently on a sample of data (2 or 3 transcripts) before comparing and reaching agreement and then completing the remaining stage independently, before again discussing and reaching agreement. For example, ALN and KC independently coded 3 transcripts, and they met to discuss coding. Agreement was good (not formally measured); therefore, the remaining transcripts were divided between ALN and KC for coding, with a final meeting to review and make amendments where required.

Results

Table 1 shows the characteristics of the study samples in Stages 1 and 2, assessed by the web questionnaire. In Stage 1, 16 participants with a mean age of 51.1 years (SD 13.9 years) took part, and 10 participants with a mean age of 43.0 years (SD 7.5 years) took part in Stage 2 (Table 1). There were no dropouts, but there was variability in interaction with the app (see the following sections). In both stages, most participants reported to have LBP for 12 weeks or more during the current episode and low to moderate levels of pain-related disability (ie, median Roland-Morris Disability Questionnaire scores were 5.0 [range 1-17] and 9.0 [range 1-14] in Stages 1 and 2, respectively).

Stage 1: Web Questionnaire and App Version With the Physical Activity Component

It took on average 18 minutes (range 10-38 minutes) to complete the questionnaire. Participants reported that the completion time was acceptable (14/16, 88%) and that it was easy to complete (15/16, 94%). Just over half (9/16, 56%) found the questions relevant, with 44% (7/16) being unsure.

The average step count goal set by participants was 7004 steps per day (SD 2932, range 3000-12,500 steps per day), with participants achieving on average 5496 steps per day (SD 4354, range 133-20,791 steps per day). The selfBACK app was opened an average of 6.2 times per day (SD 11.8, range 0-95 times per day), with participants receiving an average 1.8 motivational notifications per day (SD 2.4, range 0-10 motivational notifications per day). Over the course of the study, a total of 569 notifications were sent to the 16 participants. Participants opened 42% (239/569) of the notifications they received, with the notifications sent at the start of the day being opened most frequently. Of the opened notifications, 90% (215/239) were liked by participants, 8% (19/239) were disliked, and no

sentiment was expressed on only 2% (5/239). Notifications regarding full goal achievement were most frequently liked.

System Usability Scale

The mean SUS score was 64.7 points (SD 21.2, range 10-95 points). Inspection of individual SUS scale items identified low ratings for items 5 and 6: functions being well integrated and inconsistency. Key findings from the design questionnaire that informed further development of the selfBACK system were as follows: Approximately one-third of participants experienced technical difficulties with downloading, installing, or using the app or with synchronizing the wrist-worn activity monitor with their smartphone. The step count information was reported as useful by 60% (10/16) of participants, although only 50% (8/16) perceived it to be accurate. There was a lack of agreement on the number and appropriateness of motivational notifications, but the timing was considered appropriate (10/16, 60%), and they were perceived as personalized (13/16, 80%). Several suggestions were made by participants, which informed further development of selfBACK. Finally, 69% (11/16) said they would download the selfBACK app, and 63% (10/16) would recommend it to a friend.

Semistructured Telephone Interviews

Of the 16 participants, 10 volunteered to take part in telephone interviews (mean age 51 years, 60% [6/10] male). Findings largely reinforced those from the electronic survey. In addition, several barriers and facilitators to using selfBACK were identified, which included older age, disabilities, older smartphones, and having to carry the smartphone constantly (for participants who had difficulty synchronizing the activity monitor). Facilitators included the motivational notifications, especially when they were contextualized to the individuals; daily reports about physical activity and goal achievement; and selfBACK being recommended by a health professional.

Stage 2: Web Questionnaire and App Version With 3 Self-Management Components

Completion times for the web questionnaire were not recorded but all participants reported the time taken as acceptable. They also reported the questions as relevant (8/10, 80%) and easy to answer (10/10, 100%). The mean SUS score was 70.5 points (SD 20.5, range 45-95 points), indicating better usability than the prototype used in Stage 1. Scores on the individual SUS items showed that participants found selfBACK easy to use, felt confident using it, and thought most people would learn to use it quickly. Of the 10 participants, 9 agreed that they would "like to use the selfBACK system frequently." In general, they did not find the app to be cumbersome and did not require the support of a technical person. However, only 50% (5/10) found the functions to be well integrated, and 20% (2/10) found selfBACK to be inconsistent, suggesting that further development was required prior to testing in an RCT.

Responses to the design questionnaire showed that most participants (7/10, 70%) found the overall design and appearance of the app attractive or very attractive, with 20% (2/10) reporting it as unattractive and suggesting a more colorful layout. The professionalism of the layout was found attractive or very attractive by 60% (6/10) of participants. General comments on appearance and design were that the content was well-written and clear, but that the colors could have been more attractive. Furthermore, participants found the exercise and physical activity components most useful, with 80% (8/10) rating them as useful or very useful. The education component was rated as useful or very useful by 60% (6/10) of participants. The information on step count and goals was rated as useful or very useful by 50% (5/10) of participants. There was less agreement on the usefulness of the motivational notifications; only 50% (5/10) found them useful, whereas 30% (3/10) found them not useful. Most participants (6/10, 60%) were neutral on whether the app was helping them to self-manage their LBP, whereas 20% (2/10) found it useful and 20% (2/10) did not find it useful. The weekly tailoring questions asked in the app were only found relevant by 20% (2/10) of participants, 50% (5/10) were neutral, and 30% (3/10) found them irrelevant. However, all participants found the questions easy to answer and the time to complete them was acceptable. General comments on the usefulness and content of the app were that the amount of information in the educational module was appropriate, and the app was easy to use. Overall, the app was considered useful; however, there were too many technical challenges. Some suggestions were made by the participants to improve the app, such as making the app more attractive by using more colors and to include the ability to go back in time to review statistics and previous self-management plans.

Semistructured Telephone Interviews

Four themes emerged during analysis of the interview data: (1) Practical and Technical Factors, (2) Limitations and Barriers, (3) Strengths and Facilitators, and (4) Suggestions for Improvement. Each theme is presented in the following paragraphs.

The practical and technical factors were related to wearing the physical activity monitor and general difficulties using the app. No issues were reported with charging the physical activity monitor and most participants wore the wristband either all the time, or they only took it off at night:

> *…as this was soft, it was ok to use. I am thinking about buying something like that…it was a bit uncomfortable at night, as I am not used to wearing anything.* [Participant 03, Female, 37 years]

> *Yes, I have [worn it all the time]. It worked out well. And it was useful that it showed the time as well, it motivated me to wear it.* [Participant 10, Female, 32 years]

It was reported to be uncomfortable by one participant, but not to the extent that she stopped using it:

> *It is a bit uncomfortable, as it is a bit wide and pointy, but it worked out fine.* [Participant 08, Female, 37 years]

Most participants experienced some technical difficulties, either with initial login and synchronizing with their smartphones or with the app freezing or shutting down unexpectedly during the 4-week period. Most participants continued to use the app, but in two cases, they stopped: one due to persistent log-in

difficulties and the other due to not receiving any self-management plan for exercises after week one.

Aside from technical difficulties, limitations and barriers were related to app content, appearance, and LBP symptoms. Participants were generally positive about the appearance of the app, but some felt it could be enhanced:

> *I don't think it [layout and design of the app] catches me that well.* [Participant 08, Female, 37 years]

> *And the notifications could also be a bit more colorful. I don't know much of app development, but I believe that to get people addicted, you need a lot of colors and that it looks fancy or something like that. I did sometimes think that maybe it is a bit too boring?* [Participant 10, Female, 32 years]

Some participants perceived that their step count was inaccurate, compared to other devices they were concurrently using, and one participant was unable to set a step count goal. Most participants were positive about the suggested exercises; however, one felt they were aimed at older people, one felt they were not tailored to her symptoms, and one would have liked more variety. Participants felt the educational material was easy to understand, but for some it was too simplified, and they were ambivalent about its usefulness:

> *I think it was a bit trivial information. But it is good to have it in the app. I will not say I learned a lot, but it was OK information to read* [Participant 09, Male, 37 years]

Most participants found the notifications to be a limitation of the app. They either received very few, they perceived them as irrelevant because of unsynchronized step count, or they found them not to be motivational. However, they could generally see their benefit:

> *Yes, if synchronized well [would want more notifications], maybe a couple of times each day would be appropriate.* [Participant 07, Male, 56 years]

One participant felt his LBP symptoms prevented him from using the app as much as desired:

> *…the usage decreased due to some sleep problems. So, I don't feel I have been using it optimally. I have tried some days where I only used the stretching exercises and reduced the walking. This was somewhat better, but as soon as I started with the walking again, especially on undulant terrain, I had to lie down again for a couple of days afterwards.* [Participant 01, Male, 44 years]

Strengths and facilitators were related to content and appearance. Participants commonly reported that they liked the simple and easy-to-understand design. They also liked the visual representation of progress towards goal achievement:

> *I think it was nice with the "pies" [pie chart]. I have to fill the pie before I go to sleep. That was very good and motivational and fun.* [Participant 03, Female, 37 years]

Most participants reported the exercises as a strength of the app. They found them to be relevant and liked the instructional videos:

> *[The videos] was a very good thing. You do wonder if you are doing the exercises correct. The videos were clear and not too fast.* [Participant 06, Male, 43 years]

Despite the perceived limitations with the step count function reported in an earlier paragraph, some participants particularly valued this function:

> *I have used the step count a lot, usually on a daily basis. I tried to complete the daily step goal. It was easy to use and an apparent way to see how active you are. It was a barrier to perform the back exercises often enough, but I felt it [step goal] was OK, and it could easily be combined with other things during the day.* [Participant 09, Male, 37 years]

Not all participants received trophies (for achievements) due to technical issues; however, those who did receive them reported them to be motivating.

A number of suggestions for improvements were made by participants. Two participants felt that sleep monitoring would be a useful addition, and several participants wanted to view their history:

> *The only thing I could have wanted was the ability to go back in time to look at history of activity level. Because that is a good motivator.* [Participant 02, Female, 52 years]

More varied content was generally wanted by participants, including more variety of exercises, the ability to select or deselect exercises, and information on calories burned during physical activity. Finally, more colors and more "fancy" layout was suggested by one participant.

Discussion

Principal Findings

This 2-stage usability and acceptability study generated important knowledge for the further development of the selfBACK app for use in a pilot study and full RCT [25]. Stage 1 demonstrated acceptability of the web questionnaire; however, due to relatively low numbers of participants reporting the questions as relevant, review of participant information to accompany the web questionnaire was warranted. Interaction with the app was variable, and usability could be enhanced, with several participant-identified limitations and suggestions useful for enhancing the next version of the app. Nonetheless, we were encouraged by the high levels of participants who would download the selfBACK app and recommend it to a friend.

Stage 2 demonstrated enhanced usability and identified areas where further development was required, particularly educational content, perceived step count accuracy and goal setting, motivational notifications, and overcoming technical barriers to using the app. Overall, we demonstrated that the selfBACK app was usable and acceptable to people with LBP

and with further development, was suitable for piloting in a clinical population.

There were some conflicting results regarding the motivational notifications; most participants in Stage 1 liked the notifications they opened, whereas only 50% (5/10) of participants in Stage 2 found them to be useful. The notifications were developed at the app design stage by consulting with potential app users to gather suggestions of what they would find motivational. We found it challenging to make final selections, as feedback from our user groups reinforced that liking or not liking notifications is highly subjective and personal. For instance, some participants in Stage 1 found motivational messages to be beneficial, specifically as they were often linked to the participant's own step count, while others found that timing of messages was not meaningful and failed to grab attention. There was also general consensus that further information such as educational content on LBP was needed. Notifications have been found to enhance engagement with health apps [42], with tailored suggestions most effective [43]. In summary, these studies highlighted the need for messaging logic to be contextually relevant to the participant both in terms of content and timelines. Thus, notifications for the selfBACK app were further refined following the recommendations in these studies, and the possibility to turn on and off notifications was added.

Participant-identified limitations have been used in the continued development of selfBACK, such as adding more content with a wider selection of educational material and exercises, adding an option to look back at one's own data to see history of activity level, adding an option for skipping or replacing exercises at the participant's preference, and changing how the step goals were created by taking the last 2 weeks into account instead of only the last week. The technical barriers experienced by participants also enabled the study team to make improvements, both to the app and accompanying user instructions, in keeping with the iterative design process adopted. Despite technical and other barriers reported by participants, overall usability (mean SUS score 70.5 in Stage 2) was good [44]. We are confident that further development of the selfBACK app, in line with the findings of this study, will enhance overall usability.

Limitations

The sample sizes in both stages were small and were comprised of participants with mild to moderate chronic LBP with the ability to read and understand English as the app was only available in English at this stage. selfBACK is intended for use in 3 languages (English, Danish, Norwegian) and for people with a range of LBP severity and duration. However, it is not the intention to generalize from usability and acceptability studies, and selfBACK is being further tested in a pilot study and a full RCT [25], in keeping with guidance for the development of complex interventions [45].

Conclusions

We have demonstrated acceptability and usability of selfBACK, an evidence-based DSS for supported self-management of LBP delivered by a smartphone app, in a sample of people with non-specific LBP. Technical reliability, ability for individual adjustments, relevant educational content, and targeted notifications were highlighted as important for enhancing usability of the selfBACK app. Based on these results, a further refined version of selfBACK could be piloted [46] in order to determine whether a full-scale RCT should be conducted. Future research should focus on appropriate and effective tailoring of mHealth notifications to individual's needs and preferences, in order to develop truly personalized interventions.

Acknowledgments

The selfBACK project received funding from the European Union Horizon 2020 research and innovation program under grant agreement No. 689043.

The authors would like to thank Stephanie Lehane and Kirstyn Anderson for assistance with data collection and processing.

Authors' Contributions

All authors contributed to the design of the study. Data collection and analysis were conducted by ALN, SS, MV, and KC. All authors contributed to the preparation of this manuscript, and all authors have approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The design questionnaire used in the present study.
[DOCX File , 15 KB - rehab_v7i2e18729_app1.docx]

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Abbreviations

DSS: decision support system
EQ-5D: Euroqol 5-D (health-related quality of life)
LBP: low back pain

PHQ-8: Patient Health Questionnaire
PSEQ: Pain Self-Efficacy Questionnaire
PSFS: Patient-Specific Functional Scale
PSS: Perceived Stress Scale
RCT: randomized controlled trial
RMDQ: Roland-Morris Disability Questionnaire
SUS: System Usability Scale

Edited by G Eysenbach; submitted 15.03.20; peer-reviewed by R Smeets, G Signorelli; comments to author 20.04.20; revised version received 26.05.20; accepted 06.07.20; published 09.09.20.

Please cite as:
Nordstoga AL, Bach K, Sani S, Wiratunga N, Mork PJ, Villumsen M, Cooper K
Usability and Acceptability of an App (SELFBACK) to Support Self-Management of Low Back Pain: Mixed Methods Study
JMIR Rehabil Assist Technol 2020;7(2):e18729
URL: http://rehab.jmir.org/2020/2/e18729/
doi:10.2196/18729
PMID:32902393

Original Paper

The Needs of Older Adults With Disabilities With Regard to Adaptation to Aging and Home Care: Questionnaire Study

Laiyou Li[1], MSc; Ning Sun[1*], PhD; Libo Yu[1*], PhD; Xiaoxin Dong[1], PhD; Jing Zhao[1], MSc; Yuchen Ying[1], MSc

Ningbo College of Health Sciences, Ningbo, China

*these authors contributed equally

Corresponding Author:
Ning Sun, PhD
Ningbo College of Health Sciences
51 Xuefu Road, Yinzhou District
Ningbo
China
Phone: 86 15888174602
Email: sunning_ly@126.com

Abstract

Background: The home environment is an important means of support in home-based care services for older people. A home environment that facilitates healthy aging can help older adults maximize their self-care abilities and integrate and utilize care resources. However, some home environments fail to meet the needs of older adults with disabilities.

Objective: This paper aimed to study the needs of older adults with disabilities with respect to adaptation to aging, and to analyze the associations of individual factors and dysfunction with those needs.

Methods: A questionnaire survey was administered to 400 older adults with disabilities from 10 communities in Ningbo City, Zhejiang Province, China. The survey was conducted from August 2018 to February 2019.

Results: A total of 370 participants completed the survey. The proportion of participants with mild dysfunction was the highest (128/370, 34.59%), followed by those with extremely mild (107/370, 28.92%), moderate (72/370, 19.46%), and severe (63/370, 17.03%) dysfunction. The care needs of older adults with extremely mild and mild dysfunction pertained primarily to resting, a supportive environment, and transformation of indoor activity spaces. The care needs of older adults with moderate dysfunction pertained mainly to resting and renovation of bathing and toilet spaces. Factors influencing the needs of older adults with disabilities were dysfunction (P=.007), age (P=.006), monthly income (P=.005), and living conditions (P=.04).

Conclusions: The needs of older adults with disabilities varied by the degree of dysfunction, and many factors influenced these needs in the community. These findings may provide a scientific basis for developing community-specific aging-related adaptation services for older adults with disabilities in the future.

(JMIR Rehabil Assist Technol 2020;7(2):e16012) doi:10.2196/16012

KEYWORDS

community; disability; older people; adaptation to aging; influence factor

Introduction

Background

In 2014, it was estimated that there were 40 million older people with disabilities in China; this figure has been predicted to reach 61.68 million by the end of 2030. In 2016, at least 60-70 million people in China were reported to need long-term care [1]. Home care refers to older adults living and receiving care at home rather than at an assisted living facility, which is currently the most common pension model in China [2]. A total of 10 governmental departments have published policy documents to promote the development of home care services [3]. The home environment is an important means of support for home-based care services. A home environment that facilitates healthy aging can help older adults maximize their self-care abilities and integrate and utilize care resources. A key aspect of home care services is the assessment of aging needs in the home environment. Some home environments fail to meet the growing needs of older adults, especially of those with disabilities. Many home environments have design problems, such as the lack of barrier-free transportation systems, bathroom space security, and auxiliary facilities; unreasonable design and spatial layout; and imperfect alarms and help sign systems [4]. Thus, the needs

of older adults with disabilities during adaptation to aging in their home environment must be explored urgently.

Chinese researchers have conducted a large number of theoretical and practical studies of design transformation, focusing on the living environments of older adults and the need for redesign of their residences, and have achieved relatively significant results. Saiquan [5] suggested that through adaptation to aging, one-third to half of casualties among older adults can be prevented, and older adults can remain in their original housing for more than 10 years with adequate self-care. Xiaoyun [6] examined the environmental planning strategies for older adult–friendly communities, including the suitability of residential units, open spaces, transportation; service facilities for older people; and renovations for old buildings. Yanwei and Jiayan [7] assessed the suitability of existing residential areas with respect to adaptation to aging by considering different perspectives, such as those of developers, designers, and buyers. Outdoor activity needs of older adults were reported, and the study proposed suitable design principles for the outdoor environment, including different types of activity spaces, outdoor facilities, and garden elements [7]. Shenmao and Jijun [8] conducted a study from the perspective of the residential fitness design and discussed the "dwelling residential design" in the United States, the "House Design Guide for Longevity Society" in Japan, and "Residential Design for the Elderly" in China [8]. Most theoretical and practical reviews on the construction, renovation, and design of home environments suited to the needs of older adults, both in China and worldwide, are aimed at solving these problems in urban contexts.

Aging of the population is an inevitable result of social development. Most developed countries became societies with larger proportions of older people in the 1960s and 1970s. Early transformation into such a society has led to early emergence of theoretical studies and practical exploration of housing designs suited to the needs of the older population in these countries [9-11]. Many studies suggest that aging-appropriate transformations of home environments for older adults can help prevent falls, delay functional decline, improve quality of life, and save costs incurred in hiring care labor [12-15]. According to studies conducted across various countries, the degree of such transformation is determined by both objective and subjective factors. Objective factors refer to the material conditions of the environment. Subjective factors include individual behavior, life experience, and awareness of the living environment. Developed countries attach greater importance to the problem of suitable accommodation for older people in the home environment. The costs of aging-appropriate renovations are also covered through state subsidies or insurance in Sweden, Germany, Japan, and other developed countries [16-19].

Objectives

The aim of this study was to determine the needs of older adults with disabilities with respect to adaptation to aging in 10 communities in Ningbo City and to analyze the association of individual factors and levels of dysfunction with those needs.

Methods

Study Design

A correlational, cross-sectional design was adopted, and questionnaires were used for data collection.

Participant Selection

A total of 400 older adults with disabilities were identified and selected from August 2018 to February 2019 by convenience sampling from 10 communities in 5 districts of Ningbo: Jiangbei, Yinzhou, Haishu, Beilun, and Zhenhai. Samples from each district comprised 80 older adults with disabilities. A total of 400 questionnaires were administered to the participants, and 370 valid questionnaires were recovered.

The selection criteria were as follows: age ≥60 years, permanent residence in Ningbo, living in the community for more than 6 months, diagnosed with a disability based on the Daily Living Activity Scale, and volunteering to participate in the study. The exclusion criteria were as follows: severe cognitive dysfunction, unconsciousness, and difficulties in understanding instructions.

Sample Size Calculation

The study mainly examined the correlation between individual factors and the need for adaptation to aging. Multifactor analysis methods were applied. Based on relevant research, it was estimated that 25 variables could be entered into the model. The required sample size was estimated to be at least 10-15 times the number of variables entered into the model, thus requiring 375 research participants. The follow-up loss rate was calculated at 1%. Therefore, the required sample size was estimated at 400 people.

Data Collection

Two investigators underwent unified training. Data were collected by in-person interviews. All participants stayed at home or in nursing homes and were included in this study after a scheduled meeting arranged by the nursing home and community service center managers. The investigators explained the research objectives and methods to individuals who met the inclusion criteria and obtained consent and cooperation from participants and their families. Consenting participants received an envelope containing a packet with the questionnaires. Participants completed the questionnaires immediately upon receipt and placed them in the envelope for collection by the investigators. To ensure anonymity, each completed questionnaire was assigned a code number.

Study Measures

The following 3 questionnaires were used in this study: the Demographic Data Questionnaire, the Activity of Daily Living Scale, and the Questionnaire on Needs for Adaptation to Aging.

The Demographic Data Questionnaire

This questionnaire collected information on participants' age, gender, education level, monthly income, marital status, residence status, and payment method of medical expenses.

The Activity of Daily Living Scale

This scale was developed by American researchers in 1969 to determine the degree of dysfunction among older adults with disabilities. It consists of 14 items that are rated on a 4-point rating scale, with responses ranging from "can do it yourself" to "cannot do it yourself" [20,21]. The scores range from 14 to 56, with higher scores indicating higher levels of dysfunction. Scores ≤20 indicate completely normal function. Scores >20 indicate varying degrees of dysfunction (21-30: very mild; 31-40: mild; 41-50: moderate; >50: severe). Cronbach alpha for this scale is .92, and the content validity index is 0.86.

Questionnaire on Needs for Adaptation to Aging

This questionnaire comprises 9 first-level indicators and 55 secondary indicators. The first-level indicators include entrances and exits (12 items), indoor activities (6 items), toilet (3 items), bathing (5 items), modification/renovation (3 items), rest (5 items), preparation/meal (6 items), laundry (4 items), and supportive environment (11 items). Each item is rated on a 5-point Likert scale, with scores ranging from 1 to 5 points. The higher the score, the higher the need for adaptation to aging. The Cronbach alpha of the questionnaire is .96, and its content validity index is 0.95.

Data Analysis

SPSS 21.0 (IBM Corp) was used for data analysis after the logistic test. A *P* value <.05 was considered to be statistically significant. Mean (SD), frequencies, and percentages were used to describe demographic data, dysfunction, and the needs of older adults with disabilities for adaptation to aging. The association of individual factors and dysfunction with the needs of the participants was analyzed by multiple linear regression analysis.

Ethical Considerations

This study was approved by Ningbo College of Health Sciences (NBWY-030). All participants were included in this study following the meeting schedules provided by nursing home and community service center managers, and they were briefly informed of their right to withdraw at any time. Older individuals with disabilities who consented to or were authorized to participate in the study received the questionnaire.

Results

A total of 400 questionnaires were distributed, and 378 were completed (recovery rate of 94.5%). There were 370 valid questionnaires (effective recovery rate of 92.5%).

Of the participants, females constituted the majority (252/370, 68.1%). Participants' ages ranged from 60 to 91 years, and the average age was 70.21 (SD 5.98) years. The majority of the participants (253/370, 68.4%) were married, and 29.7% (110/370) were widowed. Regarding education levels, the majority of the participants had completed junior secondary school (141/370, 38.1%), while 28.6% (106/370) had completed high school. Most of the older adults with disabilities (281/370, 75.9%) lived with their families. Most participants' (261/370, 70.5%) monthly income ranged from 1001 yuan to 3000 yuan. Majority of the participants (254/370, 68.6%) were mainly dependent on urban medical insurance. Table 1 shows the degrees of dysfunction among the study participants.

Table 1. Degree of dysfunction among the study participants (N=370).

Degree of dysfunction	Activity of Daily Living Scale scores, mean (SD)	Values, n (%)
Extremely mild	24.54 (1.90)	107 (28.92)
Mild	32.69 (2.11)	128 (34.59)
Moderate	42.26 (1.66)	72 (19.46)
Severe	51.48 (1.71)	63 (17.03)

In cases of participants with extremely mild and mild dysfunction, needs for adaptation to aging primarily pertained to resting, a supportive environment, and suitable spaces for indoor activities. Needs of those with moderate and severe dysfunction mainly pertained to resting and suitable bathing and toilet spaces (Table 2).

Table 2. Adaptation needs of the participants by degree of dysfunction (N=370).

Needs for adaptation to aging as per the questionnaire	Degrees of dysfunction			
	Extremely mild	Mild	Moderate	Severe
Entrances and exits, score points, mean (SD)	4.29 (0.71)	4.31(0.72)	4.33 (0.73)	4.35 (0.74)
Indoor activities, score points, mean (SD)	4.44 (0.76)	4.45 (0.75)	4.45 (0.76)	4.47 (0.75)
Toilet space, score points, mean (SD)	4.41 (0.79)	4.43 (0.78)	4.49 (0.79)	4.51 (0.78)
Bathing space, score points, mean (SD)	4.42 (0.80)	4.42 (0.81)	4.50 (0.83)	4.52 (0.82)
Modifying/renovation, score points, mean (SD)	4.41 (0.88)	4.43 (0.87)	4.45 (0.89)	4.47 (0.87)
Resting, score points, mean (SD)	4.48 (0.81)	4.50 (0.82)	4.53 (0.84)	4.55 (0.83)
Meals/meal preparation, score points, mean (SD)	4.40 (0.86)	4.42 (0.85)	4.45 (0.87)	4.47 (0.88)
Laundry, score points, mean (SD)	4.35 (0.92)	4.37 (0.91)	4.39 (0.93)	4.40 (0.91)
Supportive environment, score points, mean (SD)	4.47 (0.78)	4.49 (0.77)	4.48 (0.79)	4.50 (0.80)

The correlation coefficients between participants' demographic characteristics and adaptation to aging are shown in Table 3. Age, education level, monthly income, residence status, and the degree of dysfunction are significantly correlated with adaptation to aging (Table 3).

Table 3. Correlation between participants' demographic characteristics and adaptation to aging.

Variable	Correlation coefficient (*r*) for adaptation to aging	*P* value
Age	0.335	.02
Gender	0.217	.08
Education level	0.296	.04
Monthly income	0.369	.03
Marital status	0.215	.12
Residence status	0.316	.04
Payment method	0.235	.09
Degree of dysfunction	0.398	.008

With significantly correlated demographic characteristics and dysfunction as the independent variables, factors affecting needs for adaptation to aging were analyzed by stepwise regression. By the degree of influence, dysfunction ranked the highest, followed by age, monthly income, and living conditions (Table 4).

Table 4. Factors affecting needs of the participants for adaptation to aging.

Variable	Sample regression coefficient (*b*)	Beta level (β)	*t* test scores	*P* value
Age	4.68	.22	4.98	.006
Residence status	–2.96	–.06	–2.45	.04
Monthly income	3.98	.16	–5.38	.005
Degree of dysfunction	9.86	.49	8.85	.007

Discussion

This study conducted a comprehensive questionnaire survey of the needs of older adults with disabilities with respect to adaptation to aging in 10 communities in Ningbo City. The results showed that the proportion of older adults with disabilities and mild dysfunction was the largest. The needs of older adults with disabilities varied with different degrees of dysfunction, and many factors influenced their needs in the community at large. The results of this study provide a scientific basis for the provision of targeted rehabilitation services to older people with disabilities in order to improve their quality of life.

The Status of Dysfunction Among Older Adults With Disabilities in Ningbo

In total, 34.59% (128/370) of older adults with disabilities reported mild dysfunction (Table 1). The proportion of older adults with disabilities in this study is higher than that in a study conducted in Shanghai [22]. The main reason for this difference could be that Shanghai's economic development and levels of medical care are more advanced than those of Ningbo. Thus, older adults with disabilities and their families in Shanghai have

more opportunities to choose from good-quality health care resources in case of major diseases, and this access significantly reduces the extent of dysfunction experienced by them. Furthermore, healthy behavior and the degree of health awareness among older adults depend on their level of cultural literacy. Older people with high cultural literacy are more likely to pay attention to their health and seek timely medical treatment, thus significantly reducing the incidence of dysfunction. Moreover, Shanghai's regional medical security and long-term care insurance systems are more effective than those of Ningbo. Further improvements of both systems can improve the quality of life among older adults with disabilities in Ningbo.

The Needs of Older Adults With Disabilities With Regard to Adaptation to Aging

The needs of older adults with disabilities and extremely mild or mild dysfunction mainly pertained to resting, a supportive environment, and suitable indoor activity spaces. In most cases, older people with extremely mild or mild dysfunction can eat, dress, and wash. They can take care of themselves in their daily lives and are less dependent on others. Thus, there is a high demand for a supportive environment and broader, safer spaces suitable for their indoor activities. Participants reported that they wish to switch on the lights around their beds, as indoor lighting can help them see their indoor environment clearly. They also expressed the need for sufficiently audible phone and doorbell sounds. These findings are consistent with those of another study [23].

The needs of older adults with disabilities and moderate or severe dysfunction mainly pertained to resting and safe bathing and toilet spaces. Most older people with moderate or severe dysfunction lose their daily living ability and need to rely on caregivers. Studies have shown that older people with moderate or severe dysfunction usually have 2 or more different diseases, which may restrict their functional activities and warrant complete bed rest. Therefore, they hope to have a safe bed rest environment, which includes installation of handrails on the bed to help them get up. Moreover, they hope to have a safe bathing and toilet environment, which includes handrails and alarms in the toilet and bathroom to get help when they lose their balance or fall. This finding is also consistent with the findings of another study [24].

Factors Affecting the Needs of Older Adults With Disabilities With Regard to Adaptation to Aging

The results of the present study showed that the factors influencing adaptation to aging among older adults with disabilities were degree of dysfunction, age, monthly income, and living conditions. The standardized regression coefficient of dysfunction degree was 0.49, which had the highest impact on the need for adaptation to aging. This indicates that the older the person experiencing dysfunction, the greater their need for adaptation to aging. Older adults with disabilities having greater dysfunction and poor quality of life hope to enhance the quality of their lives by improving their living environment.

The results of this study also suggest that the older the person, the higher the benefits they receive from adaptation to aging. As a person grows older, the functions of various organs in their bodies decline, resulting in 2 or more diseases and other complications. Long-term physical illness leads to psychological problems and reduced ability to engage in social activities. A study showed that the need for such adaptation increases with aging [25].

Furthermore, the standardized regression coefficient for monthly income was 0.16, indicating that the lower the monthly income, the lower the demand for adaptation to aging. As older adults with disabilities may have multiple diseases, they need long-term medication or rehabilitation, resulting in an increasing economic burden. Families experiencing financial strain are less likely to take necessary actions for adaptation to aging and to improve the residential environment of older adults with disabilities. In case of older adults with low monthly incomes, without any financial support from other sources, the income is mainly spent on dietary needs and medical treatment, rather than meeting needs specific to adaptation to aging. Other studies have shown [25] that the higher the monthly income, the stronger the willingness to adapt. Therefore, the state needs to consider the low-income groups among the older population with disabilities when formulating policies for home-based care services.

The standardized regression coefficient for living conditions was –0.06, that is, the needs of older persons living alone are high. On the contrary, older people with disabilities have fewer needs if they have family members to take care of them. The aforementioned study [25] reported that older people who do not live with their children have a strong willingness to transform their living environments, as they do not have caregivers. Moreover, there are more risk factors in such living environments. Thus, by transforming their environment, they can improve their safety. With the development of society, there has been an increase in the prevalence of "4-2-1" and "4-2-2" family structures, which indicates an increase in the number of older people who live alone and experience the empty nest syndrome. Challenges in providing long-term care to such older adults are more prominent. Therefore, the results of this study suggest that the governments or the relevant agencies should strengthen the policy guidance for these special groups when formulating policies to help older population living alone to adapt to aging and improve their quality of life.

There are some limitations to this study. First, a convenience sample was used. Second, data were obtained only from the South of China, limiting the generalizability of the findings. Therefore, in the future, the relationships between adaptation needs of older people with disabilities and the factors influencing these needs should be examined by conducting a cohort study on a more diverse sample.

Acknowledgments

The authors would like to thank the participants of this study. This work was supported by the Zhejiang Public Welfare Technology Application Research Project (LGF19H260009).

Conflicts of Interest

None declared.

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Edited by G Eysenbach; submitted 26.08.19; peer-reviewed by F Song, E Sadeghi-Demneh, F Lanfranchi; comments to author 14.06.20; revised version received 21.07.20; accepted 12.09.20; published 26.10.20.

Please cite as:
Li L, Sun N, Yu L, Dong X, Zhao J, Ying Y
The Needs of Older Adults With Disabilities With Regard to Adaptation to Aging and Home Care: Questionnaire Study
JMIR Rehabil Assist Technol 2020;7(2):e16012
URL: http://rehab.jmir.org/2020/2/e16012/
doi:10.2196/16012
PMID:33104000

Original Paper

Leveraging Digital Technology to Overcome Barriers in the Prosthetic and Orthotic Industry: Evaluation of its Applicability and Use During the COVID-19 Pandemic

Trevor Binedell[1,2,3], MSc; Karupppasamy Subburaj[1,2], PhD; Yoko Wong[4], PhD; Lucienne T M Blessing[1,2], PhD

[1]SUTD-MIT International Design Centre, Singapore University of Technology and Design, Singapore, Singapore

[2]Engineering Product Development Pillar, Singapore University of Technology and Design, Singapore, Singapore

[3]Footcare and Limb Design Centre, Tan Tock Seng Hospital, Singapore, Singapore

[4]Consortium for Clinical Research and Innovation Singapore, Singapore Clinical Research Institutes, Singapore, Singapore

Corresponding Author:
Trevor Binedell, MSc
SUTD-MIT International Design Centre
Engineering Product Development
Singapore University of Technology and Design
8 Somapah Rd
Singapore
Phone: 65 6303 6600
Email: trevor_binedell@ttsh.com.sg

Abstract

Background: The prosthetic and orthotic industry typically provides an artisan “hands-on” approach to the assessment and fitting of orthopedic devices. Despite growing interest in digital technology for prosthetic and orthotic service provision, little is known of the quantum of use and the extent to which the current pandemic has accelerated the adoption.

Objective: This study’s aim is to assess the use of digital technology in prosthetics and orthotics, and whether its use can help overcome challenges posed by the current COVID-19 pandemic.

Methods: A web-based survey of working prosthetists, orthotists, and lower limb patients was conducted between June and July 2020 and divided into three sections: lower limb amputees, prosthetist and orthotist (P&O) currently using digital technologies in their practice, and P&O not using any digital technology. Input was sought from industry and academia experts for the development of the survey. Descriptive analyses were performed for both qualitative (open-ended questions) and quantitative data.

Results: In total, 113 individuals responded to the web-based survey. There were 83 surveys included in the analysis (patients: n=13, 15%; prosthetists and orthotists: n=70, 85%). There were 30 surveys excluded because less than 10% of the questions were answered. Out of 70 P&Os, 31 (44%) used digital technologies. Three dimensional scanning and digital imaging were the leading technologies being used (27/31, 88%), primarily for footwear (18/31, 58%), ankle-foot orthoses, and transtibial and transfemoral sockets (14/31, 45%). Digital technology enables safer care during COVID-19 with 24 out of 31 (77%) respondents stating it improves patient outcomes. Singapore was significantly less certain that the industry's future is digital (P=.04). The use of virtual care was reported by the P&O to be beneficial for consultations, education, patient monitoring, or triaging purposes. However, the technology could not overcome inherent barriers such as the lack of details normally obtained during a physical assessment.

Conclusions: Digital technology is transforming health care. The current pandemic highlights its usefulness in providing safer care, but digital technology must be implemented thoughtfully and designed to address issues that are barriers to current adoption. Technology advancements using virtual platforms, digitalization methods, and improved connectivity will continue to change the future of health care delivery. The prosthetic and orthotic industry should keep an open mind and move toward creating the required infrastructure to support this digital transformation, even if the world returns to pre–COVID-19 days.

(JMIR Rehabil Assist Technol 2020;7(2):e23827) doi:10.2196/23827

KEYWORDS

rehabilitation; telehealth; telemedicine; 3D printing; additive manufacturing; prosthetics; orthotics; assistive technologies; amputee; stroke; virtual; COVID-19

Introduction

Background

In prosthetic and orthotic facilities, there is a need for a combination of care and technical expertise. Prosthetic and orthotic services are generally delivered face-to-face with a high amount of physical contact. As a result, the pandemic provides unique challenges that can be difficult to overcome. Currently, the prosthetic and orthotic industry designs devices to restore, replace, correct, protect, or immobilize a body part through handcrafted artisan approaches. These devices are highly patient-specific and are a result from the specialized skills and experience of the individual prosthetist and orthotist (P&O) [1]. The provision of these prostheses and orthoses is time-consuming and wasteful, and not completely customized [2], with production costs a burden [3]. They require ongoing maintenance and monitoring, and repeated visits to a clinic to ensure optimal fit and function throughout their use.

The introduction of digital technologies aims to improve these inefficiencies. Digital technology in this paper refers to 3D scanners, tablets, computers, computer cloud-based software programs, and computer-aided design and manufacturing (CADCAM). Virtual care refers to the use of telehealth, telerehabilitation, virtual assessments, and fittings. Digital technology and virtual care have successfully provided assistive devices assessment [4,5], therapy services [6], and diagnostic evaluations [7]. They have also eliminated distance obstacles from health care [8]. Digital technology offers possible solutions to patient care during the current pandemic, as health care systems try to limit the spread of COVID-19 by minimizing patient contact and improving hygiene practices [9].

Digitalization of the Prosthetic and Orthotic Design and Manufacturing Process

To reduce the risk of COVID-19 spread, emerging protocols are advising for less physician-patient contact, shortening the contact time, and keeping a safe distance. It is recommended that unnecessary casting of patients be avoided and that alternative methods be used [10]. Three dimensional scanning is one such method and provides high accuracy [11], reduces product waste, and improves quality [12,13]. It has a high capability to capture 3D measurement without physical contact [14,15] and minimize the need for messy plaster of Paris casting. Digital libraries of files are created, manipulated, and personalized to fit a patient's unique needs with greater precision and ease [16,17]. These files can be either outsourced for central fabrication via CADCAM technologies or printed using additive manufacturing systems. Three dimensional scanning and printing are currently used in applications across a spectrum of devices that include ankle-foot orthoses [18,19], helmets [20,21], and prostheses [22-24].

The use of CADCAM in the prosthetic and orthotic applications has been rapidly developing as a technology since the mid-1980s [25]. Although considered expensive to use due to the high infrastructure and equipment costs, the technology has shown great potential [26] but requires users with significant computer-aided design (CAD) experience [27]. The technology's benefits during COVID-19 include reducing the contact time spent with the patient or coworkers and for use in satellite clinics where central fabrication facilities can quickly produce the prostheses or orthoses and have them shipped to the provider [26]. It also delivers shorter waiting times, design consistency, repeatability, quantifiable modification, and modern manufacturing [28,29].

Digitalizing Assessment and Care

Despite its benefits to improve outcomes and use the contactless process of scanning to reduce cross-contamination [14,15], the use of digital technology is not without challenges to routine clinical care. There are often high capital costs in equipment and training, and concerns over the return of investment. Researchers still debate the ideal way to "digitize" the residual limb, whether it is better to cast and scan the negative mold, whether medical imaging (computed tomography [CT], magnetic resonance imaging [MRI], or x-ray) is more suitable [30,31], whether scanning should be done while weight-bearing [25], or not. An "expert" P&O has little to gain in the short run by adopting computerized methods [26]. A significant amount of retraining is required, and current virtual technology has not overcome typical physical characteristics of an assessment such as palpation.

Prosthetic and orthotic patient treatment during the current pandemic with digital technology has opened up the possibility for virtual measurements, fitting, and home-based rehabilitation [32-36]. Bringing care to the patient rather than the patient to care provides a safer environment for patients. The use of a mobile phone that includes inertial sensors and gyroscopes has the potential to overcome the physical assessment and contact usually associated with a consultation. The apps developed for mobile phones have shown use in measuring steps, balance, range of motion (ROM), education, and the provision of exercise programs [32,34,37] but are rarely used for assessment of patients requiring prostheses or orthoses [38,39].

Virtual care offers a unique capacity for remote screening, triage, and treatment. It could be a powerful tool for reducing transmission of contagious diseases such as COVID-19 to and among health care workers and patients who are not infected [40]. With patients using the internet to access health care increasing each year, the quality of any service provided by this means should be evidence-based and necessary [41]. Any assessment administered online needs to be followed by automated reports with scans or images, objective and subjective assessment [42,43], patient expectations, prescription, expected outcomes, and timelines. Virtual assessment can overcome many of the pitfalls of physical assessment while greatly expanding the potential pool of patients who may be unable or unwilling to attend a physical clinic. Due to the current

pandemic crisis, the British Association of Prosthetics and Orthotics recommends the use of virtual care for triage, advice, assessment, reviewing ongoing care, the provision of off-the-shelf orthoses, and the review of all patients undertaking virtual assessments once normal working conditions resume [44].

Several barriers exist in virtual care implementation, including the lack of reimbursement [45,46], patient privacy and confidentiality, medicolegal concerns, practical workflow concerns, and physicians' fears of being overwhelmed by online messages [47]. Furthermore, virtual assessments lack the vital elements of palpation, dynamic testing, and real-time feedback for the P&O. Some patients may also find virtual assessments impersonal and may feel more comfortable seeing someone in person to get the care they need. There remains the ongoing issue of internet connectivity in some regions, the high cost of hardware and software, and the patient's ability to use information technology (IT). The quality of service for livestreaming audio and video applications must be improved to provide sustained bandwidth and low latency [8].

Prosthetic and Orthotic Care Under COVID-19

Novel technologies like telemedicine may be useful in maintaining social distancing, monitoring a patient's condition, or detecting infectious diseases, protecting not only patients but also health care providers [9]. This kind of virtual care can also address several aspects of assessment and care that do not require the time and effort necessary to travel to the P&O or allow care when such travel is not possible or puts patients at risk, such as during a pandemic. The current COVID-19 situation necessitates that we use available resources to optimize patient quality and outcome of the virtual visit [27]. The result of this pandemic has propelled virtual care adoption and transformed health care delivery [40].

The delivery care model will need to change as a result of COVID-19. There may be a "new normal" that is different from traditional practice, including the increased use of digital technologies. Digital technologies can potentially lead to different and more efficient designs, provide greater access to care, and limit physical contact. However, digital technology must be implemented thoughtfully and designed to address issues that are barriers to current adoption.

This paper presents the results of a study aimed at assessing the applicability and barriers of digital technology use in prosthetics and orthotics, and whether this technology can help overcome challenges posed by the current COVID-19 pandemic on the industry.

Methods

An online survey was designed and used to survey P&Os currently practicing and lower limb amputees using a prosthesis on their use and attitudes toward digital technology. This study was approved by the Institutional Review Board (IRB) at Singapore University of Technology and Design. Interested participants agreed to a preceding statement of consent, and a participant information sheet link was provided describing the survey, including length of the survey, purpose of the study, investigators, and how data would be collected and stored. The survey was hosted and all data stored on a secure server. Participants were asked for their email only if they agreed to a follow-up interview. This information was stored separately from the responses to maintain confidentiality. Participants were able to review and change their answers before submission. The survey was developed by the authors in conjunction with ProsFit Technologies, Bulgaria and tested with five Singaporean P&Os. This data was not included in the final analysis but was analyzed to adjust the survey for any errors.

The survey was open to participants who met the inclusion criteria. The survey was administered between June and July 2020 via the SurveyMonkey platform and was voluntary to complete. Participants were recruited via IRB-approved social media platforms like LinkedIn, WhatsApp, and social chat groups.

The 68 items of the qualitative and quantitative survey were divided into three sections, with adaptive questioning routing the participant to questions based on previous responses. The first section of the survey gathered lower limb amputees' (LLA) experiences and preferences. This included questions relating to prosthetic use, barriers to care, and opinions on the use of virtual assessments and home fittings. Section two was designed for the P&O who did not use digital technology (P&O-nonDT) in their facility. Questions included the number of patients seen per day, attitudes toward digital technology, and its importance to the future of the profession. Section three was for P&O who are currently using digital technology (P&O-DT) in their facilities. Additional questions about the use and limitations of technology were included in this section.

All three sections included demographic questions and questions on the use of virtual assessments or fittings. A variety of formats were used: multiple choice with single or multiple answers, ranking of answer options, 5-point Likert-scale questions, and open-ended questions. Where options were provided, the option "Other" was included to allow respondents to enter a different answer.

Follow-up interviews were conducted on selected patients and P&O respondents. Interviews were unstructured and conducted face-to-face or via phone and email.

Survey responses were analyzed with Stata/SE software (StataCorp LLC). Time stamps were collected at the start and end of the survey. All tests were carried out using a 5% level of significance. Answer options were presented as counts (%), mean (SD), or median (IQR) as appropriate. The Pearson chi-square test was used to assess difference between frequencies as observed and expected for certain answers.

Results

Participants

We received 113 survey responses, of which 83 were eligible for inclusion (n=13 LLA; n=70 P&Os). Surveys were excluded if less than 10% of the questionnaire was answered. On average, the survey took 13 minutes for the P&O to answer and 15 minutes for the LLA to complete.

Table 1 shows the demographics of the respondents. Singapore was well represented; although only 18.6% of the respondents (n=13), this constitutes 68% of all P&O in Singapore. LLA were from Singapore (n=12) and India (n=1). Follow-up interviews were conducted with LLA from Singapore (n=3) and with P&O who were using at least one form of digital technology (P&O-DT) from Singapore (n=3), Thailand (n=2), Malaysia (n=1), and Cambodia (n=1).

Table 1. Demographics of the respondents.

Demographics	Prosthetists/orthotists (n=70), n (%)	Lower limb amputee (n=13), n (%)
Age range (years)		
18-24	5 (7.1)	1 (7.7)
25-34	33 (47.1)	2 (15.4)
35-44	22 (31.4)	3 (23.1)
45-54	8 (11.4)	4 (30.8)
55-64	2 (2.9)	3 (23.1)
Gender		
Male	41 (58.6)	13 (100)
Female	29 (41.4)	0 (0)
Country		
Southeast Asia and Asia	56 (80)	13 (100)
Singapore	13 (18.6)	12 (92.3)
Myanmar	8 (11.4)	0 (0)
Thailand	8 (11.4)	0 (0)
Malaysia	7 (10)	0 (0)
Cambodia	6 (8.6)	0 (0)
Indonesia	4 (5.7)	0 (0)
Sri Lanka	4 (5.7)	0 (0)
India	3 (4.3)	1 (7.7)
Hong Kong	1 (1.4)	0 (0)
Philippines	1 (1.4)	0 (0)
Japan	1 (1.4)	0 (0)
Middle East	2 (2.9)	0 (0)
Yemen	1 (1.4)	0 (0)
Saudi Arabia	1 (1.4)	0 (0)
Europe	8 (11.4)	0 (0)
Bulgaria	2 (2.9)	0 (0)
UK	2 (2.9)	0 (0)
Germany	1 (1.4)	0 (0)
Ireland	1 (1.4)	0 (0)
Scotland	1 (1.4)	0 (0)
France	1 (1.4)	0 (0)
Other	4 (5.7)	0 (0)
Australia	4 (5.7)	0 (0)

Table 2 shows the characteristics of the LLA respondents. LLA were primarily of K3 and K4 activity levels in the US Medicare Functional Classification levels (12/13, 92%) and had their amputation due to trauma (8/13, 62%). They reported a long duration of daily use (mean 8.69, SD 5.12 hours) and a mean socket comfort score of 6.97 (SD 1.15). Out of 13 respondents, 11 (85%) LLA had their prostheses measured using plaster, and only 2 patients used only measurements. Zero LLA used scanning to make their prosthesis. LLA's mobility was mostly

impacted by pain, followed by the ease of wearing their prosthesis, their ability to access care, and the temperature.

Table 2. Characteristics of lower limb amputees.

Characteristics	Lower limb amputee (n=13)
K2: community ambulator, n (%)	1 (8)
K3: unlimited community ambulator, n (%)	7 (54)
K4: unlimited and recreational sports, n (%)	5 (38)
Nontrauma (cancer, diabetes, vascular disease), n (%)	5 (38)
Trauma, n (%)	8 (62)
Hours of using prosthesis each day	
Range	0-18
Mean (SD)	8.69 (5.22)
Median (IQR)	8 (6.3)
Level of comfort with a prosthesis (0=least comfortable, 10=most comfortable)	
Range	4-9.4
Mean (SD)	6.97 (1.15)
Median (IQR)	7.3 (1.5)
Methods of casting, n (%)	
Plaster wrap	11 (84.62)
Scanning	0 (0)
Measurement alone	2 (15.38)
Ranking of factors that most impact mobility, mean (SD)	
Pain	2.46 (1.89)
Easy to wear	2.92 (1.85)
Access to care	4.54 (1.51)
Breathability/temperature	4.54 (1.90)
Durability	4.69 (1.93)
Stability	4.85 (2.91)
Weight	4.92 (1.71)
Appearance	7.08 (1.66)

Tables 3 and 4 shows the characteristics of the P&O respondents. The P&O had a mean of 9.33 (SD 7.37) working years. The mean number of patients seen per day was 5.81 (SD 4.28). Almost half of the P&O used digital technology (31/70, 44%). Singapore had more (11/13, 85%) P&Os use digital technology compared to Myanmar (0/8, 0%).

Table 3. Characteristics of prosthetist and orthotist respondents.

Characteristics	Prosthetist and orthotist (n=70)
Years of working	
Range	1-32
Mean (SD)	9.33 (7.37)
Median (IQR)	7 (10.0)
Number of patients seen per day	
Range	0-20
Mean (SD)	5.81 (4.28)
Median (IQR)	4 (6.0)
Use of digital technology as part of work, n (%)	
Yes	31 (44.29)
No	39 (55.71)
Years using technology (n=31)	
Range	0.5-24
Median	2

Table 4. Country of prosthetist and orthotist respondents.

Country	P&O-DT[a] (n=31), n	P&O-nonDT[b] (n=39), n
Southeast Asia and Asia	24	34
Singapore	11	2
Myanmar	0	8
Thailand	4	4
Malaysia	1	6
Cambodia	1	5
Indonesia	2	2
Sri Lanka	1	3
India	0	3
Hong Kong	1	0
Philippines	0	1
Japan	1	0
Middle East	1	1
Yemen	0	1
Saudi Arabia	1	0
Europe	5	3
Bulgaria	2	0
UK	1	1
Germany	0	1
Ireland	1	0
Scotland	1	0
France	0	1
Other	3	1
Australia	3	1

[a]P&O-DT: prosthetists and orthotists who are currently using digital technology.

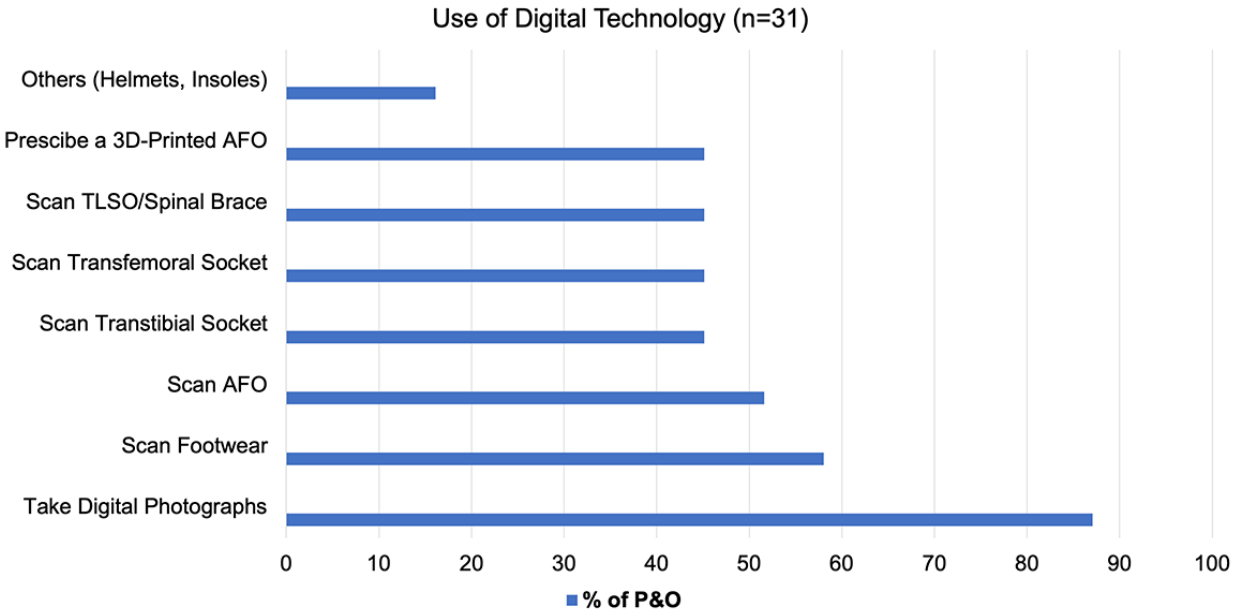
[b]P&O-nonDT: prosthetists and orthotists who did not use digital technology.

Use and Types of Technologies

The number of years the P&O-DT had been using digital technology varies greatly, from 0.5 to 24 years, with a median of 2 years. Many of the P&O had CADCAM facilities where they worked (23/31, 74%). The iPad with a structure scanner was the preferred method for digital capture (12/31, 39%) with a mix of other scanners used, including Artec Eva Lite, Omega, and Rodin 4D. Geometrical modification of the scans were performed using various programs, which can be grouped into P&O-specific software (24/31, 77%) and engineering software such as Rhinoceros or Solidworks (6/31, 19%). One P&O respondent was unsure of the program they used (1/31, 4%).

Figure 1 shows the application areas of the technology. Predominantly, the technology seems to show that taking digital photos to monitor care and to inform the design (27/31, 87%) is the most common use, followed by scanning for custom footwear (18/31, 58%). Approximately half of the subjects would scan for an ankle-foot orthosis (AFO), spinal braces, or transtibial or transfemoral sockets.

Figure 1. The applications of digital technology used in clinical practice. AFO: ankle-foot orthosis; P&O: prosthetic and orthotic; TLSO: thoracic-lumbar-sacral orthosis.



Five-point Likert-scale questions showed that the attitudes toward digital technology among P&O using technology were generally positive (see Table 5). Out of 31 respondents, 24 (77%) agreed or strongly agreed that it improves patient outcomes. The majority of participants agreed that they have the necessary skills to incorporate digital technologies (25/31, 81%) and acknowledged a strong need to continue using the technology to maintain efficacy and improve skills (30/31, 97%), and approximately two-thirds (20/31, 65%) were conscious that patients prefer them to use digital technology for their care. However, just over half (17/31, 55%) agreed that 3D printed devices were cost-effective, and 22 out of 31 (71%) felt that digitally produced prosthetic and orthotic devices did not fit better than traditionally made ones.

Table 5. Attitudes of prosthetists and orthotists who use digital technologies at work.

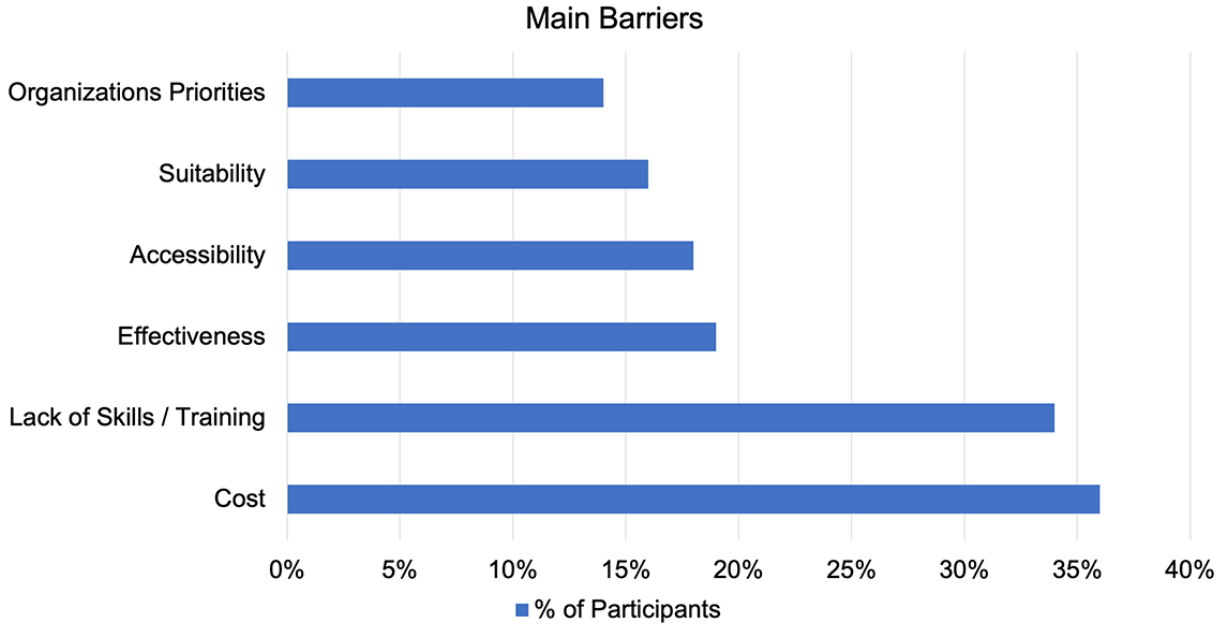
Attitudes	Total (n=31), n (%)	Singapore (n=11), n (%)	Non-Singapore (n=20), n (%)	*P* value
Digital technology improves patient outcomes				.13
Strongly agree	9 (29)	2 (18.2)	7 (35)	
Agree	15 (48.4)	8 (72.7)	7 (35)	
Disagree	7 (22.6)	1 (9.1)	6 (30)	
Strongly disagree	0 (0)	0 (0)	0 (0)	
Patients prefer me to use digital technology when making their devices				.12
Strongly agree	4 (12.9)	3 (27.3)	1 (5)	
Agree	16 (51.6)	6 (54.6)	10 (50)	
Disagree	11 (35.5)	2 (18.2)	9 (45)	
Strongly disagree	0 (0)	0 (0)	0 (0)	
It is important to practice with the hardware/software to be more efficient and effective				.28
Strongly agree	21 (67.7)	8 (72.7)	13 (65)	
Agree	9 (29)	2 (18.2)	7 (35)	
Disagree	0 (0)	0 (0)	0 (0)	
Strongly disagree	0 (0)	0 (0)	0 (0)	
Missing	1 (3.2)	1 (9.1)	0 (0)	
I do not have the technical skills to use digital technology with my patients				.19
Strongly agree	0 (0)	0 (0)	0 (0)	
Agree	5 (16.1)	0 (0)	5 (25)	
Disagree	20 (64.5)	8 (72.7)	12 (60)	
Strongly disagree	5 (16.1)	2 (18.2)	3 (15)	
Missing	1 (3.2)	1 (9.1)	0 (0)	
Digitally produced devices always fit better				.55
Strongly agree	2 (6.5)	0 (0)	2 (10)	
Agree	5 (16.1)	1 (9.1)	4 (20)	
Disagree	22 (71)	9 (81.8)	13 (65)	
Strongly disagree	0 (0)	0 (0)	0 (0)	
Missing	2 (6.5)	1 (9.1)	1 (5)	
3D printed devices enable high cost-effectiveness				.39
Strongly agree	2 (6.5)	0 (0)	2 (10)	
Agree	15 (48.4)	4 (36.4)	11 (55)	
Disagree	11 (35.5)	6 (54.6)	5 (25)	
Strongly disagree	1 (3.2)	0 (0)	1 (5)	
Missing	2 (6.5)	1 (9.1)	1 (5)	
The future of prosthesis/orthosis industry and practice is digital				.04
Strongly agree	12 (38.7)	2 (18.2)	10 (50)	
Agree	16 (51.6)	9 (81.8)	7 (35)	
Disagree	3 (9.7)	0 (0)	3 (15)	
Strongly disagree	0 (0)	0 (0)	0 (0)	

Singaporean P&Os who use technology agreed significantly less strongly (*P*=.04) than non-Singaporean P&Os that the future of prosthetics and orthotics is digital. Interviewees from Singapore suggested their current experience with technology has been both positive and negative, limiting their expectations for the future. They felt a need to use digital technology "for

appropriate cases" or "when they improve efficiencies such as casting for a large transfemoral socket or making a scoliosis brace." One interviewee stated that using digital software to "modify such large devices was more efficient and required less physical strength."

The common barriers to greater integration of digital technology for the P&O-DT respondents as obtained using open-ended questions can be seen in Figure 2. The top barriers were cost (11/31, 35%) and the lack of skills and training (10/31, 32%). The third identified barrier was the effectiveness of technology (6/31, 19%). P&O-DT cited material strength, the need to outsource, and the constant software updates limiting the effectiveness of greater integration. These main barriers were similar to P&O-nonDT, highlighting an ongoing need for continual financial reinvestment and training even when digital services have been established.

Figure 2. Barriers to greater integration of technology (prosthetist and orthotist who use technology, n=31).



Nonuse of Technologies

Where nonuse of technology was common, stable internet was still a problem, particularly in developing countries such as Sri Lanka (2/3, 66%), Cambodia (2/5, 40%), and Myanmar (2/6, 33%), and many of the P&O respondents in these countries did not have computers (35/39, 89%). Other reasons mentioned for not using technology were cost (25/39, 64%) and the lack of awareness and skills (20/39, 51%).

Virtual Care

The use of virtual assessments and virtual fittings were analyzed for agreement. A primary benefit of virtual services is to reach those who face obstacles in coming for their appointments. Out of 70 P&O respondents, 29 (41%) felt their patients had difficulties coming for their appointments. The main reasons mentioned were transportation (n=16, 19%), cost (n=11, 13%), and the lack of family members or caregivers to bring them to their appointment (n=9, 13%). P&O respondents found that virtual assessments would benefit the patient in these situations (n=59, 84%). Interestingly, 11 out of 13 (85%) LLA did not find access to care an issue and preferred to come to the clinic for their follow-ups even during the pandemic.

Out of 70 P&O respondents, 51 (73%) would use virtual assessments if it was made available. Most respondents agreed or strongly agreed that virtual assessments would be suitable in rural areas (n=47, 67%) but just over half suggest virtual fittings would improve patient outcomes (n=38, 54%). The potential benefits mentioned were to save clinical time and reduce the need to travel (n=32, 46%); this often reduces costs (n=17, 24%), and—of relevance during this current pandemic—10 (14%) suggested it would be safer for the patient and decrease the risk of infection.

Some confusion arose when P&O were asked about the format of the virtual assessments. Out of 7 selected interviewees, 5 (71%) revealed they had merely agreed to the statement without thinking how they might apply this service. Suggestions for the service included a "*triage-like*" service or checking "*simple things like whether all is well or not*" to "*assess the problem*" and "*determine whether a trip to the clinic was necessary*." When asked if they felt patients would be willing to pay for this service, many "*did not think so*" unless "*it adds value*." The LLA responses concurred with these statements. Only 6 of the 13 surveyed LLA are prepared to pay for this service, with 3 out of 3 (100%) of the LLA interviewees agreeing only if their needs were met.

The major potential challenges with virtual assessment mentioned by the P&O respondents were difficulties in assessing the limb for strength, ROM, palpation, and pain (26/70, 37%). Other problems were concerns of the skills the patient had to use for items such as computers (12/70, 17%), the high chance of miscommunication when giving advice (11/70, 16%), and internet connectivity (8/70, 12%).

Out of 70 P&O respondents, 27 (39%) were open to providing virtual fittings using a third person *fitter* with a further 15% considering it depending on the fitter's skills and training. The main benefits cited were that it provides greater outreach and maintains the ability to overcome the common barriers like the need to travel to the clinic. When the P&Os were asked about patients doing the task of fitting themselves, safety concerns were mentioned during the interviews, despite LLA feeling confident in their ability (Table 6). There were mixed results for the level of confidence LLA have to adjust their own prosthesis with or without internet guidance. We found that those LLA who were less confident with internet guidance than by themselves, tended to be older than 45 years.

Table 6. The confidence of lower limb amputees adjusting their own prosthesis (n=13).

Confidence in adjusting the prosthesis	By self, n (%)	With internet guidance, n (%)
Extremely confident	4 (30.8)	4 (30.8)
Very confident	2 (15.4)	1 (7.7)
Somewhat confident	4 (30.8)	2 (15.4)
Not so confident	0 (0)	5 (38.5)
Not at all confident	3 (23)	1 (7.7)

Discussion

Principal Findings

To date, research has focused on the development of digital technologies or how new technology can be applied to the industry for a particular application. This survey reports the actual current use of digital technologies in the prosthetic and orthotic industry and suggests its suitability during pandemics such as COVID-19. Although infection prevention practices like social distancing, the wearing of masks, and regular washing of hands have been implemented, the use of digital technology for prosthetic and orthotic services remains challenging with many barriers to overcome. Current adoption levels of technology despite the pandemic suggest the potential benefits of safer care have not outweighed the limitations of the technology to provide sufficient value to both the patient and P&O. Furthermore, changing organizational behaviors in delivering digital health care require the right skills among health care professionals to leverage technology-driven solutions toward technology adoption.

Use

Approximately half of the P&O respondents use some form of digital technology. The use of scanners, computers, and computer-augmented design and manufacturing are the most common ones. The use of scanners provides a mess-free and reduced physical contact environment, improving patient safety during the pandemic. There is still a need for the clinician to be present to conduct the scan; thus, only the physical touch component is improved.

The P&O respondents preferred the more cost-effective iPad with a structure scanner (Occipital) over high-end accurate scanners such as Vorum's Spectra scanner or Artec EVA scanner. P&O interviewees stated that the wireless iPad was easier and lighter to maneuver to capture the limb shape but can be limiting when capturing the posterior view due to the screen's position forcing an awkward posture of the person scanning. This finding is aligned with a study by Brunsman et al [48], where the positioning of the human body for surface scanning required an assortment of body postures to make all essential areas visible and the direction the patient faces can affect the quality of the scan. This repositioning may not reduce the prosthetist-patient contact as intended when trying to minimize cross-contamination, and it is lead author TB's opinion, as a principal P&O with over 21 years of experience, that having a small handheld external camera connected via a cable or wirelessly to an external screen to view the captured image would be a simple solution to overcome these issues.

The use of low-cost cloud-based engineering modeling and analysis software programs such as Rhinoceros (Robert McNeel & Associates), Fusion360 (Autodesk), and Solidworks (Dassault Systèmes) was also common due to their affordability, usability, and applicability. Considering the P&O respondents stated that more training and skills are needed to increase adoption of technology, the use of point and click options in software [49] may remove the need for advanced CAD skills, making the technology more appealing and user-friendly [50]. This could lead to reduce unnecessary visits and contact with coworkers and patients, maintaining safe distancing and limiting possible virus spread.

Interviewees appreciated the improved efficiencies of digital scanning and software for the making of larger casts like transfemoral sockets or spinal braces. Stating that these types of casts can be modified using preloaded templates in the software in a shorter amount of time than physically removing or adding plaster via traditional methods. This process is more convenient and safer for the patient and faster for the P&O.

The use of 3D printing is often touted as the next big transition for the industry [51]. Our results suggest its use is relatively low. Three dimensional printing is similar to traditional production methods, where it is necessary to get throughput, part demand, and production planning right to minimize part manufacturing cost [52]. Three dimensional printing may change the way many products are developed and produced, and herald an era of "personal manufacturing" [53]. They also provide an efficient and safe manufacturing process; however, unless a facility is consistently 3D printing prostheses or orthoses, outsourcing is more economical.

Barriers

The main barriers (cost, lack of skills or experience, and effectiveness of the technology) for adopting digital technology were found to be the same issues that prevented greater adoption in facilities already using some form of digital technology.

The initial cost outlay in purchasing scanners, computers, or 3D printers can cause apprehension over the return on investment. Interviewees reported that prosthetic- and orthotic-specific software requires special training, software updates, and yearly licensing, often based on the number of modules needed, adding to the cost and deterring more users from greater adoption. The use of 3D printing was found to be limited by the same factors identified in a systematic review of 3D printed sockets [51], including the quality of the part, choice of materials available, and the cost-effectiveness. Literature also points to associated costs of printing ignored when comparing to traditional methods, including the additional material costs for support structures, machine use rates, labor and print preparation, machine maintenance, and the error costs [54].

Even though the design and manufacturing of highly accurate prostheses and orthoses is possible with the help of digital technology, it was concerning to see that a majority of P&O who already used digital technology did not find the devices had a better fit. This result may be attributed to the need for ongoing training and practice to enhance the skills; most P&O were only using the technology for less than 5 years. Another reason could be the printing quality, which has increased over recent years but still requires the more expensive printers.

The use of scanning for AFOs was high but limitations in contactless scanning were voiced during the interviews as the P&O would often need to position the limb on a clear Perspex plastic scanning platform or the ground before scanning. The scanning of residual limbs for prosthetic sockets was easier, although—as previously discussed—positioning the scanner still remains troublesome to obtain a full 360° image with multiple positions needed to capture the entire shape [48].

Our survey suggests a low use of digital technology for transtibial socket design, with the LLA respondents complaining of poor design, fit, and ease of wearing their prostheses as major factors inhibiting their mobility. This is despite digital technology such as Finite Element Analysis, MRI, CT, and photogrammetry showing benefits to improve outcomes by predicting accurate interface pressures through better imaging of the muscles and tissues. It also allows further optimization in the design of comfortable high quality devices [55-58].

Virtual Care

Patient

Out of 13 respondents, 11 (85%) of LLA did not find access to care an issue and preferred to come to the clinic for their follow-ups even during the pandemic. It should be noted all but 1 patient was from Singapore. Almost half of all P&O respondents outside Singapore found their patients had difficulties coming for their appointment. This is at odds with other countries where patients are more comfortable using telemedicine rather than risk infection with face-to-face consultations [59]. Our study did find support for virtual assessments from the P&O interviewees, who noted it was safer for patients and protected them from possible virus infections.

Questions remain about what types of tasks are suitable for virtual care particularly during the pandemic; all P&O interviewees suggested that triaging a patient or providing education to patients may be most suitable. The National Health Service program “Attend anywhere” suggests that virtual care is only useful if it results in improved efficiencies, significant time savings, reduced need to take time off work, no travel costs, and no technical issues [60]. Our study also showed the lack of IT skills and connection issues of the patients as concerns, highlighting the need for reliable infrastructure. Although virtual care would be an excellent solution for patients in remote areas and developing countries, this is also where infrastructure is likely to be poor. These results are aligned to Mihalj et al [9], who describes five factors that support telemedicine implementation. These include technology (broadband and connection) that must support both the health care provider and patient; secure platform; training to health care providers; patients’ need to be educated on privacy, safety, efficacy, and personal benefits; and cognitive and hearing impairments [9].

In a telehealth consumer study in the United States, the authors found that 66% of patients were willing to use telemedicine in 2019, but only 8% had used it previously. The authors suggest that the main reasons were the lack of familiarity with the new technology and a lack of trust in the clinician whom they have not met in person [61]. The emotional connection to the clinician is equally important in telehealth adoption. Knowing that the consultation focuses not only on the immediate health care needs but also the emotional support is critical to gaining loyalty from the patient [62].

This same issue of trust was highlighted in this study by both LLA and P&O respondents. In an industry that customizes devices, any change in the care model should reflect a strong need for such change. By merely moving consultations online, we may overcome some barriers found in this study, such as the travel burden, the lack of support to bring patients to their appointments, and reduced overall costs. However, there appears a need to develop a rapport between P&O and LLA before the use of virtual care and certain P&O tasks may be difficult to fulfill (see next section). A thoughtful application and design of digital technology is needed, considering all stakeholders involved.

P&Os

Literature suggests minimizing casting processes to prevent the virus spread [10]. The adoption of 3D scanning would be a viable method in achieving this. Concerns over how to conduct shape capturing, residual limb assessment, palpation, and gait analysis may limit the effectiveness and adoption of digital technology, unless it can be developed to overcome these challenges. The lack of touch and feel was found to be a major hurdle to adoption. Virtual assessment tools allow implementing triage at the point of need [63], but advice-only consultations may not prove valuable. LLA suggested they may be unwilling

to pay for such services. Both LLA and P&O respondents are used to a consultation and physical contact combination. The information garnered through physical examinations, such as tissue consistency, identifying painful areas, or ROM, may prove challenging to overcome in a virtual setting.

In rural settings, our survey suggests the use of virtual care may be more suitable. This study found that P&Os would use virtual care where patients have to travel long distances for care or are too sick to come to a facility. However, in such rural locations, there may be other challenges such as internet connectivity and the IT skills of patients, limiting its applicability [9]. Our survey suggested the use of a third, local person to assist with data collection and fitting of devices, which might help to overcome some limitations. Attitudes toward the use of such persons were mixed. They would need sufficient competencies to ensure the appropriateness and quality of care. In the case of pandemic-related social distancing laws, the viability of such a third-person service would also be affected. Third person or support staff were used as a means to provide care in rural New South Wales, Australia, in combination with video calling for the provision of AFOs [39]. In this study, the authors trialed the assessment of the ROM over a video call with a third person performing the task. They found, when using the primary care giver as the third person, the measurements of the ROM were less accurate than the P&O. However, when a third person had a health care background the results were acceptable, suggesting a possible minimal educational background.

Hospital and Facility

The impetus for change and adoption of digital technology varies based on the funds and infrastructure available. Budgets may be too small to invest in digital technology and on training, government support may be low, and the use may be too infrequent to justify the investment. The purchase power to outsource may also present challenges, particularly if it is too low. Digital technology would be more widely adopted if it demonstrated enhanced patient care and outcomes, and lowered overheads of the facility, provided the infrastructure of the country can support the technology.

Limitations

Our online survey was developed to obtain a broad understanding of digitalization in the P&O industry. Its length may have been the reason why 30 of the 113 respondents answered less than 10%. Furthermore, as this was an online survey, only respondents with internet connection were able to respond. This may have particularly affected the number of LLA responses; 12 of the 13 LLA respondents were from Singapore, contacted through the amputee support chat group, where internet connection is not a barrier. The P&O respondents may have been less affected, as they could have used the internet connections at work. Another reason for the low LLA response might be that they were contacted indirectly, via their P&O, or that multiple languages of the survey were not available.

The responses for Singapore are considered an accurate reflection of the P&O use of digitalization with over 65% of all P&O in Singapore participating. Although the other respondents came from a large number of countries, their numbers were limited. The study is, therefore, not representative of current practices outside of Singapore, even though the results are informative.

Future Directions

Further investigation should focus on the exact nature of how virtual care during the pandemic can be conducted, particularly the lack of the element of touch in an assessment by the P&O. There is a clear need for the development of a digitalization framework to facilitate digital technology implementation in the industry. Understanding how, when, and why to use digital technology is vital for successful outcomes to both clinic and patient. Particular attention should be paid to delivery care models that overcome the shortfalls with current technology, including sensory feedback through palpation, low IT awareness, and poor connectivity, while maintaining safer care. The use of distributed care models (DCMs) is an alternative to switching all business to digital means. DCMs consist of a hybrid of care that includes central-based fabrication, satellite clinics, mobile clinics, and digital technology. Using a third person trained to digitalize the anatomy of a limb should be considered to enhance the outreach where prevailing laws allow.

Conclusion

The use of digitalization during a pandemic such as COVID-19 can mitigate the concerns regarding ongoing patient care and safety for both patient and P&O. The use of scanning and virtual care provides avenues for the continuum of care for the patient. However, essential characteristics of P&O assessments such as palpation and sensory feedback have yet to be overcome. Providing the patient with the appropriate technology and answering what needs the technology is addressing is essential and may encourage adoption among the industry. Education and training should be provided to centers and individuals to enhance confidence levels and awareness of digital care benefits and risks during and beyond pandemic times. Ensuring the staff has a high technology readiness level is critical. The delivery care model should be evaluated to provide sufficient outreach and an optimal level of digital technology that provides adequate care and sufficient protection against the spread of COVID-19.

Technology advancements such as virtual platforms, digitalization methods, and improved connectivity will change the future of health care. Digital technology is transforming health care into a new normal and is being accelerated during the pandemic. This transformation is expected to continue in the years to come. The prosthetic and orthotic industry should keep an open mind and move toward creating the required infrastructure to support this digital transformation or risk being left behind.

Acknowledgments

The authors wish to acknowledge Alan Hutchison, CEO ProsFit Technologies, for assistance with the development of the survey.

Conflicts of Interest

None declared.

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Abbreviations

AFO: ankle-foot orthosis
CAD: computer-aided design
CADCAM: computer-aided design and manufacturing
CT: computed tomography
DCM: distributed care model
IRB: Institutional Review Board
IT: information technology
LLA: lower limb amputees
MRI: magnetic resonance imaging
P&O: prosthetist and orthotist
P&O-DT: P&O who are currently using digital technology
P&O-nonDT: P&O who did not use digital technology
ROM: range of motion

Edited by G Eysenbach; submitted 25.08.20; peer-reviewed by E Sadeghi-Demneh, C Stunden; comments to author 12.09.20; revised version received 18.09.20; accepted 22.09.20; published 05.11.20.

Please cite as:
Binedell T, Subburaj K, Wong Y, Blessing LTM
Leveraging Digital Technology to Overcome Barriers in the Prosthetic and Orthotic Industry: Evaluation of its Applicability and Use During the COVID-19 Pandemic
JMIR Rehabil Assist Technol 2020;7(2):e23827
URL: http://rehab.jmir.org/2020/2/e23827/
doi:10.2196/23827
PMID:33006946

Publisher:
JMIR Publications
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Toronto, ON, M5A 3Y5
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Email: support@jmir.org