JMIR Rehabilitation and Assistive Technologies

Contents

Original Papers

Viewpoint

Review

Original Paper

Web-Based System to Capture Consistent and Complete Real-world Data of Physical Therapy Interventions Following Total Knee Replacement: Design and Evaluation Study

Patricia D Franklin[1], MBA, MPH, MD; Carol A Oatis[2], PT, PhD; Hua Zheng[3], PhD; Marie D Westby[4], BScPT, PhD; Wilfred Peter[5], PhD; Jeremie Laraque-Two Elk[6], PT, MPH, DPT; Joseph Rizk[7], DPT; Ellen Benbow[8], DPT; Wenjun Li[9], PhD

[1]Department of Medical Social Sciences, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States

[2]Arcadia University, Glenside, PA, United States

[3]Department of Orthopedics and Physical Rehabilitation, University of Massachusetts Medical School, Worcester, MA, United States

[4]Centre for Hip Health and Mobility, Vancouver Coastal Health Research Institute, Vancouver, BC, Canada

[5]Department of Orthopedics, Rehabilitation, and Physical Therapy, Leiden University Medical Center, Leiden, Netherlands

[6]HealthPRO Heritage, Bellevue, WA, United States

[7]Cascade Rehabilitation Associates, Everett, WA, United States

[8]Magee Rehabilitation Hospital, Philadelphia, PA, United States

[9]Department of Public Health, University of Massachusetts-Lowell, Lowell, MA, United States

Corresponding Author:
Patricia D Franklin, MBA, MPH, MD
Department of Medical Social Sciences
Feinberg School of Medicine
Northwestern University
625 N Michigan Ave
21st Floor
Chicago, IL, 60611
United States
Phone: 1 312 503 4645
Email: patricia.franklin@northwestern.edu

Abstract

Background: Electronic health records (EHRs) have the potential to facilitate consistent clinical data capture to support excellence in patient care, quality improvement, and knowledge generation. Despite widespread EHR use, the vision to transform health care system and its data to a "learning health care system" generating knowledge from real-world data is limited by the lack of consistent, structured clinical data.

Objective: The purpose of this paper was to demonstrate the design of a web-based structured clinical intervention data capture system and its evaluation in practice. The use case was ambulatory physical therapy (PT) treatment after total knee replacement (TKR), one of the most common and costly procedures today.

Methods: To identify the PT intervention type and intensity (or dose) used to treat patients with knee arthritis following TKR, an iterative user-centered design process refined an initial list of PT interventions generated during preliminary chart reviews. Input from practicing physical therapists and national and international experts refined and categorized the interventions. Next, a web-based, hierarchical structured system for intervention and intensity documentation was designed and deployed.

Results: The PT documentation system was implemented by 114 physical therapists agreeing to record all interventions at patient visits. Data for 161 patients with 2615 PT visits were entered by 83 physical therapists. No technical problems with data entry were reported, and data entry required less than 2 minutes per visit. A total of 42 (2%) interventions could not be categorized and were recorded using free text.

Conclusions: The use of user-centered design principles provides a road map for developing clinically feasible data capture systems that employ structured collection of uniform data for use by multiple practitioners across institutions to complement and augment existing EHRs. Secondarily, these data can be analyzed to define best practices and disseminate knowledge to practice.

XSL•FO
RenderX

Introduction

The health care system in the United States has moved aggressively in the last decade to the use of electronic health records (EHRs). A primary goal driving the transition to an EHR is the EHR's potential to facilitate consistent data capture to support patient care and quality improvement in health care [1,2]. Moreover, routine collection of clinical data, in conjunction with insurance claims data, has the potential to enhance comparative effectiveness research (CER), all leading to improved patient outcomes. "Pragmatic trials" using real-world evidence from EHRs can include many more diverse individuals recruited from real-world settings and can assess the interventions provided during standard clinical care. In contrast, the usefulness of traditional randomized controlled trials has been limited by the relatively small study sample sizes, the tightly controlled inclusion and exclusion criteria of participants, and the tightly regimented interventions tested [3,4]. The realization of this vision will transform the clinical care system to a "learning health care system" to generate new knowledge from real-world data, while providing optimal care to today's patients. In contrast to this vision, data regarding the EHR's ability to improve clinical care, clinical research, and ultimately patient outcomes are limited. Bartlett et al [5] report that only 15% of US-based clinical trials published in 2017 in high-impact journals could be replicated using data found in EHRs or claims data. The investigators note that fewer than 40% of the reported interventions studied in randomized controlled trials could be assessed using EHR data. The authors suggest that improved EHR systems with predefined, consistent data capture might enhance the ability to study interventions via EHRs.

As an example, osteoarthritis (OA) is the most common disabling condition in the United States, and knee OA is among the most prevalent OAs [6,7]. When knee OA symptoms persist despite medical care and physical therapy (PT), total knee replacement (TKR) surgery is commonly elected. However, limited CER evidence exists to define the components of optimal post-TKR PT to achieve peak knee performance and physical function. A 2018 retrospective study [8] of PT paper records from patients seen at home or in ambulatory settings found that of 156 records available for review, only 112 provided sufficient intervention details to assess the quality of even a portion of the interventions. Review of those records revealed that interventions varied widely among physical therapists, with only 5 exercises reported in more than 50% of the records. Review also suggested that dosage of strengthening exercises might be inadequate to derive a physiological response. However, documentation was limited by incompleteness, illegibility, lack of consistent vocabulary, and the use of jargon.

Beyond incomplete and inconsistent EHR documentation, generalizable research requires integrating data across locations and time. Today's EHRs vary in structure, functions, and their ability to capture structured data and extract and integrate existing data. Inconsistent discrete variable definitions, broad use of free-text fields, and limited embedded technical functions to identify post-TKR patients and extract data are barriers [2]. Today's PT practices use EHRs to serve billing and administrative functions, but nonstructured treatment notes persist and perpetuate the challenge of using real-world data to define optimal PT practice in patients post TKR.

The purpose of this paper is to demonstrate the ability of a user-designed, web-based data capture system to track detailed, complete, and quantifiable PT interventions in patients following TKR to serve CER. This paper presents the development, deployment, and assessment of a structured data capture system for physical therapists treating patients in any ambulatory setting following TKR. The future goal of this data capture system is to describe and quantify the interventions provided by physical therapists to patients in all ambulatory care settings after TKR, in preparation for a pragmatic study to determine the PT interventions associated with optimal functional outcomes. Although the data capture system presented in this paper is designed for the specific patient population with knee OA post TKR surgery, albeit one that constitutes a large proportion of ambulatory PT care, we believe the existing system can be applied to many patient populations with minor modifications. More importantly, this paper offers design principles and a road map for developing clinically feasible web-based data capture systems that employ a structured collection of uniform clinical data, allowing use by multiple practitioners across institutions to complement and augment existing EHRs.

Methods

Ethics Approval

This research was approved by the Human Subjects Review Board at the University of Massachusetts Chan Medical School (H00012294_19).

Patient Involvement

Development of an interoperable data capture system involved the following two distinct tasks proceeding in parallel: (1) identification of the relevant content to be captured for a thorough description of the PT intervention and (2) construction of a user-friendly, Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule–compliant web-based data capture method for use across diverse PT practices. The following section presents these two tasks separately.

Content Development

To identify the PT intervention content to be captured, we used an iterative user-centered design process building on the initial list of treatments generated during our retrospective chart review. The original list of interventions identified by chart

review was entered into a Microsoft Excel spreadsheet and provided to 7 physical therapists and PT interns at 4 ambulatory PT clinics. The clinics were located in geographic regions that were different from those of clinics used in the original study. The 7 physical therapists and interns were asked to record their interventions on the spreadsheet and to add any interventions they used that were not listed on the spreadsheet. The original list of interventions was revised using the comments from the new set of users.

The revised list was then sent to 4 nationally recognized experts in PT post TKR care. These experts were asked to review the list of interventions and revise them as needed. All 4 experts shared the list with at least one practicing clinician for additional input. We interviewed all 4 national experts to review their comments and suggestions. The suggestions were compiled in the next version of the intervention list and returned to the national experts for further comment. Another round of revisions occurred. These revisions included dividing the list of interventions into 8 distinct categories. Finally, the next version of the intervention list was sent to 2 international physical therapist experts. They reviewed the list of interventions and discussed their suggestions in a series of 2 conference calls with the investigators. These discussions included suggestions on how to describe intensity and dosage. The investigators incorporated the suggestions and developed a final menu of possible interventions that could be provided by a physical therapist in an ambulatory setting to patients post TKR.

The process of review and revision took approximately one year to complete and resulted in a list of 141 interventions organized in 8 categories. Each intervention included additional parameters used to describe dosage and intensity. A file of intervention definitions was also generated, so clinicians could recognize an intervention by the definition, regardless of the name of the intervention (Multimedia Appendix 1).

Informatics Development

The primary purpose of this research was to validate and refine, as needed, the PT intervention documentation system prior to future integration with EHRs. Because this documentation would supplement the existing PT EHR system, efficient documentation and ease of use were priorities. The informatics team identified a HIPAA-compliant web-based software (Quickbase) that can capture discrete PT interventions and intensity details. Priority features included (1) secure and simple log-in and patient registration for PT efficiency and (2) hierarchical documentation structure to allow the physical therapist to quickly review the 8 categories and select interventions within only the relevant categories for each PT visit (Figure 1).

Figure 1. Sample structure of web-based physical therapy intervention capture system.
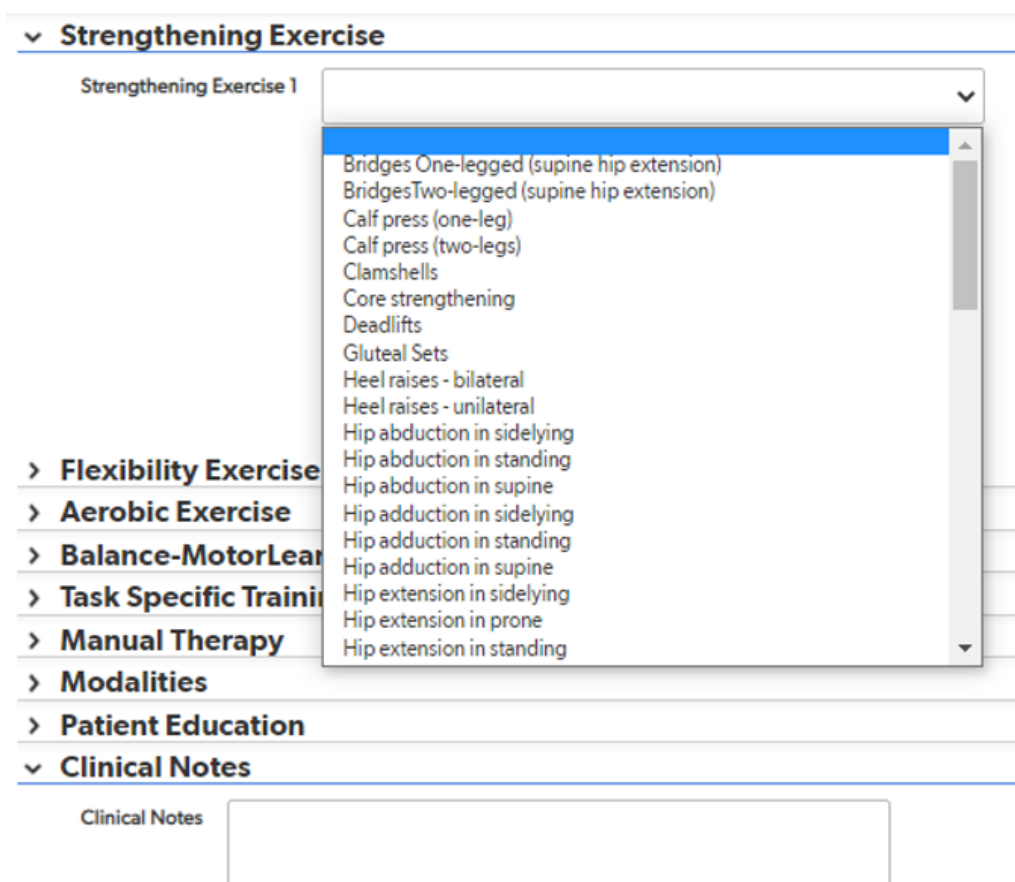
Log-in and Patient Registration

Each physical therapist is assigned a unique log-in account and the password is updated every 60 days for data security purpose. The home page of the system includes an "Add New Patient" button from which the physical therapist enters basic patient information to register a new patient. The system automatically generates a unique ID for each patient.

Intervention: Hierarchical Documentation of Interventions and Intensity

Once a patient is registered in the system, an "Add Visit" button is displayed on the patient record. The physical therapist can add as many PT visits as needed for one patient, and each visit is assigned a record ID as well. On each visit page, the visit date and the interventions provided by the physical therapist are entered. The intervention data collection is structured by category. For each of the 8 categories, the physical therapist selects interventions from the list within the relevant category. Once the intervention is selected, repetitions, sets, resistance, and other related fields appear for data entry (Figure 2). A complex branching logic was built to support the entry screen that displays or hides the data fields for each selected intervention. This hierarchical structure provides an efficient and organized user interface for detailed and accurate intervention documentation.

The workflow for the physical therapist entering documentation data into the system is listed in Figure 3. This process exactly parallels how the EHR fits into the PT clinical workflow.

Figure 2. Data entry fields for physical therapy intervention intensity details, including repetitions, sets, resistance, and other related options.

Figure 3. Workflow for physical therapist entering physical therapy intervention documentation.
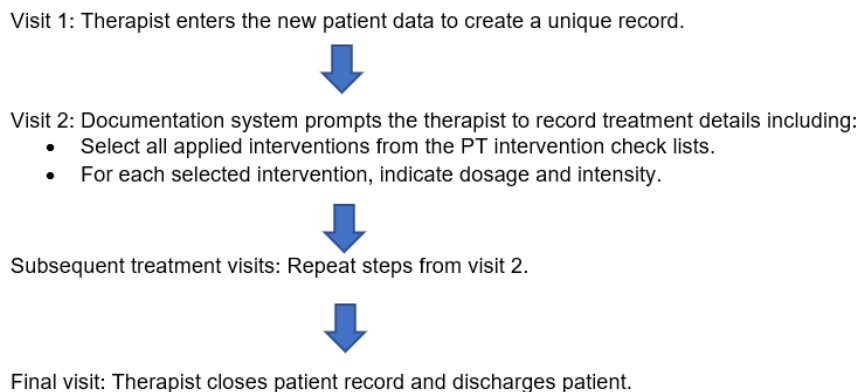
System Deployment

We deployed the data capture system in 8 PT practices with 33 different office sites; 3 practices were located in central Massachusetts, 1 in Rhode Island, and 4 in southeastern Pennsylvania. A total of 107 physical therapists and 7 physical therapist assistants who treat patients post TKR at these practices agreed to document in the intervention system at each patient visit. Each physical therapist agreed to help identify eligible patients, complete a brief survey describing his or her educational and professional background, and enter the complete intervention data for every visit for up to 5 enrolled patients. Participating practices were reimbursed US $50 for each completed patient record documenting the content of each PT visit. Each participating physical therapist attended one or two 45-minute web-based training sessions to learn about the study and to learn how to use the data capture system.

Assessment

The clinical feasibility of the data capture system was assessed in multiple ways. Therapists could contact IT support if they experienced problems with the website or technical difficulties in entering data. System function was assessed by the number and type of IT support contacts during the study. Physical therapists were also instructed to use a "Clinical Notes" text box in the data capture system to identify any interventions they used but were unable to find in the intervention menus. Therapists could also use the text box to add additional information that they wished to include for daily documentation. At least two trained PT reviewers reviewed the "Clinical Notes" text boxes to determine if they contained (1) additional information about interventions already included in the menus, (2) interventions that were available in the menu but not entered, or (3) interventions not represented in the menus. To evaluate the completeness of the documentation system, we identified the frequency of visits in which the text box was used, the frequency of visits where interventions were identified in the clinical texts but not entered in the menus, and the number of physical therapists associated with these texts. We also determined how often interventions listed in the text box were unavailable in the menus.

Statistical Methods

We used descriptive analysis of aggregate data on the use of the PT data reporting system. No other statistical analyses were used.

Results

Content and Informatics Development

The final post-TKR PT intervention system is a web-based, menu-driven data collection system using a HIPAA-compliant platform. Interventions are organized into 8 categories, each with its own drop-down menu. The categories include the following: strengthening exercises; flexibility exercises; aerobic exercises; balance, mobility, and agility; task-specific training; manual therapy; modalities; and patient education. The number of possible interventions varied within each of these categories from a high of 62 possible knee or hip strengthening interventions to a low of 6 possible patient education interventions. Within each intervention, additional drop-down menus appear to describe dose and intensity of each intervention.

The original menus included 141 interventions; however, after monitoring the "Clinical Notes" text boxes for approximately two months, two additional interventions (n=143) were added to the menus, and definitions for 3 interventions were revised for clarity.

System Deployment

A total of 107 therapists and 7 physical therapist assistants were trained in data entry. Over a period of approximately two years, data for 161 patients with 2615 patient visits were entered by 83 physical therapists or physical therapist assistants. Only therapists and assistants treating participating patients with new unilateral TKRs during the study recruitment period entered data. The characteristics of the participating patients are reported in Table 1 and are consistent with the national averages of patients receiving TKR.

Table 1. Patient characteristics (N=161).

Characteristics	Values
Age (years), mean (SD)	66 (8.4)
Female, n (%)	108 (67)
BMI, mean (SD)	30.4 (5.4)
Visits, mean (SD)	15.8 (9.8)
Side of surgery (right), n (%)[a]	42 (26.1)

[a]A total of 81 (50.2%) cases were unspecified.

Assessment

No technical problems with the data capture system were reported over that period, and therapists noted that data entry was quick and easy, typically taking less than 2 minutes. When therapists had questions about how to enter individual interventions, support was provided to help them locate the intervention in the menu. Questions regarding interventions were infrequent and usually occurred on first attempts to enter data.

A total of 47 (57%) physical therapists used the "Clinical Notes" text box at least once to describe or list at least one intervention or to add assessment data for a daily note. Investigator review found clinical notes from 16% (428/2615) of visits' listed interventions. Thus, 84% (n=2187) of total PT visits documented

all interventions using existing system categories. The most common reason (162 visits, 6.2%) for including interventions in the text box was that the therapist exceeded the maximum allowable number (ie, 10) of strengthening exercises. In 262 (10%) visits, the physical therapist listed interventions in the text box that were available in the intervention menus, but the therapist did not choose from the menu. A total of 42 (2%) visits included interventions in the text box that were not available in the menus. In these 42 visits, there were only 5 unique interventions not available in the menus.

Discussion

Principal Findings

In this paper we demonstrate that it is possible to develop a structured, menu-driven data capture system to collect detailed, discrete, and quantifiable intervention data across multiple physical therapists and practice sites in patients post TKR. The system was technically reliable with no reported technical difficulties. The system's usability is supported by the longitudinal documentation of post-TKR sessions by 83 physical therapists or physical therapist assistants across diverse PT practices. The users noted that data entry was easy and quick. One user noted that it was easier than the clinic's own EHR.

A total of 16% (428/2615) of visits included text to describe PT interventions, but much of the text provided additional information about the patient encounter, such as objective measures of outcomes. Some of the data entries listed interventions that were available in the intervention menus that the physical therapist had not identified. One reason for this was that the system imposed a maximum of 10 interventions for the strengthening exercise category. Removing this limit will eliminate the need to document more exercises in text. Some physical therapists listed interventions that they had not found in the menus, although those interventions were available. More extensive training of the users to ensure that they are familiar with all intervention menus will further minimize the need for text entry. In only 42 (2%) of over 2600 PT visits, there were new interventions listed in the text box that were not included in the menus. If our future outcome analyses find that any of these interventions are associated with positive outcomes, they can easily be added to the menus. Overall, fewer than 2% of the thousands of visits included an intervention that was not included in the documentation system.

Prusaczyk et al [9] suggest that complex interventions may be assessed through the use of EHRs if assessors evaluate all the data found in the record including open text extraction. However, wide application of open text extraction is challenged by the absence of a common vocabulary across treatment sites and the common use of jargon. Further, our preliminary research found that physical therapists did not document all interventions, compromising the use of text extraction [8]. The use of the EHRs for clinical research or quality improvement assessments of daily practice requires that uniform data are collected using a structured format.

It is important to note that the extensive list of interventions in our data capture system was designed to provide an exhaustive list of any conceivable intervention that a physical therapist or physical therapist assistant might use with a patient post TKR. The ultimate goal of our study is to identify those interventions and treatment factors that are associated with greatest knee performance and functional outcomes. These analyses are ongoing. After those interventions and factors are identified, the data capture system can be simplified and tailored to facilitate the application of the preferred interventions. For example, the most commonly used interventions can be listed first. In addition, a future iteration of the system can incorporate real-time clinical decision support principles to encourage physical therapists to adopt interventions associated with optimal outcomes or to advance intensity and repetitions. Despite the use of our exhaustive list of interventions, the users estimated that the time for data entry was approximately 2 minutes per visit. The proposed future enhancements may further improve upon the documentation efficiency and add clinical value through recording comprehensive and specific intervention details. Last, the structure and content could be integrated with existing PT EHRs to eliminate the second log-in and assure no redundancy exists between the administrative EHR functions and consistent PT intervention documentation.

The ability to successfully capture detailed intervention data representing real-world evidence, across multiple sites and providers, enhances the potential of future CER to identify best PT practices. The current data capture system can be readily adapted for use in many populations receiving PT, where care is known to exhibit significant unexplained practice variation. Importantly, we believe that the framework we used to develop this data capture system can be applied across the health care system, with a priority on treatments for which additional comparative effectiveness evidence is needed. Our data capture system was successful for several reasons. The data capture system was intended to capture relevant and detailed clinical data. Although the intervention data could easily be mapped onto reimbursement algorithms for billing purposes, its primary focus was clinical applications. Additionally, the system was designed by individuals familiar with the health services being provided, so the information gathered was consistent with clinical practice. The process of identifying the data to be captured was iterative, involving a broader review by more potential users at each level. Finally, a dictionary of clinical interventions was generated to ensure the collection of uniform data.

Limitations and Future Considerations

The data collection system described in this paper is a prototype; it is not integrated into any health system's electronic medical record. Future studies will assess its effectiveness and efficiency in the real world by integrating it into existing EHRs. Although almost 100 clinicians entered data collected from over 160 patients, testing will be improved by increasing the number of therapists entering data and the number of patients whose data are recorded. Finally, some therapists did not use the available menus effectively. Improved training for clinicians and their use of the data capture system over an extended period will improve their ability to use the system effectively and efficiently.

In conclusion, we have demonstrated that a structured data capture system to collect detailed quantifiable intervention data from multiple physical therapists at multiple sites is feasible and effective. Development of the system required involvement of potential end users and broad review to ensure the collection of a uniform yet complete data set. We believe this approach can be used by multiple health care disciplines to develop data capture systems that produce real-world evidence, suitable for quality improvement processes as well as for comparative effectiveness and outcomes research. In the future, clinical registries and EHRs can adopt structured health intervention documentation taxonomies, such as we describe, to assure complete, consistent real-world evidence to accelerate the potential for learning health systems

Acknowledgments

Authors' Contributions

PDF and CAO co-led the conception and design, study planning, conduct, analyses, and reporting. WL contributed to the conception and design and lead analyses. JL-TE, JR, and EB contributed to data acquisition. HZ contributed to informatics, data acquisition, and reporting.

Conflicts of Interest

None declared.

Multimedia Appendix 1
List of interventions (strengthening intervention category with dose and intensity).
[XLSX File (Microsoft Excel File), 13 KB - rehab_v9i4e37714_app1.xlsx]

References

1. Capturing high quality electronic health records data to support performance improvement internet. US Department of Health and Human Services: Office of the National Coordinator for Health Information Technology. 2013 Jul. URL: https://www.healthit.gov/sites/default/files/onc-beacon-lg3-ehr-data-quality-and-perform-impvt.pdf [accessed 2022-09-13]
2. Abernethy AP, Gippetti J, Parulkar R, Revol C. Use of electronic health record data for quality reporting. J Oncol Pract 2017 Aug;13(8):530-534. [doi: 10.1200/JOP.2017.024224] [Medline: 28745935]
3. Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med 2000 Jun 22;342(25):1887-1892 [FREE Full text] [doi: 10.1056/NEJM200006223422507] [Medline: 10861325]
4. Califf RM, Robb MA, Bindman AB, Briggs JP, Collins FS, Conway PH, et al. Transforming evidence generation to support health and health care decisions. N Engl J Med 2016 Dec 15;375(24):2395-2400. [doi: 10.1056/NEJMsb1610128] [Medline: 27974039]
5. LaCroix AZ, Bellettiere J, Rillamas-Sun E, Di C, Evenson KR, Lewis CE, Women's Health Initiative (WHI). Association of light physical activity measured by accelerometry and incidence of coronary heart disease and cardiovascular disease in older women. JAMA Netw Open 2019 Mar 01;2(3):e190419 [FREE Full text] [doi: 10.1001/jamanetworkopen.2019.0419] [Medline: 30874775]
6. Sloan M, Premkumar A, Sheth NP. Projected volume of primary total joint arthroplasty in the U.S., 2014 to 2030. J Bone Joint Surg Am 2018 Sep 05;100(17):1455-1460. [doi: 10.2106/JBJS.17.01617] [Medline: 30180053]
7. Singh JA, Yu S, Chen L, Cleveland JD. Rates of total joint replacement in the United States: future projections to 2020-2040 using the national inpatient sample. J Rheumatol 2019 Sep;46(9):1134-1140. [doi: 10.3899/jrheum.170990] [Medline: 30988126]
8. Oatis CA, Johnson JK, DeWan T, Donahue K, Li W, Franklin PD. Characteristics of usual physical therapy post-total knee replacement and their associations with functional outcomes. Arthritis Care Res (Hoboken) 2019 Sep;71(9):1171-1177 [FREE Full text] [doi: 10.1002/acr.23761] [Medline: 30281207]
9. Prusaczyk B, Fabbre V, Carpenter CR, Proctor E. Measuring the delivery of complex interventions through electronic medical records: challenges and lessons learned. EGEMS (Wash DC) 2018 May 25;6(1):10. [doi: 10.5334/egems.230] [Medline: 30094282]

Abbreviations

CER: comparative effectiveness research
EHR: electronic health record

XSL•FO

RenderX

HIPAA: Health Insurance Portability and Accountability Act
OA: osteoarthritis
PT: physical therapy
TKR: total knee replacement

XSL·FO
RenderX

<u>Original Paper</u>

Experiences of Persons With Executive Dysfunction in Disability Care Using a Social Robot to Execute Daily Tasks and Increase the Feeling of Independence: Multiple-Case Study

Kirstin van Dam[1], MSc; Marieke Gielissen[1,2], PhD; Rachelle Reijnders[1], MSc; Agnes van der Poel[1], PhD; Brigitte Boon[1,2,3], PhD

[1]Academy Het Dorp, Arnhem, Netherlands

[2]Siza, Arnhem, Netherlands

[3]Tranzo, Tilburg University, Tilburg, Netherlands

Corresponding Author:
Kirstin van Dam, MSc
Academy Het Dorp
Kemperbergerweg 139e, B4
Arnhem, 6816 RP
Netherlands
Phone: 31 88 377 9999
Email: kirstin.van.dam@academyhetdorp.nl

Abstract

Background: Executive functions are essential for independently navigating nearly all of our daily activities. Executive dysfunction often occurs as a result of a neurodevelopmental disorder. Persons with executive dysfunction experience challenges regarding independent execution of daily tasks. Social robots might support persons with executive dysfunction to execute daily tasks and promote their feeling of independence.

Objective: This study aimed to study the impact of interacting with social robot Tessa on goal attainment in the execution of daily tasks and perceived independence of persons with executive dysfunction.

Methods: In this multiple-case study, 18 participant–caregiver couples were followed up while using Tessa in the home environment for 3 months. Goal attainment on independently performing a self-determined goal was measured by the Goal Attainment Scale, and participant–caregiver couples were interviewed about their experience with their interaction with Tessa and how they perceived Tessa's impact on their independence.

Results: In total, 11 (61%) participants reached their goal after 6 weeks and maintained their goal after 3 months. During the study period, 2 participant–caregiver couples withdrew because of mismatch with Tessa. Participants set goals in the following domains: execution of household tasks; intake of food, water, or medication; being ready in time for an appointment; going to bed or getting out of bed on time; personal care; and exercise. Participants perceived that Tessa increased the feeling of independence by generating more structure, stimulation, and self-direction. Participant–caregiver couples reported that the auditive information provided by Tessa was more effective in coping with executive dysfunction compared to their initial approaches using visual information, and the use of Tessa had a positive impact on their relationship.

Conclusions: This study paid ample time and attention to the implementation of a social robot in daily care practice. The encouraging findings support the use of social robot Tessa for the execution of daily tasks and increasing independence of persons with executive dysfunction in disability care.

KEYWORDS

Introduction

Executive Dysfunction

Executive functions are the controlling mechanisms of the brain and enable us to plan, focus attention, remember instructions, and initiate and manage multiple tasks [1]. Executive function is defined as "the overarching regulation of goal-directed, future-oriented, higher-order cognitive processes" [2]. Executive functions are needed for goal-oriented behavior and responding to novel situations or solving problems [3]. They are essential for independently navigating nearly all of our daily activities. Executive dysfunction often occurs as a result of a neurodevelopmental disorder [4-6]. Persons with executive dysfunction experience problems with organizing and planning, such as being on time for appointments, executing household chores, and remembering and transferring information [7]. Executive dysfunction may also have a significant emotional impact and can lead to stress and feelings of anxiety, frustration, and embarrassment [8]. Moreover, executive abilities are linked with functions essential for independently executing daily tasks [9,10]. As such, executive dysfunction may impact the feeling of independence in daily life [3].

Technology to Increase Independence

Technology is increasingly used in disability care [11]. It can improve planning and memory among persons with executive dysfunction and might support the execution of daily tasks [12-14]. For example, Desideri et al [13] found that mobile devices and apps help to self-monitor attention-related behaviors while performing a task. Other studies showed that technology can be an important asset for optimizing independence for persons with acquired brain injury or intellectual disability [15,16]. Remote support services and smart home systems were found to promote independent living and enable persons to lead self-determined lives. A focus group of persons with intellectual disability, their relatives, and professional caregivers expressed that eHealth applications increased independence and provided more efficient support for daily functioning of persons with intellectual disability [17].

Social Robots

A social robot is a specific kind of technology that has been investigated in older persons but can also be of interest for persons with executive dysfunction in disability care. Among older individuals with or without dementia, the advantages of social robots are reported in relation to self-reliance, security, and emotional well-being [18]. In disability care, social robots have been a topic of interest but are mainly implemented and researched among children with autism spectrum disorder to train social behavior [19]. Recently, there has been an increasing focus on the use of social robots for adults with intellectual disabilities [20,21]. These studies report preliminary positive effects, mainly on engagement, which Shukla et al [21] defined as "the process by which individuals involved in an interaction start, maintain and end their perceived connection to one another."

Tessa is a social robot that has been developed in the Netherlands for and in co-creation with persons with executive dysfunction. Tessa is a low-complexity, easy-to-use robot with agenda functionalities. This study in everyday care practice examines the effect of Tessa on execution of daily tasks and perceived independence, focused on persons with self-reported executive dysfunction in disability care. The following research questions will be answered: (1) Do participants attain their goals on execution of daily tasks by interacting with Tessa? (2) How did the participants experience the interaction with Tessa and perceive her impact on their independence?

Methods

Design and Participants

In this multiple-case study, participant–caregiver couples were recruited via purposive sampling from a Dutch disability care organization. Persons with self-reported executive dysfunction and their professional caregivers were recruited through (1) a web-based advertisement on the intranet for employees of the care organization, (2) innovation experts within the care organization, and (3) word of mouth among colleagues. Persons expressing a care need regarding executive dysfunction were eligible to take part in the study when they (1) received care (either inpatient or ambulatory) from the care organization, (2) had legal capacity and were aged 18 years or older, (3) were able to follow verbal instructions, and (4) understood the Dutch language. Participants used Tessa in their home environment for 3 months. The participant–caregiver couple was assessed at 3 time points: at the start before using Tessa (T0), halfway after using Tessa for 1.5 months (T1), and at the end of the study period (T2).

Ethical Considerations

This study was exempted from ethical approval by the Medical Ethical Review Committee of Utrecht (19/549). Participants were provided verbal and written information about the study, and informed consent was obtained prior to start of the study.

Materials and Procedure

Tessa is a social robot with a design that resembles a flowerpot and has a height of 30 cm, blinking light-emitting diode–lit eyes, and a female voice (see Figure 1). It is designed to take in a cozy presence in the daily living spaces of its users. Tessa runs on electricity and functions via Wi-Fi connection. She provides vocal reminders of activities, tasks, or tips at a preset time to activate and support persons with executive dysfunction. Such notifications are custom programmed in a personal web app account, for which no broad digital skills are necessary.

Figure 1. Social robot Tessa provides vocal reminders and tips at a preset time to activate and support persons with executive dysfunction in their daily activities and tasks.

Social robot Tessa is distinctive from other technologies with similar purposes (eg, digital boards and apps on smartphones or tablets) because reminders are provided in the form of auditive instead of visual information. Participants of this study were interested in testing Tessa because Tessa fit their needs of receiving auditive information, which was confirmed by their caregivers.

In this study, participants used Tessa in their home environment for a period of 3 months. The researchers (KvD or RR) met with the participants at the aforementioned 3 time points during this period.

In this first visit, the following activities were carried out: (1) the researcher installed Tessa and trained the participant–caregiver couple to use it; (2) the participant–caregiver couple decided on a goal that was to be monitored during the study period, using the Goal Attainment Scale (GAS; see below); together with the researcher, they drew up the notifications belonging to this goal and programmed Tessa's web app; (3) the participant–caregiver couples were interviewed about their expectations of using Tessa; and (4) the researcher instructed the participant–caregiver couples that in the following 3 months, they were free to change or add notifications (those related to the monitored goal or to additional goals) and that they could contact a help desk provided by the researchers in case of questions or requests for help in between contact moments.

Further, the researchers monitored a dashboard to determine whether the Tessas were active on the internet. In case a Tessa was offline for a period longer than 24 hours, the researchers contacted the corresponding participant–caregiver couple.

Outcome Measures

Characteristics of Participants and Caregivers

Demographic characteristics of both participants (age, sex, and living situation) and caregivers (sex and occupation) and type of disability of the participants were assessed at T0.

Goal Attainment

The effect of using Tessa on independently performing a daily task was measured using the GAS [22]. At T0, each participant–caregiver couple chose 1 goal to be monitored during the research period. The researcher formulated this goal into attainment levels (decline; baseline; progress, but less than the goal; goal—see examples of the levels of attainment in Table 1) in agreement with the participant–caregiver couple. At T1 and T2, self-reported attainment of the goal was scored in accordance with the GAS (see scoring of goal attainment in Table 1). To gain insight on additional goals for which Tessa was used, we examined scripts containing the messages that the participant–caregiver couple placed in Tessa's web app during the study period. Additional goals were not monitored.

Table 1. Goal attainment levels in the Goal Attainment scale, scoring, and example attainment levels of a goal (drinking 4 glasses of water in a day).

Score	Attainment[a]	Definition
−1	Decline	There is a decline compared to baseline: "Participant drinks less than two glasses of water (0.8 litres) in a day"
0	Baseline	There is no change compared to baseline: "Participant drinks two glasses of water (0.8 litres) in a day"
+1	Progress, but less than goal	There is progress, but the goal has not been attained: "Participant drinks more than two glasses, but less than four glasses (0.8-1.2 litres) of water in a day"
+2	Goal	The goal has been attained: "Participant drinks four glasses of water (1.2 litres) in a day"

[a]Two levels of the original Goal Attainment Scale were excluded (ie, "more than goal," and "much more than goal"), as they were not applicable to the majority of the goals set and monitored in this study.

Participants' Experiences and Perceived Impact on Independence

Participants were interviewed face to face at 3 time points: at T0 to focus on their expectations and at T1 and T2 to focus on their experiences of using Tessa. The main questions at T0 were the following: (1) "Why do you want to use Tessa?" (2) "How do you think Tessa will help you? What do you think will change compared to your current situation? And how would you feel about that?" The main questions asked at T1 and T2 were the following: (1) "Does Tessa help you in your daily life? And how and why is that?" (2) "Do you experience any changes since you started using Tessa? And how does that make you feel?" (3) "What do you like about Tessa and what do you not like?" (4) "How do you feel about Tessa reminding you of things compared to other people reminding you about them?" Participants were supported by their caregiver in verbally indicating their answers when needed. Caregivers shared their own insights after the participants had shared theirs. Interviews had a duration from 20 to 60 minutes each.

Data Analysis

Data were pseudonymized and safely stored on a secure server. Descriptive statistics (frequencies and means) were used to describe the sample and GAS scores. Participants' goals were grouped and assigned to domains. Semistructured interviews were audio recorded and transcribed verbatim with the use of pseudonyms. Data were managed with the use of Atlas.ti (version 8.4.20; ATLAS.ti Scientific Software Development GmbH) and coded separately by 2 researchers (KvD and RR). They conducted thematic analysis as an iterative process of familiarization with the data, generating initial codes, searching for and reviewing themes, and defining and naming themes [23]. Codes and themes were discussed between the 2 researchers and a third researcher (MG) until consensus was reached.

Results

Overview

All results are visually summarized in Figure 2.

Figure 2. Overview of findings.
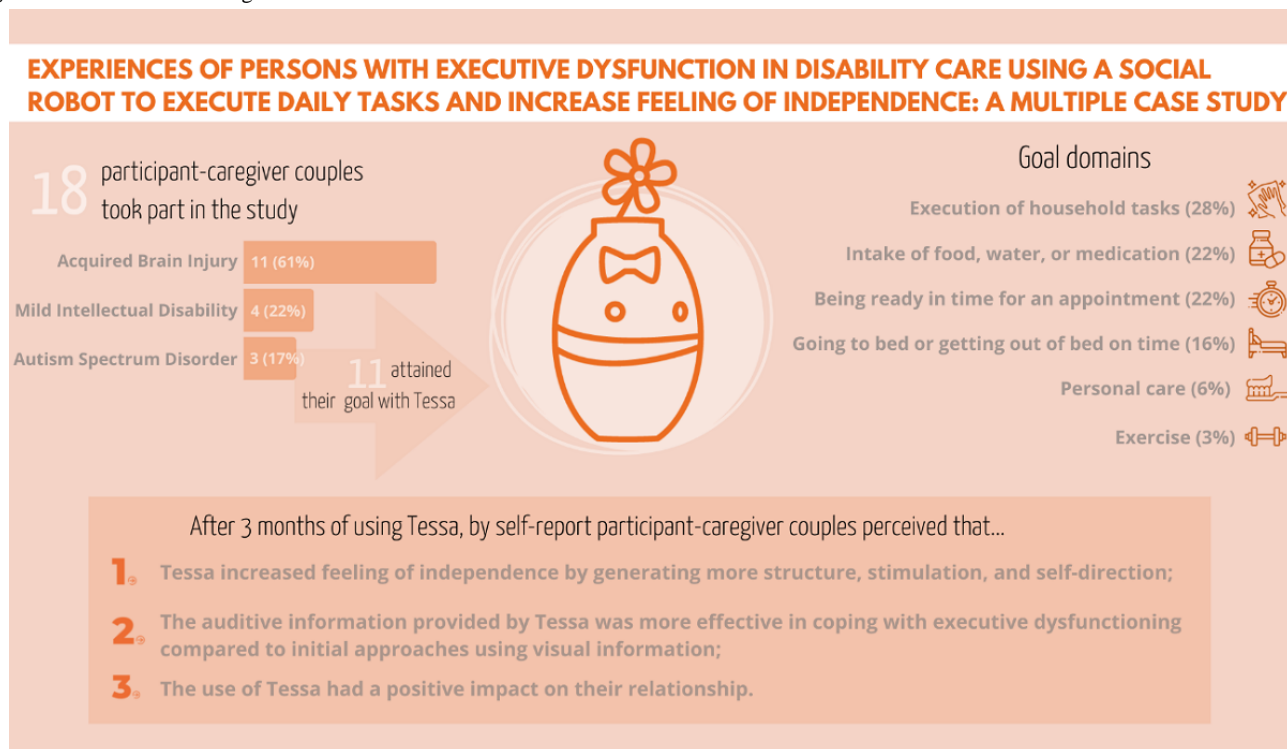
Participants

In total, 18 participant–caregiver couples participated in the study (see Table 2). In 3 cases, a caregiver dropped out of the study owing to long-term absence or sickness. In these situations, another caregiver was asked to participate in the study. In total, 2 of 18 participant–caregiver couples withdrew early on during the study period because the participant experienced irritation or stress as a reaction to Tessa instead of feeling motivated by her. Complete data were obtained for the remaining 16 participant–caregiver couples.

Table 2. Characteristics of participants and caregivers.

Characteristics	Values
Participants (n=18)	
Age (years), mean (range)	41 (18-63)
Sex, n (%)	
Male	10 (56)
Female	8 (44)
Disability, n (%)	
Acquired brain injury	11 (61)
Mild intellectual disability	4 (22)
Autism spectrum disorder	3 (17)
Type of care, n (%)	
Inpatient care	8 (44)
Ambulatory care	10 (56)
Caregivers (n=17)[a]	
Sex, n (%)	
Male	4 (24)
Female	13 (76)
Occupation, n (%)	
Inpatient caregiver	8 (47)
Ambulatory caregiver	7 (41)
Cognitive therapist	2 (12)

[a]One caregiver participated with 2 participants.

Use and Acceptance of Tessa

The Tessa account of 3 participants was offline for a short period. Two participants did not use Tessa during the Christmas holidays—one for 1 week and the other for 2 weeks. One other participant did not use Tessa for 1 week owing to personal reasons. The Tessa accounts of all other participants were continuously in use throughout the study period.

Acceptance of Tessa is crucial for using Tessa appropriately and following her reminders. During the interviews, participants mentioned a feeling of connectedness to Tessa. Several participants stated that they thought Tessa was funny or made them happy. Some said that they viewed Tessa as a buddy or that they felt less lonely because of her presence in their home. However, at times, some participants also experienced irritation because of Tessa. When they were overstimulated or stressed already owing to other factors, these participants sometimes perceived Tessa's notifications as unpleasant.

> *The funny thing is that if she asks, 'Are you getting ready for bed?', I react, 'Yes, I am', despite knowing that it's programmed and not spontaneous. She's got something.* [Participant with an acquired brain injury]

> *At those moments I'm really angry and I think; please, take away that doll! At one moment I had enough of it in such a way that I pulled Tessa's plug: I am done with this.* [Participant with a mild intellectual disability]

Goal Domains and Attainment

Each participant–caregiver couple set one primary goal that was monitored with the GAS. These 18 goals were grouped into 6 domains (see Table 3). Participant–caregiver couples were free to program notifications on additional goals in Tessa as well. On average, participants included 4 (range 1-8) additional goals. For these 34 additional goals (Table 4), one new domain emerged: leisure activities, such as taking time to sing, dance, or take a walk outside. The other additional goals were congruent with the previously established domains. All goals were equally distributed over domains, regardless of disability or type of care. Table 3 shows that at T1, 61% (11/18) of participants reached their primary goal. At T2, 72% (13/18) of

participants were able to execute daily tasks and activities as they aspired. Out of the 5 participants who did not attain their goal, 2 withdrew owing to negative responses to Tessa, and 3 of them missed Tessa's messages owing to them not being at home or in a different part of the house during these moments.

At T2, participants were asked whether they would like to continue using Tessa. Two participants decided to discontinue using Tessa; one of them reached their primary goal, while the other did not. Both of them had a relatively large house, which caused them to not always hear notifications, thus missing Tessa's messages. A total of 14 participants chose to keep using Tessa; 2 of them did not yet reach their primary goal; nonetheless, they experienced support of Tessa.

Table 3. Domains: primary goal, disability, type of care, and Goal Attainment Scale (GAS) scores of participants at T1[a] and T2[b] (n=18).

Example primary goals grouped in domains	Disability	Care	GAS score at T1	GAS score at T2
Execution of household tasks (n=5, 28%)				
Hand in cellphone to caregiver on time 3 times a week	Autism spectrum disorder	Inpatient	1	2
Vacuum-clean sleeping room once a week	Autism spectrum disorder	Ambulatory	2	2
Do the dishes every evening	Acquired brain injury	Inpatient	2	2
Make a grocery list (in an app) once a week[d]	Acquired brain injury	Ambulatory	—[c]	—
Bring laundry downstairs twice a week[d]	Acquired brain injury	Ambulatory	—	—
Intake of food, water, or medication (n=4, 22%)				
Drink 1 glass of water in the morning	Mild intellectual disability	Inpatient	1	2
Drink 1.2 L of water every day	Acquired brain injury	Ambulatory	2	2
Take medicine on time 4 times a day	Mild intellectual disability	Inpatient	2	2
Take medicine on time 3-6 times a week	Acquired brain injury	Ambulatory	2	2
Being ready in time for an appointment (n=4, 22%)				
Leave on time for volunteering work once a week	Acquired brain injury	Ambulatory	2	2
Be on time for taxi to day-care 2 days a week	Mild intellectual disability	Inpatient	2	2
Leave on time for day-care 3 days a week	Acquired brain injury	Inpatient	1	0
Leave on time for day-care 2 days a week	Mild intellectual disability	Ambulatory	0	0
Going to bed or getting out of bed on time (n=3, 16%)				
Get out of bed within half an hour every day	Autism spectrum disorder	Inpatient	2	2
Do night routine and go to bed on time every night	Acquired brain injury	Ambulatory	2	2
Go to sleep before 11:15 PM every night	Acquired brain injury	Ambulatory	2	2
Personal care (n=1, 6%)				
Shave in the morning every day	Acquired brain injury	Inpatient	2	2
Exercise (n=1, 6%)				
Do back exercises in the home gymnasium once a week	Acquired brain injury	Ambulatory	0	0

[a]T1: 6 weeks.

[b]T2: 3 months.

[c]Not available.

[d]These participants withdrew, their goals were not monitored.

Table 4. Domains: additional goals of participants (n=18).

Domains	Participants, n (%)
Execution of household tasks	6 (33)
Intake of food, water, or medication	7 (39)
Being ready in time for an appointment	7 (39)
Going to bed or getting out of bed on time	5 (28)
Personal care	4 (22)
Exercise	1 (6)
Leisure activities[a]	4 (28)

[a]New domain—this domain was not reported for the primary goals.

Perceived Impact of Tessa on Independence

Qualitative data analysis revealed that participants perceived that Tessa impacted their independence through 3 elements: structure, stimulation, and self-direction. No differences in perceived effects were found for disability and type of care.

Structure

Participants valued the repetitiveness of Tessa and the fixed moments of her messages, which, for some participants, even served as training to build new habits. Some participants appreciated the stability of Tessa's fixed spot in the house. Tessa also helped participants to have a sense of time, which is something they struggled with beforehand. Participants explained that structure in their daily lives helps them to "get into a rhythm," which gives them clarity and rest.

> *Very often I'm too late or much too early, because I can't estimate the time properly. Now when I have an appointment, Tessa says half an hour in advance, 'Remember, you have an appointment later. Get ready." This is like a helping hand.* [Participant with an acquired brain injury]

> *Sometimes we come ten minutes late or, you know, something always happens. And Tessa is always on time.* [Caregiver of participant with autism spectrum disorder]

Stimulation

Participants perceived that Tessa stimulated them to be active, which caused them to be and feel less dependent on stimulation from others to perform their daily tasks and activities. The stimuli of Tessa's messages were an active reminder to do something. Both participants and caregivers emphasized that Tessa's verbal instructions were far more stimulating than visual reminders (such as app notifications or sticky notes). They described Tessa's reminders as a "wake-up call" or "hint."

> *The activities programmed in Tessa are now much easier for me to execute. Now I pack my bag on time, not fifteen minutes late.* [Participant with autism spectrum disorder]

> *It's very nice to see that verbal information makes a difference, because we have been working towards structure for years. We tried different things: an app, calendar, whiteboard… They didn't work, as he forgot*

to check them. Which made him miss the appointment. He pushes the notification away on his mobile, and it's done. Tessa can repeat a message and thus gives a reminder that he can't push away. [Caregiver of participant with an acquired brain injury]

Self-direction

Participants perceived a sense of self-direction, as Tessa enables them to have more control over their lives and to make their own decisions. At T0, many participants expressed the aspiration that Tessa would help them be less reliant on reminders of others, which at T1 and T2 had actually happened. Both participants and caregivers confirmed that less unplanned contact was needed between them because of the reminders of Tessa. Participants explained how reminders of Tessa felt different than reminders of others.

> *What I really like about Tessa is that I put messages in it myself. Then, when Tessa says something, I know I want it myself. It feels more my own, it doesn't come from others. Instead of others telling me to do something.* [Participant with autism spectrum disorder]

> *Because Tessa helps me remember things, such as brushing my teeth, I am less irritated. It makes me feel good that caregivers no longer say it.* [Participant with a mild intellectual disability]

Caregivers

As the quotes imply, caregivers were positive about the use and effects of Tessa on participants' independence. Moreover, caregivers explained that they experienced positive effects of Tessa on their relation with the participant. With Tessa reminding the participant, caregivers experienced less of a burden and felt less friction between them and the participants. Furthermore, instead of spending the majority of time on practical issues, they were now able to spend more time on discussing more profound topics relevant to the participant. As an example of such topics, caregivers mentioned emotional or social issues such as the participant's stress regulation or social network.

> *We have more time for other things, because we're not constantly busy with reminding. We can instead focus a bit more on support and counselling, not only*

the very practical daily tasks. [Caregiver of participant with autism spectrum disorder]

It also relieves us a bit. Sometimes other situations have priority. When we need to be with someone who is having an epileptic seizure, for example, we can't be here to remind the participant to put on his jacket. In that moment Tessa is still reminding him, so we know it will be fine. [Caregiver of participant with a mild intellectual disorder]

Discussion

Principal Findings

This study provides encouraging findings supporting the use of social robot Tessa for the execution of daily tasks and increasing independence of persons with executive dysfunction in disability care. In total, 18 participants stated goals in the following domains: execution of household tasks; intake of food, water, or medication; being ready in time for an appointment; going to bed or getting out of bed on time; personal care; and exercise. For additional purposes, participants used Tessa for the same domains and to remind them to perform leisure activities. A total of 11 (61%) participants reached their goal after 6 weeks (T1) and maintained their goal after 3 months (T2). Tessa increased participants' independence by generating more structure, stimulation, and self-direction. Considering our results between the type of disability (autism spectrum disorder, acquired brain injury, and mild intellectual disability) and type of care (inpatient versus ambulant care), no differences were found in the type of goals that were stated, attainment of the primary goals, and perceived impact on independence by participants. All caregivers were positive about the use of Tessa in the care for persons with executive dysfunction. The caregivers and participants reported that the auditive information provided by Tessa was more effective in coping with executive dysfunction than their initial approaches using visual information; in addition, the use of Tessa had a positive impact on their relationship.

The findings of this study show that in the majority of cases, Tessa was suitable to reach personal goals and increase independence in persons with executive dysfunction in disability care. However, in some cases Tessa was not helpful owing to mismatch. Tessa's messages were not always heard by participants who lived in a big house or had irregular schedules, and 2 participants stopped using Tessa as they experienced irritation or stress as a reaction to Tessa's notifications. As preferences and needs differ from person to person, a person-oriented approach in deciding whether or not and how to deploy Tessa is essential. At the same time, the use of technologies such as Tessa may support the person-centeredness of care [24], as it initiates conversation about the goals and challenges of persons with executive dysfunction and how they want to work toward reaching or overcoming these. In using

Tessa, the participant and caregiver started by setting personal goals and placing corresponding messages in Tessa, and they evaluated these together over time.

Comparison With Prior Work

To our knowledge, this is the first study that reports on the effect of a social robot for the execution of daily tasks and independence of persons with executive dysfunction in disability care. The existing literature mainly describes the deployment of social robots in therapy and care for purposes related to support for teaching social behavior to children with autism spectrum disorder or to companionship or assistance to older individuals in the home environment [25]. Similar results were found in studies examining a different technology with the same objectives [26-29]. Several studies observed that smartphone-based systems supported persons with intellectual disability to successfully start and carry out daily activities [26-28], and O'Neill et al [29] found that interactive prompting technology reduced the support needed for the morning routine of persons with executive dysfunction due to acquired brain injury.

Limitations

This study paid ample time and attention to the implementation of Tessa, as a good implementation process is not only important for successful dissemination of interventions but also has a major influence on the effectiveness of the intervention. Research shows that interventions that are well implemented are 2-12 times more effective [30]. Tessa was studied in daily care practice where caregivers already have a heavy workload owing to staff shortages. Hence, we attempted to minimize the burden on participant–caregiver couples. First, a resulting limitation of this study is the fact that we only used self-reported measurements. To gain more insight in the characteristics of the end-user of Tessa, future studies should include a multiple-format assessment using neuropsychological tests and self-report measures to assess participants' level of functioning and execution of daily activities. Second, the use of purposive sampling and therefore the heterogeneity of the sample can be seen as a limitation. The sample represents the situation in the participating organization but might not be generalizable to all populations in disability care. Future studies should preferably include large homogenous populations to determine the effect and suitability of social robots for specific target groups in disability care.

Conclusions

Technology is and will be increasingly used in disability care [31,32]. We studied the utility of social robot Tessa in disability care practice and found it to be a helpful technology for different target groups that experience challenges owing to executive dysfunction. These promising results are an example of how technology can support the independence of persons in disability care.

XSL•FO

RenderX

Data Availability

The data that support the findings of this study are available on request from the corresponding author.

Conflicts of Interest

None declared.

References

1. Evans J. Rehabilitation of executive deficits. In: Neuropsychological Rehabilitation: Theory and Practice. London: CRC Press; 2003:53-70.

2. Demetriou EA, DeMayo MM, Guastella AJ. Executive function in autism spectrum disorder: history, theoretical models, empirical findings, and potential as an endophenotype. Front Psychiatry 2019;10:753 [FREE Full text] [doi: 10.3389/fpsyt.2019.00753] [Medline: 31780959]

3. Chung CSY, Pollock A, Campbell T, Durward BR, Hagen S. Cognitive rehabilitation for executive dysfunction in adults with stroke or other adult non-progressive acquired brain damage. Cochrane Database Syst Rev 2013 Apr 30(4):CD008391 [FREE Full text] [doi: 10.1002/14651858.CD008391.pub2] [Medline: 23633354]

4. Rabinovici GD, Stephens ML, Possin KL. Executive dysfunction. Continuum (Minneap Minn) 2015 Jun;21(3 Behavioral Neurology and Neuropsychiatry):646-659 [FREE Full text] [doi: 10.1212/01.CON.0000466658.05156.54] [Medline: 26039846]

5. Panerai S, Tasca D, Ferri R, Genitori D'Arrigo V, Elia M. Executive functions and adaptive behaviour in autism spectrum disorders with and without intellectual disability. Psychiatry J 2014;2014:941809 [FREE Full text] [doi: 10.1155/2014/941809] [Medline: 24829905]

6. Stuss DT. Traumatic brain injury: relation to executive dysfunction and the frontal lobes. Curr Opin Neurol 2011 Dec;24(6):584-589. [doi: 10.1097/WCO.0b013e32834c7eb9] [Medline: 21968550]

7. ter Stal M, Patel S, de Groot V, Gielissen M, van der Poel A, Boon B. Verbeteren van dagstructuur bij mensen met niet-aangeboren hersenletsel (NAH) door inzet van technologie. 2021. URL: https://docplayer.nl/219076082-Verbeteren-van-dagstructuur-bij-mensen-met-niet-aangeboren-hersenletsel-nah-door-inzet-van-technologie-innovatie-impuls-van-volwaardig-leven.html [accessed 2022-03-15]

8. Larsson Lund M, Lövgren-Engström AL, Lexell J. Using everyday technology to compensate for difficulties in task performance in daily life: experiences in persons with acquired brain injury and their significant others. Disabil Rehabil Assist Technol 2011;6(5):402-411. [doi: 10.3109/17483107.2011.574309] [Medline: 21500979]

9. Nguyen CM, Copeland CT, Lowe DA, Heyanka DJ, Linck JF. Contribution of executive functioning to instrumental activities of daily living in older adults. Appl Neuropsychol Adult 2020;27(4):326-333. [doi: 10.1080/23279095.2018.1550408] [Medline: 30646749]

10. Cahn-Weiner DA, Boyle PA, Malloy PF. Tests of executive function predict instrumental activities of daily living in community-dwelling older individuals. Appl Neuropsychol 2002;9(3):187-191. [doi: 10.1207/S15324826AN0903_8] [Medline: 12584085]

11. Zander V, Gustafsson C, Landerdahl Stridsberg S, Borg J. Implementation of welfare technology: a systematic review of barriers and facilitators. Disabil Rehabil Assist Technol 2021 Jun 15:1-16. [doi: 10.1080/17483107.2021.1938707] [Medline: 34129802]

12. Torra Moreno M, Canals Sans J, Colomina Fosch MT. Behavioral and cognitive interventions with digital devices in subjects with intellectual disability: a systematic review. Front Psychiatry 2021;12:647399 [FREE Full text] [doi: 10.3389/fpsyt.2021.647399] [Medline: 33927655]

13. Desideri L, Lancioni G, Malavasi M, Gherardini A, Cesario L. Step-instruction technology to help people with intellectual and other disabilities perform multistep tasks: a literature review. J Dev Phys Disabil 2020 Nov 17;33(6):857-886. [doi: 10.1007/s10882-020-09781-7]

14. Gillespie A, Best C, O'Neill B. Cognitive function and assistive technology for cognition: a systematic review. J Int Neuropsychol Soc 2012 Jan;18(1):1-19. [doi: 10.1017/S1355617711001548] [Medline: 22152338]

15. Jamwal R, Jarman HK, Roseingrave E, Douglas J, Winkler D. Smart home and communication technology for people with disability: a scoping review. Disabil Rehabil Assist Technol 2022 Aug;17(6):624-644. [doi: 10.1080/17483107.2020.1818138] [Medline: 32924660]

16. Tassé MJ, Wagner JB, Kim M. Using technology and remote support services to promote independent living of adults with intellectual disability and related developmental disabilities. J Appl Res Intellect Disabil 2020 May;33(3):640-647. [doi: 10.1111/jar.12709] [Medline: 32050053]

17. Frielink N, Oudshoorn CEM, Embregts PJCM. eHealth in support for daily functioning of people with intellectual disability: Views of service users, relatives, and professionals on both its advantages and disadvantages and its facilitating and impeding factors. J Intellect Dev Disabil 2020 Apr 19;46(2):115-125. [doi: 10.3109/13668250.2020.1744878]

XSL•FO
RenderX

18. Góngora Alonso S, Hamrioui S, de la Torre Díez I, Motta Cruz E, López-Coronado M, Franco M. Social robots for people with aging and dementia: a systematic review of literature. Telemed J E Health 2019 Jul;25(7):533-540. [doi: 10.1089/tmj.2018.0051] [Medline: 30136901]

19. Kumazaki H, Muramatsu T, Yoshikawa Y, Matsumoto Y, Ishiguro H, Kikuchi M, et al. Optimal robot for intervention for individuals with autism spectrum disorders. Psychiatry Clin Neurosci 2020 Nov;74(11):581-586 [FREE Full text] [doi: 10.1111/pcn.13132] [Medline: 32827328]

20. Mitchell A, Sitbon L, Balasuriya S, Koplick S, Beaumont C. Social robots in learning experiences of adults with intellectual disability: an exploratory study. 2021 Presented at: 18th IFIP TC 13 International Conference; August 30-September 3, 2021; Bari. [doi: 10.1007/978-3-030-85623-6_17]

21. Shukla J, Cristiano J, Oliver J, Puig D. Robot assisted interventions for individuals with intellectual disabilities: impact on users and caregivers. Int J of Soc Robotics 2019 Feb 1;11(4):631-649. [doi: 10.1007/s12369-019-00527-w]

22. Barbieri T, Fraternali P, Bianchi A, Tacchella C. Autonomamente: using goal attainment scales to evaluate the impact of a multimodal domotic system to support autonomous life of people with cognitive impairment. 2010 Presented at: 12th International Conference, ICCHP 2010; July 14-16, 2010; Vienna. [doi: 10.1007/978-3-642-14097-6_52]

23. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]

24. Chu CH, Ronquillo C, Khan S, Hung L, Boscart V. Technology recommendations to support person-centered care in long-term care homes during the COVID-19 pandemic and beyond. J Aging Soc Policy 2021;33(4-5):539-554. [doi: 10.1080/08959420.2021.1927620] [Medline: 34278980]

25. Cifuentes CA, Pinto MJ, Céspedes N, Múnera M. Social robots in therapy and care. Curr Robot Rep 2020 Jun 29;1(3):59-74. [doi: 10.1007/s43154-020-00009-2]

26. Lancioni GE, Singh NN, O'Reilly MF, Sigafoos J, Alberti G, Chiariello V, et al. Extended smartphone-aided program to sustain daily activities, communication and leisure in individuals with intellectual and sensory-motor disabilities. Res Dev Disabil 2020 Oct;105:103722. [doi: 10.1016/j.ridd.2020.103722] [Medline: 32623249]

27. Lancioni GE, Singh NN, O'Reilly MF, Sigafoos J, Alberti G, Del Gaudio V, et al. People with intellectual and sensory disabilities can independently start and perform functional daily activities with the support of simple technology. PLoS One 2022;17(6):e0269793 [FREE Full text] [doi: 10.1371/journal.pone.0269793] [Medline: 35696373]

28. Resta E, Brunone L, D'Amico F, Desideri L. Evaluating a low-cost technology to enable people with intellectual disability or psychiatric disorders to initiate and perform functional daily activities. Int J Environ Res Public Health 2021 Sep 14;18(18) [FREE Full text] [doi: 10.3390/ijerph18189659] [Medline: 34574584]

29. O Neill B, Best C, O Neill L, Ramos SDS, Gillespie A. Efficacy of a micro-prompting technology in reducing support needed by people with severe acquired brain injury in activities of daily living: a randomized control trial. J Head Trauma Rehabil 2018;33(5):E33-E41. [doi: 10.1097/HTR.0000000000000358] [Medline: 29194177]

30. Durlak JA, DuPre EP. Implementation matters: a review of research on the influence of implementation on program outcomes and the factors affecting implementation. Am J Community Psychol 2008 Jun;41(3-4):327-350. [doi: 10.1007/s10464-008-9165-0] [Medline: 18322790]

31. Lancioni GE, Olivetti Belardinelli M, Singh NN, O'Reilly MF, Sigafoos J, Alberti G. Recent technology-aided programs to support adaptive responses, functional activities, and leisure and communication in people with significant disabilities. Front Neurol 2019;10:643 [FREE Full text] [doi: 10.3389/fneur.2019.00643] [Medline: 31312169]

32. Prevalence of coverage of assistive technology in the European Region: a scoping review. World Health Organization. Regional Office for Europe. 2021. URL: https://apps.who.int/iris/handle/10665/344520 [accessed 2022-07-19]

Abbreviations

GAS: Goal Attainment Scale

Original Paper

Facebook Experiences of Users With Traumatic Brain Injury: A Think-Aloud Study

Reihaneh Ahmadi[1], MSc; Hajin Lim[2], PhD; Bilge Mutlu[3], PhD; Melissa Duff[4], PhD; Catalina Toma[5], PhD; Lyn Turkstra[6], PhD

[1]Department of Psychology, Neuroscience & Behaviour, McMaster University, Hamilton, ON, Canada

[2]Department of Communication, Seoul National University, Seoul, Republic of Korea

[3]Department of Computer Sciences, University of Wisconsin-Madison, Madison, WI, United States

[4]Department of Hearing & Speech Sciences, Vanderbilt University Medical Center, Nashville, TN, United States

[5]Department of Communication Arts, University of Wisconsin-Madison, Madison, WI, United States

[6]School of Rehabilitation Science, McMaster University, Hamilton, ON, Canada

Corresponding Author:
Reihaneh Ahmadi, MSc
Department of Psychology, Neuroscience & Behaviour
McMaster University
280 Main St W
Hamilton, ON, L8S 4L8
Canada
Phone: 1 905 525 9140
Email: reihaneh.ahmadi24@gmail.com

Abstract

Background: A critical gap in our knowledge about social media is whether we can alleviate accessibility barriers and challenges for individuals with traumatic brain injury (TBI), to improve their social participation and health. To do this, we need real-time information about these barriers and challenges, to design appropriate aids.

Objective: The aim of this study was to characterize the ways people with TBI accessed and used social media websites and understand unique challenges they faced.

Methods: We invited 8 adults with moderate to severe TBI to log onto their own Facebook page and use it as they regularly would while *thinking aloud*. Their comments were recorded and transcribed for qualitative analysis. We first analyzed participants' utterances using a priori coding based on a framework proposed by Meshi et al to classify adults' motives for accessing social media. We next used an open coding method to understand the *challenges* that people with TBI faced while using Facebook. In other words, we analyzed participants' needs for using Facebook and then identified Facebook features that made it challenging for them to meet those needs.

Results: Participants used all categories of codes in the framework by Meshi et al and provided detailed feedback about the Facebook user interface. A priori coding revealed 2 dimensions that characterized participants' Facebook use: whether they were active or passive about posting and self-disclosure on Facebook and their familiarity and fluency in using Facebook. The open coding analysis revealed 6 types of challenges reported by participants with TBI, including difficulty with language production and interpretation, attention and information overload, perceptions of negativity and emotional contagion, insufficient guidance to use Facebook, concerns about web-based scams and frauds, and general accessibility concerns.

Conclusions: Results showed that individuals with TBI used Facebook for the same reasons typical adults do, suggesting that it can help increase social communication and reduce isolation and loneliness. Participants also identified barriers, and we propose modifications that could improve access for individuals with brain injury. On the basis of identified functions and challenges, we conclude by proposing design ideas for social media support tools that can promote more active use of social media sites by adults with TBI.

KEYWORDS

XSL•FO

RenderX

Introduction

Traumatic Brain Injury and Social Participation

Social isolation is a common reality for many people with traumatic brain injury (TBI) [1,2], especially when the injury is severe enough to affect thinking and behavior. TBI-related social isolation has profound negative effects on well-being [3] and is associated with psychological symptoms such as anxiety and depression [4]. Social inclusion has the opposite effect: adults with TBI who have greater social engagement and community integration report greater life satisfaction and less emotional distress [5,6]. Social connection also plays a critical role in regaining identity after a TBI [7], which in turn is central to injury recovery [8].

Following a TBI, an individual must overcome many cognitive, physical, and psychological barriers, making it difficult for them to return to their everyday social lives [9]. Cognitive impairments in particular can cause behavioral and communication changes that are difficult for friends and family members to understand [9]. These impairments include memory problems, slower thinking speed, difficulty recognizing social cues across multiple types of media, and impairments in higher-level executive functions such as reasoning as well as behavioral and psychosocial changes and social inappropriateness [10-19]. These cognitive impairments translate into communication challenges, especially in everyday social interactions [5,16,20], and are thought to be a main contributor to loss of friendships and social isolation in the chronic phase after injury [21].

TBI and Social Media

Social media platforms may offer a mechanism for adults with TBI to increase their social connections. These platforms can provide opportunities to maintain preinjury networks and make new connections with a broad community of users. A user community can include groups with shared interests and groups with shared experience, who may be a source of support and encouragement for people with TBI, as well as groups that advocate and raise awareness about TBI. All of these provide opportunities for meaningful social interactions after injury. As noted by Brunner et al [22], regaining participation on social media platforms can be a meaningful goal for a person with TBI, and goals with personal meaning are more likely to be achieved in rehabilitation. Most platforms also provide mechanisms for asynchronous communication, a significant benefit for individuals with TBI who have difficulty understanding and producing social language under time pressure [23,24]. In adults without TBI, use of social media has been shown to provide many psychological and relational benefits, including increased social connectedness and sense of belonging, and decreased loneliness for users [25,26]; as well as opportunities for relationship maintenance [27,28]. These benefits map directly to the needs of people with TBI.

There is evidence that people with TBI want to be engaged in social media but encounter significant barriers with typical platforms that were not designed to accommodate users with cognitive impairments [1,3,29,30]. The main barriers relate to the cognitive demands of accessing and using social media,

including the need to remember how to access a site, find relevant information and ignore distractions, and understand stated and implied content, and do all of these things quickly and efficiently [30]. Social communication impairments may also prevent individuals with TBI from being able to engage appropriately with others on social media or understand content they encounter. These factors may generate a negative experience for individuals with TBI and discourage them from using social media in the future.

This Study

For individuals with TBI to benefit from social media use, it is critical to address the barriers they may encounter so we can provide solutions to overcoming those barriers. Studies to date have advanced our understanding of the needs and challenges of adults with TBI but are largely based on retrospective reflection (eg, via self-report surveys) or analysis of previous posts [29,31-33]. Retrospective recall and self-reflection can be particularly challenging for adults with TBI, who commonly have impairments in declarative recall and metacognition [34,35], and analysis of posts does not illuminate the process of accessing social media in real time.

To overcome challenges of retrospection-based methods, we used a *think-aloud* method to collect responses of adults with TBI while accessing their social media. Think-aloud methods ask participants to verbalize their thoughts and actions as they navigate and use an interface [36]. Think aloud has been widely used as a technique to understand users' system use patterns and identify usability issues in a wide variety of user interfaces [37,38]. Think aloud has been recognized as a valid tool to both collect reliable descriptions of user behaviors and also naturally encourage users to describe motivation, doubt, confusion, and challenges in using computer interfaces [37,38].

The aim of this study was to use the think-aloud method to characterize the ways people with TBI accessed and used social media websites, including challenges they faced. We focused on Facebook because it is the most popular social networking site worldwide and the dominant social media platform for adults, with 2.8 billion monthly active users, 1.84 billion of whom log on on a daily basis [39]. In our recent survey of 50 adults with TBI, Facebook also was the most commonly used platform [33]. Facebook provides a mechanism for users to build and maintain a wide range of social connections, from family, friends, colleagues, and coworkers to strangers from around the world. Facebook allows users to share messages and images with their connections and involve themselves in local events, pages they support, or groups; thus, it may be particularly useful for people with TBI as they rebuild identity and interests after injury.

Methods

Recruitment

Participants were 5 females and 3 males in the chronic stage after moderate to severe TBI. All participants were recruited from individuals and agencies providing services to adults with TBI in the local area in Southern Ontario, in Canada. Organizations providing services to individuals with TBI were

initially contacted via email and invited to share study information with adults with TBI. If an adult with TBI expressed interest in the study either they were invited to visit the university campus to participate in the study, or the principal investigator would travel to the participant's location. Participants' ages were from 26 to 64 years and the mean age of participants was 49 (SD 14.69) years. The mean years of education were 12.3 (SD 2.06) years.

Participants met the following inclusion criteria: (1) moderate to severe TBI, defined according to standard injury criteria [40], that is, loss of consciousness for 30 minutes or more, posttraumatic amnesia of 24 hours or more, and worst Glasgow Coma Scale full score in the first 24 hours of less than 13, or 13 or higher with evidence of brain damage; (2) more than 6 months post injury, as social impairments emerge in the chronic stage after injury; (3) self-identification as a native English speaker, to rule out challenges and barriers related to English proficiency; (4) aged 18 to 65 years, as individuals in this age group are the highest Facebook users [41] and to limit potential confounds due to cognitive decline with age after TBI [42]; and (5) self-reported active social media use or passive social media use (eg, observing but not posting). Average scores on neuropsychological tests were consistent with larger studies of adults with TBI [43], that is, showing impairments in task switching, processing speed, and delayed recall of verbal information

Informed Consent and Study Intake Form

Participants were provided with a consent form outlining the purpose and procedure of the study and risks and benefits. As users would be accessing their own Facebook accounts, the risks and benefits section of the consent form included specific language about Facebook's privacy policy. The first author then completed a study intake form in collaboration with each participant. The intake form consisted of questions about participants' age, sex, race, years of education, and TBI history.

Measures to Characterize the Sample

The Common Data Elements Committee for TBI research [44] recommended standardized tests that participants with TBI should complete, to characterize the sample and allow researchers to compare results obtained by different studies and publications. Per the Common Data Elements Committee recommendations, participants completed the following tests: the California Verbal Learning Test [45], Wechsler Adult Intelligence Scales Processing Speed Index tests [46], and Trails making tests A and B (Trails A and B) [47].

Think-Aloud Procedure

Participants were asked to log into their personal Facebook account on the laboratory computer and use it as they typically would while *thinking aloud*. Camtasia software [48] was used to capture a screen recording of each participants' activity while they were using their social media accounts and a video camera was physically placed in front of the participant to capture their facial expressions and body movements. The first study participant was instructed to *think aloud* while using their Facebook account for 60 minutes. If the researcher noticed that the participant was not *thinking aloud* for a period longer than

60 seconds, they would provide the participant with a reminder to do so.

On the basis of feedback from the first participant, remaining participants were instructed to use their personal Facebook account for 15 minutes while they were *thinking aloud*. We also observed that some participants had challenges simultaneously talking and accessing their Facebook pages, so we generated a list of prompt questions to use if participants did not speak while accessing their Facebook account. Prompts included the following: "Are you more comfortable socializing online or in person?"; "When you come across a public post on Facebook, are you likely to comment with other users in the comment section?"; "Who do you socialize and interact with on Facebook?"; "Are you actively posting content on your Facebook profile?"; "If you could filter out content that you see on Facebook, what would you filter out?"; "What do you think of the Facebook format?"; "Do you find it easy to use the platform?"; and "What would you change about the format?"

Ethics Approval

All documents and procedures were approved by the Hamilton Integrated Ethics Review Board (Study No. 4974).

Scoring and Data Analysis

Comments were recorded, transcribed, and segmented into turns for analysis. Turns were defined according to criteria summarized by Traum and Heeman [49] as speech by a single speaker that was syntactically complete, defined a single speech act, was an intonational phrase, and was separated by a pause. Utterances were entered into Atlas.ti [50] for analysis.

A Priori Coding

Meshi et al [51] described social media use according to a biopsychosocial framework. They proposed that social media is a platform for users to fulfill their basic human need to connect and "manage their reputation," which ultimately would result in greater well-being and enhance social connections that would promote reproductive success. The authors identified five key behaviors adults used to meet their needs for social connection and reputation management: (1) broadcasting information, including words and images that are personal or shared from others; (2) observing others' broadcasts; (3) giving feedback on others' broadcasts, for example, via *liking* posts; (4) receiving feedback on broadcasted information; and (5) engaging in social comparison, which can be by comparing posts and feedback or using metrics such as network size or relationship status. Meshi et al [51] linked these 5 uses to 3 human cognitive functions: social cognition (also known as social thinking or *mentalizing*), self-referential cognition, and social reward processing. Each cognitive function was mapped to specific neural networks, based on human and animal research in neuroscience. The Meshi et al [51] framework was intended to guide researchers in using social media to study brain functions. It worked equally well, however, to describe social media use in adults with TBI, who often have impairments in the 3 cognitive domains listed.

We chose the Meshi et al [51] framework for this study because it focused on use of social media to satisfy basic social needs,

and so provided a way or conceptualize Facebook functions for our participants. We used the 5 key behaviors described by Meshi et al [51] to create a high-level coding taxonomy. As one aim of the study was to obtain feedback specifically about Facebook, we added a coding category for Facebook feedback related to the user interface. Furthermore, 2 researchers coded each transcript, and any disagreements were resolved by discussion.

Open Coding

We used an open coding method to understand the challenges that people with TBI faced while using Facebook. For the field notes and transcriptions, we conducted an open coding process in which codes were assigned to significant instances and references using Atlas.ti [50]. The first and second authors read the field notes and transcriptions repeatedly and coded them individually. Next, we compared each other's codes and worked iteratively to find patterns and themes while resolving disagreements. To gain an in-depth understanding, we elaborated our coding schemes and analyzed relevant quotes to build rich descriptions and concrete examples of unique challenges faced by adults with TBI.

Research Team and Stance

Our study team included researchers with extensive experience in rehabilitation services for people with TBI and computer scientists who specialize in creating social computing systems based on the think-aloud method. The combined expertise of these experts provided a solid foundation for understanding social media challenges faced by adults with TBI and developing design ideas for future tools to facilitate more active social media engagement.

Results

Overview

Cognitive test scores were obtained for 7 participants and are listed in Multimedia Appendix 1. Scores were unavailable for 1 participant as the tests were added to the protocol after they had completed the study. In the following sections participants are identified by number (eg, P 1). If participants self-identified as male or female, we used gender-specific pronouns in the results; otherwise, we used gender-neutral pronouns. Raw data are available in Multimedia Appendix 2, with participant transcripts organized based on the Meshi et al [51] subthemes. A description of each theme is provided in Multimedia Appendix 2 along with the number of times the code was assigned.

A Priori Coding

Overview

Participants used all categories of codes in the Meshi et al [51] framework and also provided detailed feedback about the Facebook user interface. In some cases, participants *thought aloud* about what they were seeing on Facebook pages (eg, "There's a cow playing fetch that's pretty cool") and in others they shared comments about how and when they used Facebook, prompted by what they were seeing (eg, "Sometimes when I am nosey I go on to see what I can see"). We included both

types of comments in analysis, and in the following sections we describe themes that emerged.

Observe

The most common behavior from the Meshi et al [51] framework was to *observe* information broadcasted by others. Participants used Facebook to observe posts by paid sources, such as advertisements; news stories; socially shared videos, memes, and jokes; posts related to interests, such as musical groups and nature; and posts by others in their social networks, including friends, family, and employment-related contacts, which they used to keep up with what others "were up to." Most participants were interested in observing content posted by friends and family to see "what's going on" (P 3). Participants who were parents also used social media as a way of keeping up to date with the activities of their children. Some would scroll through to see if their children had posted anything new, while others would go through "the old pictures that [their children] have" (P 7).

Reasons for observing posts varied across participants. The sixth participant (P 6) only accessed Facebook to read things that other people posted, whereas P 5 accessed Facebook primarily for memes. P 3 indicated that she used Facebook because she was a curious person, and looking at people's posts would allow her to form a better opinion of them.

P 2 stated that Facebook was a useful research tool for her to get a better sense of what kind of people her coworkers were. For example, if she saw that one of her coworkers was the type to share inspirational quotes like "live life or live long" (P 2), she would decide to limit her interaction with that coworker because this would indicate that they would be "sensitive to anything that I say" (P 2).

Participants P 1, P 2, and P 7 talked about being a member of a TBI group on Facebook. They reported that although they were not active on the pages, they did enjoy the content they would come across on those pages. Being able to share a common space with other members of their community was understood as a type of social interaction and one that kept them engaged and entertained.

Broadcast

Meshi et al [51] stated that individuals who are using social media either broadcast information in the form of a text, picture, video, link; or post something that is not in reference to themselves but rather an article or media content that they came across somewhere else. Participants in our study did both. As an example, P 2 both generated their own posts and also posted quotes and gifs from other web-based sources:

> *Every day I say hi everybody, happy Tuesday or happy Wednesday. This is what I cooked last night I did a chicken breast with some pepper and salsa*
>
> *I do quotes every day. Like "if we take the mistake everyday of being grumpy or sour we are wasting today"* [P 2]

P 6 indicated that she used Facebook sometimes to share her political and religious views as well other facts about herself and her interest that she would like people to know:

I update my status about political topics and controversies. I also share my religious beliefs and views. I like that I can tell people something immediate happening in my life. On my profile you can see different movies and books I like. I have here some of my fav quotes [P 6]

P 7 and P 8 both indicated that they posted pictures of their families going out on trips and engaging in different activities.

Compare

Meshi et al [51] stated that individuals tend to engage in social comparison by observing what others broadcast and receive feedback on and contrast that to their own user experience. Users also can compare variables such as number of friends, relationship status, and age. As an example, in this study P 3 made some comparisons while browsing through her Facebook feed:

I don't like when people post their whole lives online. I find them to be self-absorbed like how important do you think you are? [P 3]

Provide Feedback

Meshi et al [51] noted that social media can be used to provide social feedback to others. As this feedback is visible to the poster and often to the public, it contributes to the social comparison function of social media by providing *data* people use to compare themselves with others on dimensions such as popularity and likability. Participants described providing feedback to friends and others, including emojis (P 1: "Give that a hahaha emoji"), likes, and comments. P 5 used feedback to console a family member:

My sister-in-law's sister had passed away today so she just posted a photo. I just want to put hugs on her photo for her. [P 5]

P 4, P 5, and P 6 said they only made comments if posts were by family members, although they might "like" a post if they felt strongly.

Receive Feedback

According to Meshi et al [51], users receive feedback on posts they share through likes and comments. Receiving feedback is also another contribution to the social comparison function, as this feedback is also visible to the public. Participants described receiving feedback on content they shared on their social media. Feedback was in the form of emojis, comments, getting tagged, or direct messages. P 1 received feedback about a post he shared on his timeline: "Someone's asking about the first tune."

P 7 indicated that her children posted photos of her, tagged her in other photos, or sent her messages about things she had posted on her Facebook.

Patterns of Facebook Use

The a priori coding also revealed 2 dimensions that characterized participants' Facebook use. The first dimension was whether they were active or passive about posting and self-disclosure on Facebook. Four of the participants were very active in posting, messaging, and disclosing themselves on Facebook. This included P 1, who stated the following:

I like to share my process about how I am doing things. It is more like I got up today, I brushed my teeth, so like, you know. [P 1]

The remaining 4 participants used Facebook passively, mainly focusing on observing and consuming others' posts. As P 7 replied when asked if he posted on his timeline, "No. I never have. It is not my thing."

The second dimension was familiarity and fluency in using Facebook. Four participants described high confidence and fluency in using the variety of features and functions of Facebook, whereas the other 4 reported difficulties in learning and using Facebook. The distinction in fluency appeared to relate mainly to participant age. The first 4 participants were in their 20's to 40's and described themselves as relatively tech-savvy, and they were confident and capable of using digital devices and the Facebook Interface (eg, "Everything is easy to use. It is right there basically" (P 5). The other 4 participants were in their 50 to 60s and reported challenges in accessing and using Facebook (eg, "Sometimes I have a hard time learning things. There are all these other things that go with it that I don't understand." [P 3]).

Open Coding

The open coding analysis revealed 6 major types of challenges reported by participants with TBI. Participants also provided suggestions for Facebook features and modifications that would support their access.

Difficulty With Language Production and Interpretation

Most participants expressed difficulties communicating on the web as part of the challenges they faced with social communication after their injury. As they lost contact with friends and acquaintances after injury, many of them had also lost confidence in communicating with others:

There are people I used to hang out with but I barely see them anymore...Either I scared them away or life in general I guess. [P 7]

Some of the participants were unfamiliar with the communication norms and conventions of social media, and thus felt uncomfortable communicating with others on the web:

I wouldn't do it online because I don't like social media because I can't control when to end the conversation. [P 2]

Some participants reported challenges *reading* others' emotions and intents. P 8 appeared to be uncertain about inferring the researcher's thoughts and feelings, to determine appropriateness of a comment: "I want to ask you a lot but I don't know if that's appropriate."

P 5 showed similar challenges:

But I can't stop that when I meet people I want to tell them my life history. Now you don't want to hear my life history, but I think you do. [P 5]

Some participants showed awareness of their social cognition challenges, as in P 2's comment about challenges conveying emotions:

When I am having text conversations, my sister said that my tone doesn't carry well in my text. So when you are writing something, you have to be careful with your tone because people can't read your face and tell that you are kidding or sarcastic and that just creates more problems. So that's where I struggle with this. [P 2]

P 6 likewise showed awareness of social cognition limitations in this comment:

I get self-conscious sometimes like what if what the person wrote wasn't understood by me, what if they were trying to be funny and I didn't understand the joke. I don't wanna look stupid like I didn't get what was said. [P 6]

The absence of visual and nonverbal cues also led to some participants feeling less confident about the clarity and appropriateness of their messages when communicating on the web. Because of lacking confidence in social communication, participants stated that they became overly self-conscious about their communication skills and worried about their self-image on social media. For example, P 1 wanted to have a better spell checker so that he could compose better messages to improve his social image:

My spelling is bad. So it would be nice to have spellcheck to make me look a little bit better to my friends and stuff. [P 1]

Information Overload

More than half of the participants reported they felt overwhelmed by the amount of information they received on Facebook and via the Facebook user interface:

Too much of that and too many videos keep going and going keeps going and going. It is overwhelming, sometimes too much. [P 6]

The overwhelming feelings usually stemmed from the fact that the basic Facebook interface structure presented them with a comprehensive set of Facebook features. The interface was crowded and cluttered, and they wanted to "make it less crowded" (P 7) and customize it so that they could keep only the features they used most often on the screen.

Umm I would filter out...I wish I could control this. Like I don't like the marketplace thing. I knew I am not interested in fundraiser so I would like to take them out of the side menu. [P 2]

Also, some users felt lost because they were unable to quickly locate the posts or messages they wanted to keep and follow up. Whenever they saw the Facebook newsfeed showing the new list of posts that were automatically updated and algorithmically curated, they found it difficult to keep track of information. Participants wished for an "easier way of finding things" (P 6), so that they would not have to scroll or search indefinitely:

Like there are people I follow that posted a lot of stuff on here and now they are gone, what happened? Did they get taken off? [P 3]

Furthermore, some participants found it particularly difficult to manage and catch up with notifications. This was due to some of them not knowing how to effectively manage the types and number of notifications they would receive, as illustrated in P 7's account:

I didn't know how to stop being notified of all the comments [from the post that I commented on earlier] Cuz it kept notifying me. I don't comment any more. [P 7]

As it was difficult for participants to keep track of all the notifications they received, they often forgot to respond to messages from their close friends:

My problem is that I contacted these people and then I forget [to respond to them]. Then 5 months later I am like I haven't done anything about that. [P 3]

Emotional Contagion and Emotion Overload

A few participants expressed negativity toward the posts they saw, such as having a "short tolerance for people" so they "ignore them" most of the time (P 4). A few participants also reported that they were easily influenced and triggered by emotions and topics in posts. For example, P 1 stated that he was very triggered by every topic he saw in the post, and he expressed all of his thoughts and feelings about each post. Similarly, P 7 reported that the posts from TBI survivor groups made her feel very sad: "It's nice to see things that are related to me but sometimes it makes me sad."

As a way to regulate their triggering feelings and negative thoughts while browsing their newsfeeds, P 6 suggested a mood-based filter that would curate the posts based on their mood:

I wanna see things based on my mood. If I'm happy, I don't wanna see posts about sad things. Don't make me sad. [P 6]

Insufficient Guidance to Use Facebook

Participants who were in their 50s and 60s said they did not feel they could use Facebook to its full potential because of insufficient guidance resources. In some cases, their children helped them to set up their account (eg, P 3), but they still felt that they did not have much knowledge or guidance to effectively use Facebook:

My kids put this (Facebook profile) up for me. [P 3]

I wanna see pictures my kids post. They should send them to me [directly], but they share them here. My kids tag me in their photos or they message me. I tell them to call me instead. [P 6]

Many participants found it particularly challenging to locate and retrieve information. For example, as mentioned earlier, many participants found it particularly difficult to retrieve posts they wanted to keep:

There was this one thing I saw. I wish I could find it. I always lose things I find interesting. My daughter says I can save them but that's hard anyway. [P 7]

Although Facebook offers a feature to save and retrieve posts users want to keep (the *Save* feature), many participants were not aware of it or how to use it. Particularly, they felt overwhelmed by the constantly changing interface of Facebook. When the Facebook layout they were familiar with was changed or removed, they felt confused. For example, P 6 mentioned that having to learn everything all over again made him not want to stay on Facebook:

> *It looks different every few years, which bothers me too. I get used to it then it changes, which makes me not want to use it because I have to learn again. I would stop changing it.* [P 6]

Internet Scams and Fraud

A few participants expressed concern about potential internet scams targeting people with brain injuries. P 2, who was involved in the local TBI community, stated that many TBI survivors were vulnerable to internet scams:

> *The other concern I have about this, especially for people with brain injury. When it comes to this, there is potential for fraud for people to be taken advantage of...I see a lot of fraud people take advantage of romantically. They can scam and rip people off.* [P 2]

Some of the participants were aware of potential scams, so they did not respond to people outside of their close social network:

> *I don't talk to strangers much. I get random messages, but I don't respond unless I like know them.* [P 5]

To reduce the potential risk of internet fraud, P 2 recommended limiting Facebook friends to members with something in common, such as belonging to the same TBI support group or enjoying activities together.

General Accessibility Concerns

Participants also raised the issue of general web accessibility. For example, a few participants found that on Facebook "the font is so small and very faint" (P 2), which could be a problem because "a lot of people with brain injury have trouble seeing" (P 1).

Another user stated that it was difficult for her to understand how she could stop being notified when she posts a comment on a photo. She said that, "other people started commenting [on the post] and I didn't know how to stop being notified of all the comments...so yeah, I don't comment anymore" (P 3). The same user identified problems saving posts that she would like to access later, saying, "my daughter says I can save them, but that's hard" (P 3).

Discussion

Principal Findings

We invited 8 adults with TBI to describe their thoughts and actions as they navigated their Facebook accounts. We chose the *think-aloud* method to better understand how Facebook functioned for these users, as well as their challenges and barriers, and to avoid limitations of previous studies that relied on retrospective recall and self-reflection. Participants' comments showed the 5 key social media behaviors described by Meshi et al [51], and extended beyond those, capturing important Facebook functions and barriers to use. In the following sections, we discuss both sets of results and suggest Facebook features and modifications that could address barriers identified by adults with TBI in this study.

Meshi et al [51] proposed that adults use social media to broadcast information, receive feedback, observe others, provide feedback, and compare themselves to others. These behaviors were based on how social media is used to satisfy the basic social needs of healthy individuals, to guide research in social neuroscience. We found the framework equally useful for understanding Facebook use among adults with TBI. Participants in our study showed the same social behavioral motivations as uninjured adults, and both the content and structure of their comments revealed barriers to using social media to fulfill basic social functions.

Open coding of participants' comments revealed unique challenges that adults with TBI faced while using Facebook. These challenges included structural barriers, such as distracting visual content and frequent updates that change the user interface; content barriers, such as information that triggered negative feelings; learning barriers, such as lack of accessible guides to Facebook use; and safety concerns related to the risk of internet fraud and exploitation. Participants' comments also revealed their strengths and challenges in cognitive functions needed for successful social media use, including evidence of impairments in social cognition, which have been extensively documented in the TBI literature [17,21,52-54]. Participants' comments also revealed strengths in these areas, including self-reflection on how their own social media posts could be interpreted by others. A few participants were using Facebook as a way of "keeping up with the news" (P 6). This could be a concern, given that news excerpts on Facebook are typically trimmed and not always accurate or reliable sources of news.

Comparison With Prior Work

Our results aligned with findings from previous studies on social media use in adults with TBI [3,29,32]. Adults with TBI interviewed by Brunner et al [32] reported similar feelings of being overwhelmed and cognitively fatigued by the demands of using social media and confused by technological variations across platforms. About 1 in 4 adults with TBI surveyed by Baker-Sparr et al [29] reported difficulty using social media because of their TBI-related challenges, including memory problems and general technical difficulties with site functions. Cognitive challenges may also discourage potential users from trying Facebook, as was the case with nonusers with TBI in a Facebook survey by Tsaousides et al [3]. Safety concerns were identified by participants in a few studies and were the main focus of clinicians interviewed by Brunner et al [9].

Future Directions

In addition to identifying challenges, participants recommended features that could help them to use Facebook more effectively. Table 1 summarizes the main suggestions from participants, along with our own ideas for features.

Table 1. Challenges for adults with TBI using Facebook, and features suggested by the authors to improve access.

Challenges	Feature suggestions
Difficulty with language production and interpretation	• Visual aids (emojis and appended images) • Spelling and grammar check functionality • Aids to analyze and monitor tone and meanings
Information overload	• Simpler, customizable interface • Setting that selects types of notifications • Cues to follow up with messages • An easier way to locate and search information
Emotional contagion and emotion overload	• Filter to hide posts expressing strong negative emotions • Mood-based feed curation
Insufficient guidance to use Facebook	• Way to revert back to the old interface • Interactive guide
Internet scams and fraud	• Friend request filter to limit friends to someone who shares a common connection or background
General accessibility concerns	• Larger text font and user interface elements (eg, buttons)

Supporting Language Comprehension and Production

To provide adults with TBI with resources to interpret and express the meaning and tone of text messages, future systems might encourage users to include visual cues such as images and emojis. A spelling and grammar checker that is universal across social media sites could also assist users in composing messages with more confidence. System developers can create new interfaces that automatically analyze and provide information about sentiment, tone, and emotion in texts and images using natural language and image-processing methods. These tools would support comprehension and expression of literal meaning, as well as meaning that requires mentalizing (eg, understanding others' emotions and responding appropriately).

Reducing Information Overload

Users with TBI could benefit from a simplified and customizable interface that keeps only the features that users want on the screen and allows users to control the types and number of notifications they receive. As participants reported that excessive notifications often made it difficult to follow up with meaningful relationships, system developers could also provide mechanisms to prioritize certain types of notifications and remind users to reply to high-priority notifications. Such options, however, must be presented in ways that do not overwhelm users, for example, in the forms of presets from which users can select. In addition, it would be beneficial to have simpler and more intuitive ways to store and retrieve fast-fading information, as many participants could not easily locate and keep track of the information they want to retrieve.

Minimizing Emotional Contagion and Emotion Overload

Social media sites may provide users with a customizable filter that users could set to block emotionally triggering topics and people, so that they do not have such content on their feeds.

Furthermore, a mood-based filter using sentiment analysis models could curate posts based on the user's mood.

Providing Accessible Guidance for Using Facebook

As many participants felt that there was little guidance and information on Facebook, there should be an easily accessible and universal guide to Facebook. As some participants expressed lack of confidence to learn unfamiliar features, it would be useful to provide materials or websites that would guide both users and others in their lives on how to use Facebook. Users commented on challenges with the interface changing with updates, it would be helpful to have an option to revert back to the old version of the interface, as that would reduce confusion and frustration caused by changes to the layout and features.

Protecting Users From Internet Scams

One participant suggested a filtering feature to allow users to select "Facebook friends" who have something in common, such as belonging to the same TBI support group or participating in the same activities. Such a screening process could reduce the potential risk of internet scams. In a qualitative study of rehabilitation professionals' views on social media use after TBI, Brunner et al [9] found that professionals often viewed their roles as "gatekeepers," to protect individuals with TBI from exploitation and other harms associated with social media use. If users with TBI had more control over their networks, they could have more autonomy in choosing friends rather having professionals in the gatekeeper role. Facebook allows users to control who they choose to "friend," but it is not possible to choose a subgroup of friends with whom to share a post. A friend-subgroup-selection feature could be useful, although we acknowledge that it would require a multistep routine that could be challenging for many adults with TBI.

Improving Overall Accessibility

As TBI affects visual processing abilities, future social media sites will need to make it easier for users to resize font size and user interface elements such as buttons on their websites.

Limitations

The first limitation of this study was the small sample size, with participants from the same geographic region. These limitations were unanticipated consequences of pandemic restrictions in 2020. Despite the small and relatively homogeneous sample, participants generated a range of Facebook uses and recommendations, but information from a larger sample would be informative.

A second limitation was the challenge for some participants in following the think-aloud protocol. This group of participants had impairments in speed of processing, verbal learning, and shifting between tasks. That cognitive profile represents the target population for whom we aim to improve social media access, which was a strength of the study, but use of the think-aloud method in an unstructured task like browsing might have been overly challenging. Participants also sometimes initiated conversation with the researcher on the content that they saw on Facebook rather than discussing their Facebook use. The study could have been done with the researcher outside the room, but that would be atypical for a think-aloud study and would have its own set of challenges, for example, inability to cue participants if they stopped commenting.

A third limitation of the study was that we observed users with TBI in a single session and on a device provided by the researcher, which likely did not reflect the users' experience more broadly. Participants might have used the platform differently if they were using their iPad, tablet, or mobile phone, and the appearance and functions of Facebook differ across different devices. Although this study provided useful preliminary information, future research should include extended use of the participants' preferred platform on their preferred device

Conclusions

Results of this study provided insights into the benefits and challenges of Facebook use for adults with TBI. A key finding was that participants in this study used Facebook for the same functions as typical adults, which suggests that Facebook and other social media might help reduce the social isolation and loneliness often reported by people with TBI. Although participants' intentions were like those of typical adults, their experiences were not: participants encountered significant barriers, including both features of Facebook that could be challenging to anyone, such as being bothered by advertising, and also barriers specifically due to their TBI-related cognitive impairments, such as challenges in inferring others' thoughts and feelings and expressing their own feelings and intents. As a result, Facebook use was often a frustrating experience that increased rather than decreased social isolation.

While barriers identified here were similar to those reported in previous studies of social media use after TBI [29,32,33], the think-aloud method yielded unique information about specific features of Facebook that posed challenges for users with TBI. The study findings in turn suggested modifications and technological aids that could help people with TBI succeed in the web-based social world. If supported by future studies in larger groups, these modifications, could support people with TBI in being part of web-based social and community life. As increasing social media use also can be a target of rehabilitation, the type of clinician training proposed by Brunner et al [22] also would be important, as clinicians might not have specific skills in how to support social media access for individuals with TBI.

Data Availability

Raw data are included as Multimedia Appendix 1.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Participant cognitive test scores.
[DOCX File , 14 KB - rehab_v9i4e39984_app1.docx]

Multimedia Appendix 2
Participant transcripts.
[DOCX File , 43 KB - rehab_v9i4e39984_app2.docx]

References

XSL•FO

RenderX

1. Ownsworth T, Fleming J, Tate R, Beadle E, Griffin J, Kendall M, et al. Do people with severe traumatic brain injury benefit from making errors? A randomized controlled trial of error-based and errorless learning. Neurorehabil Neural Repair 2017 Dec;31(12):1072-1082. [doi: 10.1177/1545968317740635] [Medline: 29139337]

2. Salas CE, Casassus M, Rowlands L, Pimm S, Flanagan DA. "Relating through sameness": a qualitative study of friendship and social isolation in chronic traumatic brain injury. Neuropsychol Rehabil 2018 Oct;28(7):1161-1178. [doi: 10.1080/09602011.2016.1247730] [Medline: 27802787]

3. Tsaousides T, Matsuzawa Y, Lebowitz M. Familiarity and prevalence of Facebook use for social networking among individuals with traumatic brain injury. Brain Inj 2011;25(12):1155-1162. [doi: 10.3109/02699052.2011.613086] [Medline: 21961574]

4. Gomez-Hernandez R, Max JE, Kosier T, Paradiso S, Robinson RG. Social impairment and depression after traumatic brain injury. Arch Phys Med Rehabil 1997 Dec;78(12):1321-1326. [doi: 10.1016/s0003-9993(97)90304-x] [Medline: 9421985]

5. Burleigh SA, Farber RS, Gillard M. Community integration and life satisfaction after traumatic brain injury: long-term findings. Am J Occup Ther 1998 Jan;52(1):45-52. [doi: 10.5014/ajot.52.1.45] [Medline: 9426858]

6. Williams MW, Rapport LJ, Millis SR, Hanks RA. Psychosocial outcomes after traumatic brain injury: life satisfaction, community integration, and distress. Rehabil Psychol 2014 Aug;59(3):298-305. [doi: 10.1037/a0037164] [Medline: 25019312]

7. Douglas JM. Conceptualizing self and maintaining social connection following severe traumatic brain injury. Brain Inj 2013;27(1):60-74. [doi: 10.3109/02699052.2012.722254] [Medline: 23252437]

8. Ownsworth T, Haslam C. Impact of rehabilitation on self-concept following traumatic brain injury: an exploratory systematic review of intervention methodology and efficacy. Neuropsychol Rehabil 2016;26(1):1-35. [doi: 10.1080/09602011.2014.977924] [Medline: 25384260]

9. Brunner M, Togher L, Palmer S, Dann S, Hemsley B. Rehabilitation professionals' views on social media use in traumatic brain injury rehabilitation: gatekeepers to participation. Disabil Rehabil 2021 Jul;43(14):1955-1964. [doi: 10.1080/09638288.2019.1685604] [Medline: 31694430]

10. Angeleri R, Bosco FM, Zettin M, Sacco K, Colle L, Bara BG. Communicative impairment in traumatic brain injury: a complete pragmatic assessment. Brain Lang 2008 Dec;107(3):229-245. [doi: 10.1016/j.bandl.2008.01.002] [Medline: 18267340]

11. Bogart E, Togher L, Power E, Docking K. Casual conversations between individuals with traumatic brain injury and their friends. Brain Inj 2012;26(3):221-233. [doi: 10.3109/02699052.2011.648711] [Medline: 22372410]

12. Finset A, Dyrnes S, Krogstad JM, Berstad J. Self-reported social networks and interpersonal support 2 years after severe traumatic brain injury. Brain Inj 1995;9(2):141-150. [doi: 10.3109/02699059509008187] [Medline: 7787834]

13. Shorland J, Douglas JM. Understanding the role of communication in maintaining and forming friendships following traumatic brain injury. Brain Inj 2010;24(4):569-580. [doi: 10.3109/02699051003610441] [Medline: 20235759]

14. Struchen MA, Davis LC, Bogaards JA, Hudler-Hull T, Clark AN, Mazzei DM, et al. Making connections after brain injury: development and evaluation of a social peer-mentoring program for persons with traumatic brain injury. J Head Trauma Rehabil 2011;26(1):4-19. [doi: 10.1097/HTR.0b013e3182048e98] [Medline: 21209559]

15. Channon S, Crawford S. Mentalising and social problem-solving after brain injury. Neuropsychol Rehabil 2010 Oct;20(5):739-759. [doi: 10.1080/09602011003794583] [Medline: 20526955]

16. Johnson JE, Turkstra LS. Inference in conversation of adults with traumatic brain injury. Brain Inj 2012;26(9):1118-1126. [doi: 10.3109/02699052.2012.666370] [Medline: 22642382]

17. McDonald S. Impairments in social cognition following severe traumatic brain injury. J Int Neuropsychol Soc 2013 Mar;19(3):231-246. [doi: 10.1017/S1355617712001506] [Medline: 23351330]

18. McDonald S, Flanagan S. Social perception deficits after traumatic brain injury: interaction between emotion recognition, mentalizing ability, and social communication. Neuropsychology 2004 Jul;18(3):572-579. [doi: 10.1037/0894-4105.18.3.572] [Medline: 15291735]

19. Turkstra LS. Conversation-based assessment of social cognition in adults with traumatic brain injury. Brain Inj 2008 May;22(5):397-409. [doi: 10.1080/02699050802027059] [Medline: 18415720]

20. Brown M, Gordon WA, Spielman L. Participation in social and recreational activity in the community by individuals with traumatic brain injury. Rehabil Psychol 2003 Nov;48(4):266-274. [doi: 10.1037/0090-5550.48.4.266]

21. Milders M. Relationship between social cognition and social behaviour following traumatic brain injury. Brain Inj 2019;33(1):62-68. [doi: 10.1080/02699052.2018.1531301] [Medline: 30325217]

22. Brunner M, Hemsley B, Togher L, Dann S, Palmer S. Social media and people with traumatic brain injury: a metasynthesis of research informing a framework for rehabilitation clinical practice, policy, and training. Am J Speech Lang Pathol 2021 Jan 27;30(1):19-33. [doi: 10.1044/2020_AJSLP-20-00211] [Medline: 33332986]

23. Brunner M, Hemsley B, Palmer S, Dann S, Togher L. Review of the literature on the use of social media by people with traumatic brain injury (TBI). Disabil Rehabil 2015;37(17):1511-1521. [doi: 10.3109/09638288.2015.1045992] [Medline: 25985717]

24.   VanSolkema M, McCann C, Barker-Collo S, Foster A. Attention and communication following TBI: making the connection through a meta-narrative systematic review. Neuropsychol Rev 2020 Sep;30(3):345-361. [doi: 10.1007/s11065-020-09445-5] [Medline: 32712759]

25.   Deters FG, Mehl MR. Does posting Facebook status updates increase or decrease loneliness? An online social networking experiment. Soc Psychol Personal Sci 2013 Sep 01;4(5):10.1177/1948550612469233 [FREE Full text] [doi: 10.1177/1948550612469233] [Medline: 24224070]

26.   Grieve R, Indian M, Witteveen K, Anne Tolan G, Marrington J. Face-to-face or Facebook: can social connectedness be derived online? Comput Human Behav 2013 May;29(3):604-609. [doi: 10.1016/j.chb.2012.11.017]

27.   Ellison NB, Boyd D. Sociality through social network sites. In: Dutton WH, editor. The Oxford Handbook of Internet Studies. Oxford, UK: Oxford University Press; 2013:151-172.

28.   Vitak J. Facebook makes the heart grow fonder: relationship maintenance strategies among geographically dispersed and communication-restricted connections. In: Proceedings of the 17th ACM conference on Computer supported cooperative work & social computing. 2014 Presented at: CSCW '14; February 15-19, 2014; Baltimore, MD, USA p. 842-853. [doi: 10.1145/2531602.2531726]

29.   Baker-Sparr C, Hart T, Bergquist T, Bogner J, Dreer L, Juengst S, et al. Internet and social media use after traumatic brain injury: a traumatic brain injury model systems study. J Head Trauma Rehabil 2018;33(1):E9-17 [FREE Full text] [doi: 10.1097/HTR.0000000000000305] [Medline: 28422898]

30.   Vaccaro M, Hart T, Whyte J, Buchhofer R. Internet use and interest among individuals with traumatic brain injury: a consumer survey. Disabil Rehabil Assist Technol 2007 Mar;2(2):85-95. [doi: 10.1080/17483100601167586] [Medline: 19263543]

31.   Kennedy MR. Retrospective confidence judgements made by adults with traumatic brain injury: relative and absolute accuracy. Brain Inj 2001 Jun;15(6):469-487. [doi: 10.1080/02699050010007380] [Medline: 11394967]

32.   Brunner M, Palmer S, Togher L, Hemsley B. 'I kind of figured it out': the views and experiences of people with traumatic brain injury (TBI) in using social media-self-determination for participation and inclusion online. Int J Lang Commun Disord 2019 Mar;54(2):221-233 [FREE Full text] [doi: 10.1111/1460-6984.12405] [Medline: 29873159]

33.   Morrow EL, Zhao F, Turkstra L, Toma C, Mutlu B, Duff MC. Computer-mediated communication in adults with and without moderate-to-severe traumatic brain injury: survey of social media use. JMIR Rehabil Assist Technol 2021 Aug 27;8(3):e26586 [FREE Full text] [doi: 10.2196/26586] [Medline: 34448727]

34.   Mathias JL, Mansfield KM. Prospective and declarative memory problems following moderate and severe traumatic brain injury. Brain Inj 2005 Apr;19(4):271-282. [doi: 10.1080/02699050400005028] [Medline: 15832873]

35.   Dockree PM, O'Connell RG, Robertson IH. Connecting clinical and experimental investigations of awareness in traumatic brain injury. Handb Clin Neurol 2015;128:511-524. [doi: 10.1016/B978-0-444-63521-1.00032-7] [Medline: 25701904]

36.   Nielsen J. Estimating the number of subjects needed for a thinking aloud test. Int J Human Comput Stud 1994 Sep;41(3):385-397. [doi: 10.1006/ijhc.1994.1065]

37.   Jaspers MW, Steen T, van den Bos C, Geenen M. The think aloud method: a guide to user interface design. Int J Med Inform 2004 Nov;73(11-12):781-795. [doi: 10.1016/j.ijmedinf.2004.08.003] [Medline: 15491929]

38.   Johnstone CJ, Bottsford-Miller NA, Thompson SJ. Using the Think Aloud Method (Cognitive Labs) to Evaluate Test Design for Students with Disabilities and English Language Learners. Technical Report 44. National Center on Educational Outcomes, University of Minnesota. 2006 Aug. URL: https://files.eric.ed.gov/fulltext/ED495909.pdf [accessed 2021-04-09]

39.   Facebook Reports Fourth Quarter and Full Year 2020 Results. Meta | Meta Investor Relations. 2020. URL: https://investor.fb.com/investor-news/press-release-details/2021/Facebook-Reports-Fourth-Quarter-and-Full-Year-2020-Results/default.aspx [accessed 2021-04-09]

40.   Malec JF, Brown AW, Leibson CL, Flaada JT, Mandrekar JN, Diehl NN, et al. The mayo classification system for traumatic brain injury severity. J Neurotrauma 2007 Sep;24(9):1417-1424. [doi: 10.1089/neu.2006.0245] [Medline: 17892404]

41.   Auxier B, Anderson M. Social media use in 2021. Pew Research Center. 2021 Apr 7. URL: https://www.pewresearch.org/internet/2021/04/07/social-media-use-in-2021/ [accessed 2022-04-30]

42.   Wood RL. Accelerated cognitive aging following severe traumatic brain injury: a review. Brain Inj 2017;31(10):1270-1278. [doi: 10.1080/02699052.2017.1332387] [Medline: 28686063]

43.   Dikmen SS, Corrigan JD, Levin HS, Machamer J, Stiers W, Weisskopf MG. Cognitive outcome following traumatic brain injury. J Head Trauma Rehabil 2009;24(6):430-438. [doi: 10.1097/HTR.0b013e3181c133e9] [Medline: 19940676]

44.   Wilde EA, Whiteneck GG, Bogner J, Bushnik T, Cifu DX, Dikmen S, et al. Recommendations for the use of common outcome measures in traumatic brain injury research. Arch Phys Med Rehabil 2010 Nov;91(11):1650-60.e17. [doi: 10.1016/j.apmr.2010.06.033] [Medline: 21044708]

45.   Delis DC, Kramer JH, Kaplan E, Ober BA. California Verbal Learning Test - Adult version (CVLT-II). 2nd edition. Austin, TX, USA: The Psychological Corporation; 2000.

46.   Wechsler D. Wechsler Adult Intelligence Scale. 4th edition. San Antonio, TX, USA: Pearson; 2008.

47.   Tombaugh TN. Trail Making Test A and B: normative data stratified by age and education. Arch Clin Neuropsychol 2004 Mar;19(2):203-214. [doi: 10.1016/S0887-6177(03)00039-8] [Medline: 15010086]

48.   Camtasia Studio. TechSmith Corporation. 2019. URL: https://www.techsmith.com/video-editor.html [accessed 2021-04-10]

XSL•FO
RenderX

49.   Traum DR, Heeman PA. Utterance units in spoken dialogue. In: Proceedings of the 1996 Dialogue Processing in Spoken Language Systems Workshop. 1997 Presented at: ECAI '96; August 13, 1996; Budapest, Hungary p. 125-140. [doi: 10.1007/3-540-63175-5_42]

50.   Qualitative Data Analysis 9.12. ATLAS.ti Scientific Software Development. URL: https://atlasti.com/ [accessed 2021-04-10]

51.   Meshi D, Tamir DI, Heekeren HR. The emerging neuroscience of social media. Trends Cogn Sci 2015 Dec;19(12):771-782. [doi: 10.1016/j.tics.2015.09.004] [Medline: 26578288]

52.   Milders M, Ietswaart M, Crawford JR, Currie D. Social behavior following traumatic brain injury and its association with emotion recognition, understanding of intentions, and cognitive flexibility. J Int Neuropsychol Soc 2008 Mar;14(2):318-326. [doi: 10.1017/S1355617708080351] [Medline: 18282329]

53.   McDonald S. Neuropsychological studies of sarcasm. Metaphor Symbol 2000;15(1-2):85-98. [doi: 10.1207/s15327868ms151&2_6]

54.   Muller F, Simion A, Reviriego E, Galera C, Mazaux JM, Barat M, et al. Exploring theory of mind after severe traumatic brain injury. Cortex 2010 Oct;46(9):1088-1099. [doi: 10.1016/j.cortex.2009.08.014] [Medline: 19828142]

Abbreviations

TBI: traumatic brain injury

XSL·FO
RenderX

Original Paper

Playfully Assessing Lower Extremity Selective Voluntary Motor Control in Children With Cerebral Palsy: Psychometric Study

Annina Fahr[1,2,3*], MSc; Julia Balzer[1,2*], PhD; Jeffrey W Keller[1,2,4], PhD; Hubertus J A van Hedel[1,2], PhD

[1]Swiss Children's Rehab, University Children's Hospital Zurich, Affoltern a.A., Switzerland

[2]Children's Research Center, University Children's Hospital Zurich, University of Zurich, Zurich, Switzerland

[3]Institute for Biomechanics, ETH Zurich, Zurich, Switzerland

[4]Doctoral Program Clinical Science, Faculty of Medicine, University of Zurich, Zurich, Switzerland

[*]these authors contributed equally

Corresponding Author:
Annina Fahr, MSc
Swiss Children's Rehab
University Children's Hospital Zurich
Mühlebergstrasse 104
Affoltern a.A., 8910
Switzerland
Phone: 41 44 762 52 97
Email: annina.fahr@kispi.uzh.ch

Abstract

Background: Objective measures specifically assessing selective voluntary motor control are scarce. Therefore, we have developed an interval-scaled assessment based on accelerometers.

Objective: This study provided a preliminary evaluation of the validity and reliability of this novel gamelike assessment measuring lower limb selective voluntary motor control in children with cerebral palsy (CP).

Methods: Children with CP and their neurologically intact peers were recruited for this psychometric evaluation of the assessgame. The participants played the assessgame and steered an avatar by selective hip, knee, or ankle joint movements captured with accelerometers. The assessgame's scores provide information about the accuracy of the selective movement of the target joint and the amplitude and frequency of involuntary movements occurring in uninvolved joints. We established discriminative validity by comparing the assessgame scores of the children with CP with those of the neurologically intact children, concurrent validity by correlations with clinical scores and therapists' opinions, and relative and absolute test-retest reliability.

Results: We included 20 children with CP (mean age 12 years and 5 months, SD 3 years and 4 months; Gross Motor Function Classification System levels I to IV) and 31 neurologically intact children (mean age 11 years and 1 month, SD 3 years and 6 months). The assessgame could distinguish between the children with CP and neurologically intact children. The correlations between the assessgame's involuntary movement score and the therapist's rating of the occurrence of involuntary movements during the game were moderate (Spearman $\rho=0.56$; $P=.01$), whereas the correlations of the assessgame outcomes with the Selective Control Assessment of the Lower Extremity and Gross Motor Function Classification System were low and not significant ($|\rho| \leq 0.39$). The intraclass correlation coefficients were >0.85 and indicated good relative test-retest reliability. Minimal detectable changes amounted to 25% (accuracy) and 44% (involuntary movement score) of the mean total scores. The percentage of children able to improve by the minimal detectable change without reaching the maximum score was 100% (17/17) for the accuracy score and 94% (16/17) for the involuntary movement score.

Conclusions: The assessgame proved reliable and showed discriminative validity in this preliminary evaluation. Concurrent validity was moderate with the therapist's opinion but relatively poor with the Selective Control Assessment of the Lower Extremity. We assume that the assessment's gamelike character demanded various other motor control aspects that are less considered in current clinical assessments.

Introduction

Background

A loss of selective voluntary motor control (SVMC) is a common negative sign in patients with lesions of the upper motor neuron, for instance, children with cerebral palsy (CP) [1,2]. A reduction in SVMC is defined as the impaired ability "to isolate the activation of muscles in a selected pattern in response to demands of a voluntary posture or movement" [1]. Thus, reduced SVMC manifests as involuntary movements that accompany a voluntary movement. Impaired SVMC belongs to the International Classification of Functioning, Disability, and Health Core Sets for Children and Youth with CP alongside other common impairments in this patient group (eg, spasticity, contractures, and muscle weakness) [3]. In comparison to these impairments, reduced SVMC seems to limit other body functions such as muscle strength or activities such as walking [4-8].

Despite the well-known importance of lower limb SVMC for motor activities, only a few tools are used to measure it [9]. According to the systematic review by Balzer et al [10], only 7 assessment tools for the selectivity of single-joint movements of the lower extremities have been tested for their psychometric properties in children with upper motor neuron lesions. The Selective Control Assessment of the Lower Extremity (SCALE) is considered to have the best properties. Its ordinal scoring system with 3 levels (normal, impaired, and unable) is likely to be able to classify SVMC impairments. Nevertheless, the sensitivity of the SCALE in detecting small (therapy-induced) changes could be low because of the relatively broad ordinal scoring system [10]. To address this problem, we aimed to measure SVMC more precisely on an interval-based scale and created a playful computer assessment game ("assessgame") based on accelerometers that is attractive for (young) patients [11]. It assesses SVMC in terms of both the accuracy of a selective movement of the target joint and the amplitude and frequency of involuntary movements occurring. With involuntary movements, we refer to all unintended movements that co-occur with the performance of a voluntary task (eg, mirror movements or abnormal movement synergies) [12]. A first evaluation of the assessgame and the algorithms to process the data showed that the assessgame could be a valid approach to quantify SVMC in a more attractive manner [11]. Moreover, psychometric testing showed that the assessgame is valid and reliable to measure upper extremity SVMC [13]. The assessgame metrics correlated with the Selective Control of the Upper Extremity Scale (an assessment similar to the SCALE but for the upper limbs), with higher correlation coefficients for average scores over all joints (accuracy $\rho=-0.37$, involuntary movement score $\rho=-0.55$; all $P<.05$) than for individual joints ($0.04<|\tau|<0.52$). The assessgame discriminated well between patients with upper motor neuron lesions and healthy children. Its relative reliability was good with intraclass correlation coefficients (ICCs) >0.75 for all average scores.

Objective and Hypotheses

The focus of this study was to perform a similar preliminary investigation of several psychometric properties of the assessgame for the lower limbs in children with CP. As a gold standard is lacking for measuring SVMC, we evaluated the discriminative and concurrent validity. In line with the findings for the upper limbs [13], we hypothesized that the assessgame scores would differ significantly between children with CP and neurologically intact age-matched participants. We expected the differences between patients and their healthy peers to increase with age because healthy young children may still show signs of reduced SVMC (eg, mirror movements) that recede with age [12].

For concurrent validity, we expected moderate to high correlations ($0.50\leq|\rho|\leq0.70$) between the assessgame outcomes and the SCALE. In addition, we expected low correlations ($|\rho|<0.50$) with the Gross Motor Function Classification System (GMFCS), as it is not a specific measure of SVMC. We expected high positive correlations ($|\rho|>0.70$) of the assessgame scores with a therapist's rating of movement selectivity during the game to internally validate the analysis algorithm.

Finally, we investigated the test-retest reliability of the assessgame. We considered test-retest reliability as good when ICCs exceeded 0.75 and absolute measurement errors were acceptable.

Methods

Participants

Inpatients and outpatients of the Swiss Children's Rehab of the University Children's Hospital Zurich were recruited by convenience sampling from June 2017 to March 2018. Inclusion criteria comprised a clinical diagnosis of predominantly spastic CP (ie, unilateral or bilateral spastic CP or mixed CP with distinct spastic components), an age between 6 and 18 years, and the ability to follow simple verbal instructions. Children with a primarily dystonic or ataxic impairment, those with an unstable situation regarding their tonus-regulating medications, or those who had a botulinum toxin injection within the last 6 months or any surgical correction of the lower extremity within the last year were excluded.

For establishing discriminative validity, neurologically intact children aged between 6 and 18 years were recruited. Only children without any medical history of neurological or orthopedic diagnosis within the lower extremity were included. In addition, we recruited neurologically intact adults because the algorithm for the accelerometer data analysis [11] relates children to adult references who have fully complemented the maturation of SVMC to create the final score. The inclusion criteria for this reference group were age between 18 and 50 years, no symptoms in terms of any central or peripheral neurological injury, and no surgery of the lower limbs within

the last year. An upper age limit was selected because involuntary movements were shown to increase with age [12,14].

Ethics Approval

The study was conducted in accordance with the necessary guidelines and approved by the ethical committee of the Canton of Zurich (Nr PB_2016_01843). A member of the study team explained the study to the participants and their parents and provided them with written participant information in age-adapted versions. Sufficient time was provided to reach a decision. Formal consent was obtained before any measurements were conducted. All the participants provided oral informed consent, and written informed consent was obtained from the adults, adolescents aged ≥14 years, and minors' parents. They were further informed that they may withdraw from the study at any time and that the withdrawal of consent will not affect the participant's subsequent medical treatment at the Swiss Children's Rehab.

SVMC Assessgame

On the basis of a previous publication [15], we refined the single-joint SVMC-testing concept that was at the base of the development of our assessgame "Catch the Stars." The assessgame measures SVMC by capturing (accurately) controlled target joint movements and (potentially) simultaneously occurring involuntary movements. The target movements for which SVMC can be measured with the assessgame encompass hip, knee, and ankle flexion and extension. Detailed methodological information about the assessgame can be found in our methodological paper [11]. In short, the participants had to steer an owl avatar on a predefined path made up of stars by the isolated movement of 1 selected target joint. The path consisted of upward and downward curves, lasted 30 seconds, and was presented on a screen placed in front of the participants (Figures 1A and 1B). Six pairs of 3D accelerometers were positioned bilaterally over the hip, knee, and ankle joints (Reha-Stim Medtec AG; Figure 1C). The accelerometer sensors were applied proximally (reference sensor) and distally of the joints to ensure that only movements of those particular joints but not compensatory movements influenced the avatar's motion. The game was calibrated to the participant's maximum active range of motion (ROM) of the selected target joint. For the assessment, the participants had to move within 90% of their maximum active ROM.

Figure 1. Measurement setup of the assessgame "Catch the Stars." (A and B) Screenshots from the assessgame showing the owl avatar following and collecting the stars on the target trajectory. (C) Standardized testing position and placement of 6 accelerometer pairs (master-slave) that were fixed proximally and distally to each tested joint.
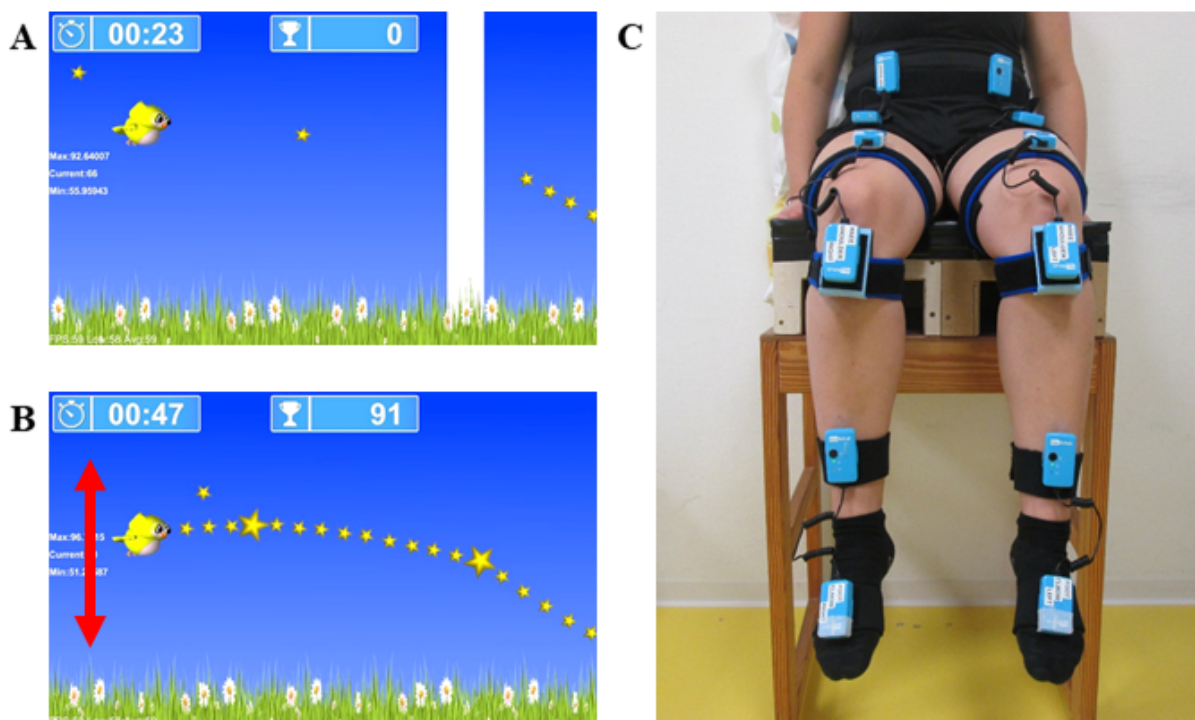
The participants performed 3 try-out trials (hip, knee, and ankle joints once on a self-selected side) to get familiarized with the game. During the actual measurement, each possible joint was selected once as the target joint (ie, resulting in a total of 6 trials) in a randomized order to control for possible learning effects. After completing the calibration, each game round started with an accommodation phase lasting 25 seconds. During this time, the children could familiarize themselves with steering the avatar by collecting a few stars at different positions on the screen.

Immediately at the end of the accommodation phase, which was visualized by a starting line, the star-studded path, that is, the target trajectory, began (Figures 1A and 1B). The participant was instructed to follow this trajectory as accurately as possible with the avatar to collect the stars by only moving the target joint and no other joints. The test phase ended with crossing the finish line after 30 seconds.

To quantify how selectively the game was played, we calculated offline for each target joint an accuracy score and an involuntary

movement score that included all simultaneously occurring movements in contralateral or adjacent joints or the trunk (refer to the study by Keller et al [11] for details). First, the data recorded during the assessgame were imported to Matlab (Matlab 2016a, The MathWorks Inc). The accelerometer data were transformed to joint angles, and the time derivative was calculated to yield the angular joint speeds (angle/second). We were interested in these changes in joint angles and not in the absolute position because they represent the movements that occurred while playing the game. We replaced occasionally missing data points (0.8%) because of undetected breakdowns of 1 sensor with the mean of 50 simulated values using multiple imputation by chained equations. For detailed information, refer to the supplementary material of our methods paper [11].

Then, we calculated the accuracy score and the involuntary movement score, which we standardized to the reference values of 31 neurologically intact adults representing movement mastery. The accuracy score represents the standardized error value (standardized to the SD of neurologically intact adults) between the actual trajectory of the avatar and the target path. It displayed how well the participant could move the target joint to follow the target path accurately. The involuntary movement score describes for all nontarget joints the average difference of the joint movement (angular joint speed) of the participant from the adult mean and is expressed in adult SD units. Larger values suggest worse selective control for both the outcomes.

Comparator Measures

The first comparator assessment was the SCALE, a valid and established clinical assessment of lower limb SVMC [16]. It requires the child to perform specific and timed individual reciprocal joint movements (in this study, the hip, knee, and ankle joints). According to the grading criteria, a therapist classifies the impairments of SVMC during these movements on an ordinal 3-point scale. Each joint can be scored as 0=unable, 1=impaired, or 2=normal SVMC. We used the validated German version of the SCALE [17], and it was always rated by the same physiotherapist based on a video recording.

As a second comparator measure, we used the GMFCS, which classifies the functional abilities and limitations in the gross motor function of children with CP, emphasizing on sitting, transfers, and mobility [18]. It focuses on the children's performance in their habitual environment rather than their capacity in a standardized setting. Functional limitations and the need of assistive technology for mobility are described with 5 levels. Level 1 describes children who walk without restrictions, whereas the self-mobility of children with GMFCS level 5 is severely limited.

The third comparator measure was the physiotherapist's expert opinion. She rated the occurrence of involuntary movements during the assessgame by evaluating the video recordings afterward. Possible types of involuntary movements were mirror movements, trunk movements, or movements in any other joint. For the analysis, we assigned 1 point for each type of involuntary movement that occurred at least once; for example, if all 3 types of involuntary movements were observed, 3 points were given. A selectively performed movement was assigned 0 points. This therapist rating of involuntary movements

occurring during the assessgame (ie, not during the SCALE) allows a simple validation of the algorithm extracting involuntary movements from the accelerometer data.

Measurements

The standardized measurement procedure was carried out by 2 people out of a team of 3 testers (1 experienced neuropediatric physiotherapist and 2 human movement scientists) within 1 hour per session. The entire measurement was performed in a sitting position on a custom-made wooden seat to standardize the body position. For testing ankle movements, the active lower leg was placed on a support with the knee extended at 30°. First, the SCALE assessment was performed. Then, the participants were equipped with the accelerometers, the try-out trials were performed, and the actual measurements took place.

To evaluate the test-retest reliability of the assessgame, the measurement was repeated by the same team under similar conditions (time of day and room). Inpatients who received intensive multimodal rehabilitation were measured again within 1 week to ensure that they remained stable. Outpatients who received no intensive therapy were measured again within 3 weeks.

Statistical Analysis

For all outcomes, we calculated the means of the joints on the more and less affected side as well as an overall mean. If a joint could not be tested with the assessgame (eg, too small ROM), we also excluded the corresponding SCALE score from the analysis. Shapiro-Wilk tests and visual inspection of the data showed that most scores were not normally distributed. Therefore, we applied robust methods to test our a priori formulated hypotheses.

Discriminative validity was determined by a robust, bootstrapped analysis of covariance [19] to compare the assessgame scores between the children with CP and their neurologically intact peers at predefined ages of 9.5, 12.5, and 15.5 years (number of bootstrap samples=2000, span parameter=0.7, data were not trimmed, and CIs were adjusted for multiple comparisons).

Concurrent validity was evaluated by correlating the 2 assessgame outcomes (accuracy and involuntary movement scores) with (1) the SCALE score and (2) the GMFCS level. Furthermore, the game's involuntary movement score was correlated with the therapist's rating. For summary scores (total and leg means), we calculated Spearman rank correlation coefficients, whereas we used Kendall Tau-b rank correlation coefficients for individual joints, where we expected a high number of ties in the data. The magnitudes of the correlation coefficients were interpreted as negligible ($0.00 \leq |r| \leq 0.29$), low ($0.30 \leq |r| \leq 0.49$), moderate ($0.50 \leq |r| \leq 0.69$), high ($0.70 \leq |r| \leq 0.89$), or very high ($|r| \geq 0.90$) [20].

Relative test-retest reliability was investigated using a 2-way random effects model based on absolute agreement (ICC 2,1 according to Shrout and Fleiss nomenclature [21]). To account for nonnormally distributed data, we calculated bias-corrected and accelerated bootstrap 95% CIs (number of bootstrap samples=1000) [22]. ICCs and their corresponding CIs were

interpreted according to the guidelines of Koo et al [23]: ICCs <0.50 indicate poor reliability, those between 0.50 and 0.75 indicate moderate reliability, those between 0.75 and 0.90 indicate good reliability, and those >0.90 indicate excellent reliability. Absolute reliability was determined by the SE of measurement (equation 1, σ_t=variance of trial and σ_e=variance of residual [random] error) and the minimal detectable change (MDC) at a 95% confidence level (MDC$_{95\%}$; equation 2) [24].

All statistical analyses were performed with R statistical package (version 3.4.4; R Foundation for Statistical Computing) [25] using the additional packages boot version 1.3-20 [26], ICC version 2.3.0 [27], mice version 3.3.0 [28], and WRS2 version 0.10-0 [19]. The significance level was set at α=.05 (2-tailed).

Results

Participants' Characteristics

A total of 24 children with CP provided informed consent. As 4 children were not able to complete the assessgame because of a lack of cognitive understanding of the game (3/4, 75%) or visual impairment (1/4, 25%), we included the data of 20 children with spastic and mixed types of CP (bilateral: 17/20, 85%; unilateral: 3/20, 15%).

Their age ranged from 7 years and 11 months to 17 years and 5 months with a mean age of 12 years and 5 months (SD 3 years and 4 months). Of the 20 participants, 7 (35%) were female. In total, 35% (7/20) of children had GMFCS level I, 15% (3/20) had GMFCS level II, 25% (5/20) had GMFCS level III, and 25% (5/20) had GMFCS level IV. Descriptive statistics of all SVMC measures are presented in Table 1.

A descriptive summary of the peer control group (neurologically intact children: n=31; mean age 11 years and 1 month, SD 3 years and 6 months; n=16, 52% females) and adult reference group (n=31; mean age 33 years and 9 months, SD 7 years and 5 months; n=15, 48% females) is shown in Multimedia Appendix 1.

Table 1. Descriptive statistics of the outcome measures.

	More affected leg[a]		Less affected leg		Total	
	Median (IQR[b])	Range	Median (IQR[b])	Range	Median (IQR[b])	Range
Assessgame						
Accuracy	2.42 (1.91-3.20)	0.82-5.52	2.20 (1.63-3.88)	0.81-5.84	2.55 (1.65-3.38)	0.81-5.03
Involuntary movements	1.65 (1.34-2.65)	0.82-3.58	1.74 (1.23-2.44)	0.75-4.13	1.73 (1.27-2.79)	0.78-3.16
SCALE[c]	1.0 (1.0-1.66)	0.0-2.0	1.33 (1.0-1.75)	0.0-2.0	1.2 (1.0-1.66)	0.0-2.0
Therapist's opinion	0.83 (0.62-2.00)	0.00-3.00	1.17 (0.46-1.88)	0.00-3.00	1.00 (0.50-1.88)	0.00-3.00

[a]The summary scores (for each leg and total) represent the average values of the individual joints, n=20.

[b]1st-3rd quartile.

[c]SCALE: Selective Control Assessment of the Lower Extremity.

Discriminative Validity

Concerning our hypothesis on discriminative validity, a robust analysis of covariance compared the assessgame total scores between the children with CP and neurologically intact children at the discrete ages of 9.5, 12.5, and 15.5 years. The bootstrapped CIs for the mean difference did not include 0 in any of the comparisons, indicating that the children with CP had significantly worse SVMC (ie, higher scores) than their neurologically intact peers (Figure 2). The group differences were similar across all ages.

Figure 2. The assessgame scores and age. Scatterplots of the assessgame outcomes by age with smoothing lines are shown for children with cerebral palsy and neurologically intact children separately. Dashed lines depict at which age the patients and neurologically intact children were compared with a robust analysis of covariance. The differences between the groups and the bootstrapped 95% CIs are presented below.
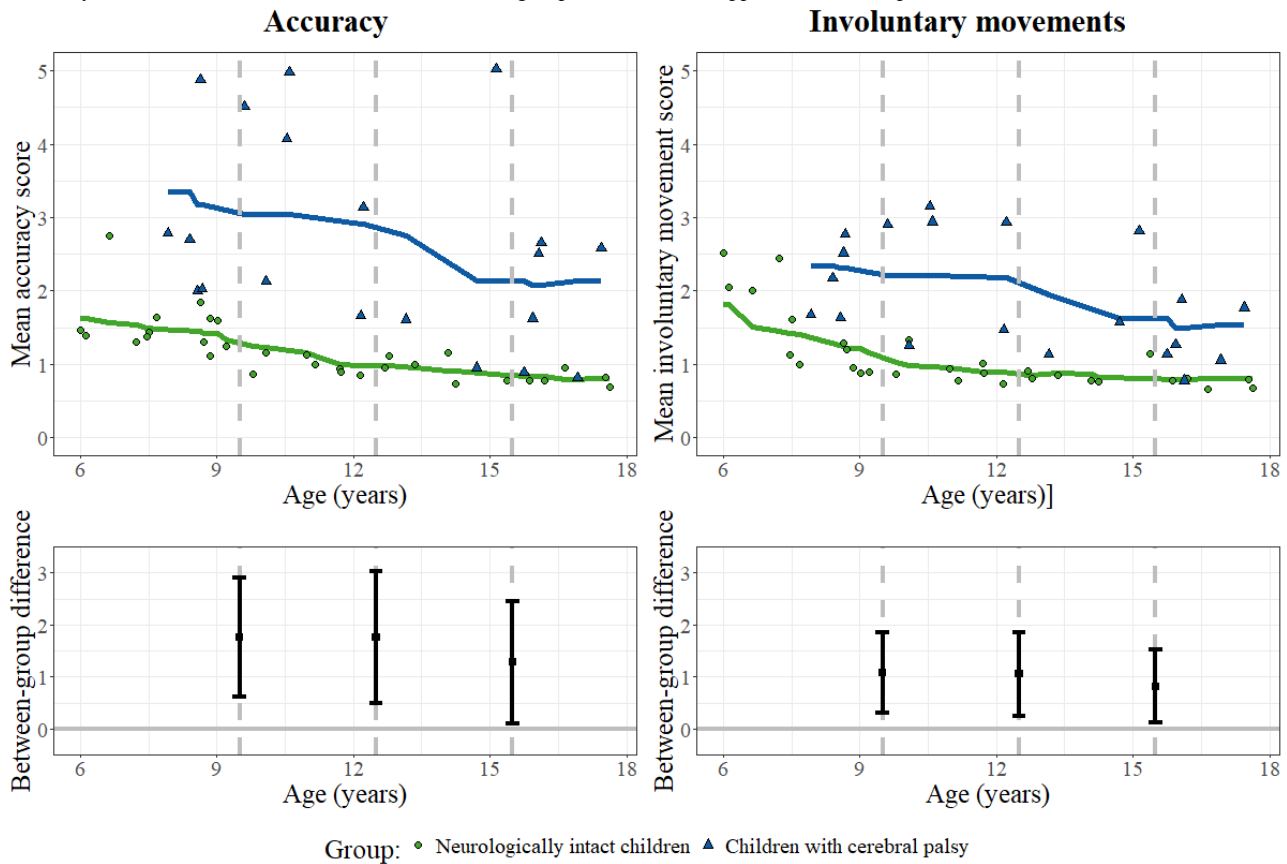
Concurrent Validity

The correlations between the assessgame outcomes and the SCALE and between the assessgame outcomes and GMFCS were negligible to low and nonsignificant (Table 2). Significant correlations of moderate magnitude were found between the involuntary movement score and the therapist's opinion (Table 2). Correlations with the therapist's rating were also significant on individual joint level for the ankle and knee ($0.47 \leq \tau \leq 0.74$). Complete results for all the individual joints are presented in Multimedia Appendix 1.

Table 2. Relationships between the assessgame outcomes and the comparator measures.

	More affected leg		Less affected leg		Total	
	ρ	*P* value	ρ	*P* value	ρ	*P* value
SCALE[a]						
Game accuracy	−0.25	.28	−0.14	.57	−0.29	.21
Game involuntary movements	−0.19	.43	−0.19	.42	−0.14	.54
GMFCS[b] level						
Game accuracy	0.42	.06	0.30	.19	0.39	.09
Game involuntary movements	0.18	.45	0.24	.32	0.23	.32
Therapist's opinion						
Game involuntary movements	0.59	.006	0.57	.009	0.56	.01

[a]SCALE: Selective Control Assessment of the Lower Extremity.

[b]GMFCS: Gross Motor Function Classification System.

Test-Retest Reliability

Of the 20 participants, 3 (15%) children could not participate in a second measurement owing to organizational issues. Inpatients were reassessed 1 to 8 days (mean 5.3, SD 2.5 days) after the first appointment, and outpatients were reassessed 6 to 21 days (mean 14.9, SD 6.5 days) later.

With ICC values for the total scores ≥0.86 and the 95% CIs >0.75, the test-retest reliability was in a good range (Table 3). The ICCs for each leg fell into the range of moderate to good test-retest reliability, whereas the CIs of the ICCs for involuntary movement scores were wide. The MDCs listed in Table 3 appeared to be smaller for the accuracy score than for the involuntary movement score and corresponded to 25% to 99%

of the mean patient score. The percentage of children (out of 17) that could improve (ie, reduce their assessgame score) by the MDC without surpassing 0 (ie, theoretically, the best possible score) was 100% (n=17) and 94% (n=16) for the total scores (accuracy and involuntary movements, respectively), 82% (n=14) and 29% (n=5) for the more affected side, and 71% (n=12) and 82% (n=14) for the less affected side.

Table 3. Test-retest reliability of the assessgame of selective voluntary motor control.

	More affected leg		Less affected leg		Total	
	Game AS[a]	Game IMS[b]	Game AS	Game IMS	Game AS	Game IMS
Mean (SD) 1	2.60 (1.34)	1.88 (0.84)	2.49 (1.48)	1.86 (0.84)	2.55 (1.35)	1.87 (0.73)
Mean (SD) 2	2.62 (1.47)	2.09 (1.19)	2.33 (1.35)	1.62 (0.68)	2.47 (1.35)	1.84 (0.84)
P value[c]	.78	.06	.99	.89	.75	.55
ICC[d] (2,1) (95% CI)	0.94 (0.80-0.98)	0.52 (0.06-0.85)	0.87 (0.57-0.96)	0.80 (0.17-0.93)	0.97 (0.88-0.99)	0.86 (0.76-0.93)
MDC_{95}[e]	0.97	1.97	1.40	0.98	0.63	0.82
MDC_{95}/grand mean[f] (%)	37	99	58	56	25	44

[a]AS: accuracy score.

[b]IMS: involuntary movement score.

[c]Uncorrected P value of Wilcoxon signed-rank test for systematic differences between the test and retest assessgame scores.

[d]ICC: intraclass correlation coefficient; the P values of intraclass correlation coefficients were all <.001, except for the involuntary movement score of the more affected leg (P=.008).

[e]MDC_{95}: minimal detectable change at 95% confidence level.

[f]The grand mean was the average of the first and second means.

Discussion

Principal Findings

We investigated the discriminative and concurrent validity and test-retest reliability of a gamelike assessment for SVMC in children with CP. In summary, the assessgame could differentiate well between the neurologically intact children and children with CP. Although the assessgame's involuntary movement sum scores correlated moderately with the therapist's expert opinion about the involuntary movements that occurred during the game, these correlations were high for the ankle and knee joints of the more affected side. The assessgame's accuracy and involuntary movement scores correlated worse with the SCALE score and the GMFCS level as hypothesized. Test-retest reliability was generally good to excellent, and most ICCs exceeded the minimum required threshold of 0.75, except for the occurrence of involuntary movements of the more affected leg. The acceptability of the absolute reliability was more challenging to interpret, but a high percentage of patients would be able to improve their total scores by the MDC without showing a ceiling effect. When interpreting the scores for the more and less affected sides separately, it seemed that most children with CP could improve in accuracy. At the same time, only some children might be able to reduce the occurrence of involuntary movements. The poorer reliability of the involuntary movement score of the more affected leg might indicate that such movements occur less regularly.

Discriminative Validity

The assessgame could differentiate well between neurologically intact children and children with CP, with similar differences independent of age. Although we had expected smaller differences in the assessgame scores between young (ie, aged 6-7 years) patients and their neurologically intact peers, our data could not confirm this, as we were not able to recruit children with CP in this age range (Figure 2). When interpreting the running interval smoother in Figure 2 qualitatively, a maturation effect in neurologically intact children can be observed, particularly for the involuntary movement score.

Concurrent Validity

A comparison with other psychometric studies is only partly possible, as only a few other SVMC tools exist, and their psychometric properties have rarely been investigated [10,16]. When the same assessgame was applied to the upper limbs, the correlations also were the strongest between the assessgame outcomes and the therapist's rating and weaker between the assessgame outcomes and clinical SVMC measures or classifications of the severity of the disability [13]. However, their absolute correlation coefficients between the assessgame scores and the upper limb equivalent of the SCALE, the selective control of the upper extremity scale, were higher (ie, ρ=−0.37 for accuracy and −0.55 for involuntary movements). Several factors might explain this difference. First, the assessgame for the upper extremity considers a higher number of *df*, allowing more possibilities for involuntary movements than the assessgame for the lower extremities. Second, playing a

computer game with the upper extremities is more common, whereas steering an avatar with isolated hip, knee, or foot movements was a new experience for the participants. Third, the assessgame asked for fine-tuned movements. Despite some leg muscles such as the tibialis anterior receiving direct corticospinal projections [29,30], which would allow fine motor control, the lower limbs are generally involved in gross motor movements concerning weight bearing, posture, and ambulation.

The relationships with comparator measures were also weaker than those observed in other lower extremity studies. Although other studies using clinical lower extremity SVMC assessments such as the selective motor control scale or the SCALE found relationships with gross motor function [6,8,16,17,31], the assessgame outcomes did not correlate with the GMFCS level or the SCALE. We expect that this is caused by the differences between the assessgame and clinical assessments of SVMC. First, strength might influence these SVMC measures differently. As the SCALE scores depend on whether the child can actively move through the entire passive ROM, the SCALE correlated strongly with lower limb strength [17,32], which is again a strong prerequisite for walking. By calibrating the assessgame to the active ROM, we aimed to minimize the effect of strength. Second, although the assessgame and a measure such as the SCALE rely on a common definition of SVMC, the assessgame represents a more advanced task requiring graded joint movements of varying amplitudes and speeds. On the basis of the nature of the assessgame, we think that playing the game involved additional visuomotor coordination, action planning, anticipation, and higher cognitive functions. These are all body functions known to vary highly in children with CP [33].

Furthermore, during the measurements, we observed that the children were quite immersed in the assessgame. They focused on collecting as many stars as possible rather than on movement quality (ie, no involuntary movements). Therefore, the assessgame resembles a more playful situation where selective control is required but not the focus of the action. By contrast, during the SCALE, the children had immediate visual control and feedback over their movement, were continuously guided by the therapist, and could display their undivided attention solely on performing selective movements.

Although the relationships between the assessgame outcomes and SCALE were indeed weaker than we had anticipated, the moderate correlations between the assessgame outcomes and therapist's rating of involuntary movements occurring during the game, which were moderate to high for the knee and high for the ankle joint specifically, indicate that the assessgame is valid in assessing SVMC. The relationships might have been even stronger if the therapist had also quantified the intensity and frequency of the occurring movements.

In our opinion, the assessgame seems to measure SVMC during a more difficult task in a different context (ie, an immersive gaming environment) and in greater detail compared with the current clinical SVMC assessments. It assesses movement control more accurately (ie, finer graded and accurately timed movements) and includes the magnitude and frequency of involuntary movements. These differences make the concurrent validity testing difficult.

Test-Retest Reliability

As for the reliability results, the English and German versions of the SCALE and the selective motor control scale were shown to have nearly excellent relative reliability in children with CP [16,17,34]. Although we found similarly large ICC values for the total scores in this study, ICCs for the more and less affected sides were lower, especially for the involuntary movement score. We consider 2 explanations. First, although the ordinal clinical scales with only a few levels might mask some possible variability, leading to higher ICCs, the interval-scaled assessgame fully captures this variability. Second, we investigated the test-retest reliability of the assessgame on different test occasions. Previous studies examined the interrater or intrarater reliability by evaluating consecutive assessments on the same day or by rating videotaped assessments. Such protocols might result in smaller variability compared with 2 different test occasions.

The MDCs relative to the grand mean were mostly higher than those found for the SCALE. Balzer et al [17] found values in the range of approximately 30% to 40%. We found comparable values for the total and more affected side accuracy scores, but the values exceeded 40% for the other outcomes. This discrepancy between good relative reliability and rather low absolute reliability can be attributed (in part) to the heterogeneous sample. ICCs can be high even if the trial-to-trial variability is large when between-subject variability is high [35]. The participants, reflecting the population undergoing rehabilitation in our center, varied highly in the level of SVMC impairment as SCALE total scores varied between 1 and 12 out of 12 points. Although these values reflect the reliability one could expect when applying the measure on a daily basis in a heterogeneous clinical population, we expect that for research purposes, more homogeneous patient populations would need to be selected to improve the absolute reliability and allow the assessment of longitudinal changes.

Limitations

First, the sample size was relatively small; however, with 20 participants, we were sufficiently powered to detect correlations of ≥0.58 (pwr.r.test [36], α=.05, power=80%), which lie clearly below what we expected for the therapist's opinion and in the lower range of the expected correlations with the SCALE.

Second, the game requires good cognitive functions of participants to maintain concentration and an active ROM of at least 10°; this resulted in dropouts and missing data for some joints. Owing to dynamic or fixed ankle contractures in children with CP, their active ROM was often too small to play the game, and important information on ankle control was lost.

Third, we decided to study children with unilateral and bilateral spastic CP for this preliminary investigation of psychometric properties and usability. Although this sample was more homogeneous than the sample included in the psychometric study of the upper limb assessgame [13], the heterogeneity between patients was large, and the sample represented a population seen in clinics to whom the tool will be applied.

Fourth, reliability could likely be improved by testing each joint more than once and taking the average outcome. Several

repetitions would also allow better control for learning effects, if they exist. However, repeating joint assessments seems unfeasible in terms of motivation and compliance if all joints are to be tested. The assessgame was developed to keep motivation and emotional engagement high during testing. Nevertheless, engagement differed between participants and might have influenced the outcomes independent of the participant's selective control abilities.

Finally, we underestimated the differences in patient requirements for performing the clinical SCALE and the assessgame. Although both assessments build on the definition of reduced selective motor control, the assessgame differs in various aspects, as discussed earlier, which has negatively influenced parts of the validity analyses. Future psychometric studies (on similar assessments) should consider this and could further evaluate the validity of the assessgame by including comparator assessments of more refined control of movement or muscle activation, action planning or visuomotor coordination, and the frequency and amplitude of involuntary movements.

Clinical Implications

Unlike the SCALE, whose single outcome includes both timed gross motor control and the presence of involuntary movements, the assessgame separates movement accuracy from the occurrence of involuntary movements. This separation is of clinical importance, as it could direct therapists in personalizing the therapy program (eg, improving accurate motor control or inhibiting involuntary movements). However, in particular, the assessgame's involuntary movement score should become more refined to inform therapeutic decisions in more detail (ie, differentiating between mirror movements and comovements). As a first attempt, we developed a possible clinical output for the assessgame providing information similarly to the descriptors of the SCALE (an example is shown in Multimedia Appendix 2). This output displays in detail how selectively the child was able to play the assessgame for each joint compared with the recorded reference values (neurologically intact adults and control children of approximately the same age as the patient).

The setup, test conduction, and analysis of the assessgame are rather time consuming, which limits the practicability of such an assessment in its current form. Technical adaptations could help optimize the setup such that fewer sensors are required.

Furthermore, instead of testing all joints, the test could be focused on 1 or 2 specific target joints selected based on their relevance for the children and their families.

Future studies should investigate SVMC in a larger sample of healthy children to establish robust norm values for the assessgame scores. A first analysis of the current data from 31 healthy children already showed a strong correlation with age [37]. In addition, in a larger sample of children with CP, it might be possible to find SVMC subcategories, which might serve to predict or optimize (physiotherapeutic) treatment output, as has been shown for the SCALE and orthopedic knee surgery [38,39].

Another clinical and scientific application could be to adapt the concept of the assessgame for an intervention to train SVMC in children with CP. Meanwhile, we have developed an interactive computer game for improving SVMC [40]. We took advantage of the assessgame's motivational effect due to the gaming character and the enriched environment, as these components are indicated to enhance motor learning and neuroplasticity [41,42]. Regardless of which therapeutic approach is taken to improve SVMC, a responsive outcome measure is needed to measure the real changes stemming from interventions. Therefore, future studies might investigate the responsiveness and clinically important changes of the assessgame.

Finally, although we evaluated this assessgame in children with CP, it could be applied to various patient groups with upper motor neuron lesions, both young and adult, as shown for the upper limbs [13].

Conclusions

This study provided preliminary evidence for the validity and good relative test-retest reliability of a new playful assessgame to measure SVMC of the lower extremities in children with CP. The assessgame differs from the existing assessments of SVMC, and its gaming character might have a complementary value in the measurement of SVMC. This may deepen our understanding of the complex mechanism of motor control. Future studies must show whether and which other aspects of motor control the assessgame includes for it to become an appropriate assessment for clinical or research use. As the relative reliability was good but the absolute reliability was rather low, further studies are needed to investigate the responsiveness of the assessment.

Data Availability

The data sets generated and analyzed during this study are not publicly available owing to ethical concerns about the small number of patients but are available from the corresponding author upon reasonable request.

XSL•FO
RenderX

Authors' Contributions

AF carried out the data collection and analysis, performed the statistical analyses, and drafted the manuscript. JB conceived and designed the study, carried out the data collection and analysis, drafted the manuscript, and acquired funding. JWK conceived and designed the study, carried out the data collection and analysis, and performed the statistical analyses. HJAvH conceived and designed the study, acquired funding, and obtained ethics approval. All the authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Descriptive statistics of the healthy reference groups, the relationships between the assessgame outcomes and comparator measures for individual joints, and test-retest reliability analyses for individual joints.
[DOCX File , 22 KB - rehab_v9i4e39687_app1.docx]

Multimedia Appendix 2
Example of a clinical output for the assessgame.
[XLSX File (Microsoft Excel File), 69 KB - rehab_v9i4e39687_app2.xlsx]

References

1. Sanger TD, Chen D, Delgado MR, Gaebler-Spira D, Hallett M, Mink JW, Taskforce on Childhood Motor Disorders. Definition and classification of negative motor signs in childhood. Pediatrics 2006 Nov;118(5):2159-2167. [doi: 10.1542/peds.2005-3016] [Medline: 17079590]
2. Cahill-Rowley K, Rose J. Etiology of impaired selective motor control: emerging evidence and its implications for research and treatment in cerebral palsy. Dev Med Child Neurol 2014 Jun;56(6):522-528 [FREE Full text] [doi: 10.1111/dmcn.12355] [Medline: 24359183]
3. Schiariti V, Mâsse LC. Relevant areas of functioning in children with cerebral palsy based on the international classification of functioning, disability and health coding system: a clinical perspective. J Child Neurol 2015 Feb;30(2):216-222. [doi: 10.1177/0883073814533005] [Medline: 24810085]
4. Balzer J, Marsico P, Mitteregger E, van der Linden ML, Mercer TH, van Hedel HJ. Influence of trunk control and lower extremity impairments on gait capacity in children with cerebral palsy. Disabil Rehabil 2018 Dec;40(26):3164-3170. [doi: 10.1080/09638288.2017.1380719] [Medline: 28944697]
5. Vos RC, Becher JG, Voorman JM, Gorter JW, van Eck M, van Meeteren J, PERRIN+ Study Group. Longitudinal association between gross motor capacity and neuromusculoskeletal function in children and youth with cerebral palsy. Arch Phys Med Rehabil 2016 Aug;97(8):1329-1337. [doi: 10.1016/j.apmr.2016.03.012] [Medline: 27085848]
6. Ostensjø S, Carlberg EB, Vøllestad NK. Motor impairments in young children with cerebral palsy: relationship to gross motor function and everyday activities. Dev Med Child Neurol 2004 Sep;46(9):580-589 [FREE Full text] [doi: 10.1017/s0012162204000994] [Medline: 15344517]
7. Zhou JY, Lowe E, Cahill-Rowley K, Mahtani GB, Young JL, Rose J. Influence of impaired selective motor control on gait in children with cerebral palsy. J Child Orthop 2019 Feb 01;13(1):73-81 [FREE Full text] [doi: 10.1302/1863-2548.13.180013] [Medline: 30838079]
8. Chruscikowski E, Fry NR, Noble JJ, Gough M, Shortland AP. Selective motor control correlates with gait abnormality in children with cerebral palsy. Gait Posture 2017 Feb;52:107-109. [doi: 10.1016/j.gaitpost.2016.11.031] [Medline: 27889619]
9. Dobson F. Assessing selective motor control in children with cerebral palsy. Dev Med Child Neurol 2010 May;52(5):409-410 [FREE Full text] [doi: 10.1111/j.1469-8749.2010.03589.x] [Medline: 20345962]
10. Balzer J, van der Linden ML, Mercer TH, van Hedel HJ. Selective voluntary motor control measures of the lower extremity in children with upper motor neuron lesions: a systematic review. Dev Med Child Neurol 2017 Jul;59(7):699-705 [FREE Full text] [doi: 10.1111/dmcn.13417] [Medline: 28272744]
11. Keller JW, Balzer J, Fahr A, Lieber J, Keller U, van Hedel HJ. First validation of a novel assessgame quantifying selective voluntary motor control in children with upper motor neuron lesions. Sci Rep 2019 Dec 30;9(1):19972 [FREE Full text] [doi: 10.1038/s41598-019-56495-8] [Medline: 31889062]
12. Addamo PK, Farrow M, Hoy KE, Bradshaw JL, Georgiou-Karistianis N. The effects of age and attention on motor overflow production--a review. Brain Res Rev 2007 Apr;54(1):189-204. [doi: 10.1016/j.brainresrev.2007.01.004] [Medline: 17300842]
13. Keller JW, Fahr A, Balzer J, Lieber J, van Hedel HJA. Validity and reliability of an accelerometer-based assessgame to quantify upper limb selective voluntary motor control. J Neuroeng Rehabil 2020 Jul 13;17(1):89 [FREE Full text] [doi: 10.1186/s12984-020-00717-y] [Medline: 32660569]
14. Baliz Y, Armatas C, Farrow M, Hoy KE, Fitzgerald PB, Bradshaw JL, et al. The influence of attention and age on the occurrence of mirror movements. J Int Neuropsychol Soc 2005 Nov;11(7):855-862. [doi: 10.1017/s1355617705051003] [Medline: 16519264]

XSL•FO

RenderX

15. van Hedel HJ, Häfliger N, Gerber CN. Quantifying selective elbow movements during an exergame in children with neurological disorders: a pilot study. J Neuroeng Rehabil 2016 Oct 21;13(1):93 [FREE Full text] [doi: 10.1186/s12984-016-0200-3] [Medline: 27769301]

16. Fowler EG, Staudt LA, Greenberg MB, Oppenheim WL. Selective Control Assessment of the Lower Extremity (SCALE): development, validation, and interrater reliability of a clinical tool for patients with cerebral palsy. Dev Med Child Neurol 2009 Aug;51(8):607-614 [FREE Full text] [doi: 10.1111/j.1469-8749.2008.03186.x] [Medline: 19220390]

17. Balzer J, Marsico P, Mitteregger E, van der Linden ML, Mercer TH, van Hedel HJ. Construct validity and reliability of the selective control assessment of the lower extremity in children with cerebral palsy. Dev Med Child Neurol 2016 Feb;58(2):167-172 [FREE Full text] [doi: 10.1111/dmcn.12805] [Medline: 25991061]

18. Palisano R, Rosenbaum P, Walter S, Russell D, Wood E, Galuppi B. Development and reliability of a system to classify gross motor function in children with cerebral palsy. Dev Med Child Neurol 1997 Apr;39(4):214-223 [FREE Full text] [doi: 10.1111/j.1469-8749.1997.tb07414.x] [Medline: 9183258]

19. Mair P, Wilcox R. Robust statistical methods in R using the WRS2 package. Behav Res Methods 2020 Apr;52(2):464-488. [doi: 10.3758/s13428-019-01246-w] [Medline: 31152384]

20. Hinkle D, Wiersma W, Jurs SG. Applied Statistics for the Behavioral Sciences Volume 663. Boston, Massachusetts, United States: Houghton Mifflin; 1994.

21. Shrout PE, Fleiss JL. Intraclass correlations: uses in assessing rater reliability. Psychol Bull 1979 Mar;86(2):420-428. [doi: 10.1037//0033-2909.86.2.420] [Medline: 18839484]

22. Efron B. Better bootstrap confidence intervals. J Am Stat Assoc 1987 Mar;82(397):171-185. [doi: 10.1080/01621459.1987.10478410]

23. Koo TK, Li MY. A guideline of selecting and reporting intraclass correlation coefficients for reliability research. J Chiropr Med 2016 Jun;15(2):155-163 [FREE Full text] [doi: 10.1016/j.jcm.2016.02.012] [Medline: 27330520]

24. de Vet HC, Terwee CB, Knol DL, Bouter LM. When to use agreement versus reliability measures. J Clin Epidemiol 2006 Oct;59(10):1033-1039. [doi: 10.1016/j.jclinepi.2005.10.015] [Medline: 16980142]

25. R: A Language and Environment for Statistical Computing. Vienna, Austria: R Foundation for Statistical Computing; 2018.

26. Canty A, Ripley B. boot: Bootstrap Functions (Originally by Angelo Canty for S). CRAN. 2019. URL: https://cran.r-project.org/web/packages/boot/boot.pdf [accessed 2019-11-22]

27. Wolak ME, Fairbairn DJ, Paulsen YR. Guidelines for estimating repeatability. Methods Ecol Evol 2011. [doi: 10.1111/j.2041-210X.2011.00125.x]

28. van Buuren S, Groothuis-Oudshoorn K. mice: multivariate imputation by chained equations in R. J Stat Soft 2011;45(3):1-67. [doi: 10.18637/jss.v045.i03]

29. Brouwer B, Ashby P. Corticospinal projections to upper and lower limb spinal motoneurons in man. Electroencephalogr Clin Neurophysiol 1990 Dec;76(6):509-519. [doi: 10.1016/0013-4694(90)90002-2] [Medline: 1701119]

30. Brouwer B, Ashby P. Corticospinal projections to lower limb motoneurons in man. Exp Brain Res 1992;89(3):649-654. [doi: 10.1007/BF00229889] [Medline: 1644127]

31. Kusumoto Y, Hanao M, Takaki K, Matsuda T, Nitta O. Reliability and validity of the Japanese version of the selective control assessment of the lower extremity tool among patients with spastic cerebral palsy. J Phys Ther Sci 2016 Dec;28(12):3316-3319 [FREE Full text] [doi: 10.1589/jpts.28.3316] [Medline: 28174443]

32. Kusumoto Y, Takaki K, Matsuda T, Nitta O. Relation of selective voluntary motor control of the lower extremity and extensor strength of the knee joint in children with spastic diplegia. J Phys Ther Sci 2016 Jun;28(6):1868-1871 [FREE Full text] [doi: 10.1589/jpts.28.1868] [Medline: 27390436]

33. Bax M, Goldstein M, Rosenbaum P, Leviton A, Paneth N, Dan B, Executive Committee for the Definition of Cerebral Palsy. Proposed definition and classification of cerebral palsy, April 2005. Dev Med Child Neurol 2005 Aug;47(8):571-576 [FREE Full text] [doi: 10.1017/s001216220500112x] [Medline: 16108461]

34. Löwing K, Brogren Carlberg E. Reliability of the selective motor control scale in children with cerebral palsy. Adv Physiother 2009 Aug 13;11(2):58-63. [doi: 10.1080/14038190801999620]

35. Weir JP. Quantifying test-retest reliability using the intraclass correlation coefficient and the SEM. J Strength Cond Res 2005 Feb;19(1):231-240. [doi: 10.1519/15184.1] [Medline: 15705040]

36. Champely S, De Rosario H. pwr: Basic functions for power analysis. CRAN. 2020 Mar 6. URL: https://cran.r-project.org/web/packages/pwr/pwr.pdf [accessed 2020-12-15]

37. Fahr A, Keller JW, Balzer J, Lieber J, van Hedel HJA. Quantifying age-related differences in selective voluntary motor control in children and adolescents with three assessments. Hum Mov Sci 2021 Jun;77:102790 [FREE Full text] [doi: 10.1016/j.humov.2021.102790] [Medline: 33798928]

38. Goldberg EJ, Requejo PS, Fowler EG. Joint moment contributions to swing knee extension acceleration during gait in individuals with spastic diplegic cerebral palsy. Gait Posture 2011 Jan;33(1):66-70. [doi: 10.1016/j.gaitpost.2010.09.026] [Medline: 21036047]

39. Goldberg EJ, Fowler EG, Oppenheim WL. Case reports: the influence of selective voluntary motor control on gait after hamstring lengthening surgery. Clin Orthop Relat Res 2012 May;470(5):1320-1326 [FREE Full text] [doi: 10.1007/s11999-011-2028-2] [Medline: 21863394]

40. Fahr A, Kläy A, Keller JW, van Hedel HJ. An interactive computer game for improving selective voluntary motor control in children with upper motor neuron lesions: development and preliminary feasibility study. JMIR Serious Games 2021 Jul 28;9(3):e26028 [FREE Full text] [doi: 10.2196/26028] [Medline: 34319236]

41. Morgan C, Novak I, Badawi N. Enriched environments and motor outcomes in cerebral palsy: systematic review and meta-analysis. Pediatrics 2013 Sep;132(3):e735-e746. [doi: 10.1542/peds.2012-3985] [Medline: 23958771]

42. Holden MK. Virtual environments for motor rehabilitation: review. Cyberpsychol Behav 2005 Jun;8(3):187-211; discussion 212. [doi: 10.1089/cpb.2005.8.187] [Medline: 15971970]

Abbreviations

CP: cerebral palsy
GMFCS: Gross Motor Function Classification System
ICC: intraclass correlation coefficient
MDC: minimal detectable change
ROM: range of motion
SCALE: Selective Control Assessment of the Lower Extremity
SVMC: selective voluntary motor control

XSL•FO

RenderX

Systematic Development of the ReWin Application: A Digital Therapeutic Rehabilitation Innovation for People With Stroke-related Disabilities in India

Sureshkumar Kamalakannan[1,2*], BOT, MPH, PhD; Vijay Karunakaran[3*], PhD; Ashwin Balaji Kaliappan[3*], MSc; Ramakumar Nagarajan[4*], MPT

[1]Department of Social Work Education and Community Wellbeing, Faculty of Health and Life Sciences, Northumbria University, Newcastle Upon Tyne, United Kingdom

[2]South Asia Centre for Disability Inclusive Development and Research, Indian Institute of Public Health Hyderabad, Public Health Foundation of India, Hyderabad, India

[3]Department of mHealth Design and Development, InGage Technologies Pvt, Ltd, Chennai, India

[4]Neurological Rehabilitation Department, Chennai Advanced Rehabilitation Centre, Chennai, India

[*]all authors contributed equally

Corresponding Author:
Sureshkumar Kamalakannan, BOT, MPH, PhD
South Asia Centre for Disability Inclusive Development and Research
Indian Institute of Public Health Hyderabad
Public Health Foundation of India
Plot No: 1, ANV Arcade, Amar Cooperative Society
Kavuri Hills, Madhapur
Hyderabad, 500033
India
Phone: 91 9676333412
Email: sureshkumar.kamalakannan@northumbria.ac.uk

Abstract

This is a viewpoint paper that aims to describe the systematic approach to the development of a technology-driven stroke rehabilitation innovation to manage disabilities following a stroke at home in India. This paper intends to sensitize public health innovators and intervention development experts about the important aspects that need to be considered to develop a culturally sensitive, patient-centered, scalable solution for stroke care using technology. Stroke has been the second-leading cause of death and the third-leading cause of disability globally for the past 3 decades. The emerging technological innovations for stroke care were predominantly designed and developed by digital technology experts as stand-alone products with very minimal efforts to explore their feasibility, acceptability, and, more importantly, scalability. Hence, a digital therapeutic rehabilitation innovation for people with stroke-related disabilities in India was systematically developed and is being evaluated. ReWin is an innovation that is technologically driven and envisions digital therapeutics as a medium for the provision of rehabilitation to persons with disabilities. It is conceptualized and developed based on the International Classification of Functioning, Disability and Health. ReWin encompasses specific technological aspects to enable its scientific framework and conceptualization to suit the context and needs of stroke care providers and consumers. The framework is built with 2 separate applications, one for the providers and one for the patients and caregivers. Each of these applications has a specific inbuilt design to add data about the demographic details of the user, stroke severity using the National Institute of Health Stroke Scale, and self-assessment of disability measured by the modified Barthel Index. Users can communicate with each other and decide on their therapeutic goals, therapy training information, and progress remotely from where they are. The ultimate outcome expected from the ReWin innovation is a continuum of care for stroke survivors that is effective, safe, and of good quality. Systematic development cannot make the intervention scalable. The intervention needs to be evaluated for its feasibility, acceptability, and effectiveness. Currently, ReWin is being evaluated for its feasibility and acceptability. The evaluation of ReWin will provide an opportunity to develop a scalable solution for empowering therapists and persons with disabilities, in general, to objectively self-manage their treatment. Findings from this study will also provide valuable information about the resources required to deliver such interventions in resource-constrained settings like India.

XSL•FO
RenderX

Introduction

Stroke has been the second-leading cause of death and the third-leading cause of disability globally for the past 3 decades [1]. There have been several innovations to meet the growing need for stroke rehabilitation in the community [2]. Most recently, the approach to innovations for stroke rehabilitation has amalgamated the strengths of technology and digital therapeutics [3]. However, these technological innovations for stroke care were predominantly designed and developed by digital technology experts as stand-alone products with very minimal efforts to explore their feasibility, acceptability, and more importantly, scalability [4]. Perhaps this could be one reason why these technologically driven rehabilitation innovations have not been optimally used in primary stroke care, especially in the context of low- and middle-income countries including India.

As recommended by the Medical Research Council, United Kingdom, the development of innovative interventions, especially those that are complex, must be systematic and phased [5]. This will enable the design as well as the development of context-specific, culturally sensitive, and patient-centered interventions [6]. It is also important that these technological innovations connect patients with providers of rehabilitation. Most of the innovations for stroke rehabilitation that are available in the market are aimed at supporting stroke survivors or stroke service providers [7]. This potentially creates a gap in the continuum of care between the users and providers of stroke care, and therefore, the supply of rehabilitation services could never meet the demands [8]. The development of innovative stroke rehabilitation interventions that consider the aspects of feasibility, acceptability, and scalability is therefore of utmost public health importance [9]. It also stresses the importance of innovations targeting the continuum of care, especially for a condition like a stroke, which results in a long-term permanent disability [10].

In this paper, we aim to describe the systematic approach to the development of a technology-driven stroke rehabilitation innovation to manage disabilities following a stroke at home in India. The innovation is called ReWin. ReWin is a digital therapeutics platform conceptualized, developed, and owned by TNQ InGage Technologies, a company based out of Chennai, India. It is an innovation that was systematically designed with the utmost consideration for scalability and a continuum of care. This paper intends to sensitize public health innovators and intervention development experts about the important aspects that the authors considered to develop the ReWin innovation, which is a culturally sensitive, patient-centered, scalable solution for stroke care using technology in India. The paper highlights the technical as well as scientific aspects of the ReWin innovation and its implications for addressing the growing burden of stroke and the demand for stroke care in India as well as in similar contexts.

ReWin Conceptualization

ReWin is a technology-driven innovation for stroke care that aims to provide a scalable solution for stroke care and subsequently generate evidence for informed decision-making among both the consumers and providers of stroke rehabilitation and care. It is conceptualized as an innovation that could visualize disability through a bio-psycho-social lens as defined by the International Classification of Functioning, Disability and Health [11]. This conceptualization enables ReWin to move beyond the boundaries of impairment-based rehabilitation, which is a purely medical model, to an inclusive model that considers activity limitations and participation restrictions, including the environment in which one experiences stroke-related disabilities. Figure 1 describes this conceptualization.

Although it looks straightforward, it is not easy to translate this conceptualized innovation into a scalable solution, especially in a country such as India where there is no general system for the rehabilitation of persons with disabilities [12]. Even the national program for noncommunicable diseases, which includes stroke, does not have an operational strategy to address the unmet need for disability and rehabilitation among stroke survivors [13]. In addition, rehabilitation services for stroke survivors, especially outside the hospital setting, are hardly available in India. This provides the opportunity to tap the strengths of technology and optimize it for bridging the existing gaps in the provision of rehabilitation for stroke survivors and meeting their needs, especially outside the hospital setting.

Figure 1. Bio-psycho-social model of the International Classification of Functioning, Disability and Health.
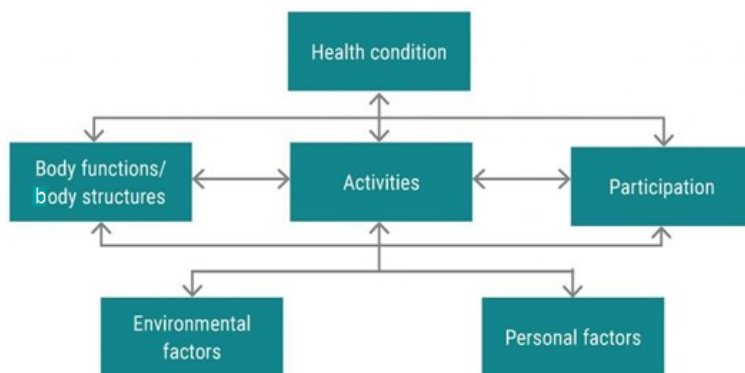
Scientific Framework of ReWin

ReWin's scientific framework is more aligned with its conceptualization. Rehabilitation services for people with disabilities in general have been inaccessible in the Indian context until now [14]. Whatever is available and accessible is limited to the major cities and provided predominately by private service providers. More importantly, rehabilitation services are restricted only to hospital or institutional settings [15]. Services for people with disabilities outside the hospital context are hardly nonexistent, and this provides an opportunity as well as implies a need for innovation to address these gaps.

The key aspects of ReWin's framework are the continuum of care as well as the bio-psycho-social model for disability conceptualization, which is nonexistent for people with disabilities in general in an Indian context. Communication of the therapy needs and rehabilitation plans between therapists and stroke survivors and their families is crucial to achieving a continuum of care. ReWin ensures the follow-up of stroke survivors post discharge from their hospital. The application also envisions follow-up for functional independence, enabling stroke survivors to decide what goals need to be achieved based on their self-assessment of activities of daily living (ADL). Lastly, the scientific framework is not just educational. It enables supervised therapeutic rehabilitation at home using video-based educational content as well as the sensor- and virtual reality–based therapeutic training supervised remotely by the therapists based at the hospitals or rehabilitation centers. Figure 2 depicts the continuum of care framework of ReWin.

Figure 2. Continuum of care framework of ReWin.

The Technological Framework of ReWin

ReWin encompasses specific technological aspects to enable its scientific framework and conceptualization to suit the context and needs of stroke care providers and consumers. The framework is built with 2 separate applications, one for the providers and one for the patients and caregivers. Each of these applications has a specific inbuilt design to add data about the demographic details of the user, stroke severity using the National Institute of Health Stroke Scale (NIHSS), and self-assessment of disability measured by the modified Barthel Index. Users can communicate with each other and decide on their therapeutic goals, therapy training information, and progress remotely from where they are.

ReWin Stroke Rehabilitation Intervention

The ReWin stroke telerehabilitation intervention is designed to provide continuum care for stroke survivors in India. It is

XSL·FO
RenderX

designed and developed to address the unmet need for stroke rehabilitation in the country by bridging the gap between stroke rehabilitation clinicians or health professionals and stroke survivors. The stroke experts considered for delivering the intervention are stroke physicians, neurologists, physiotherapists, occupational therapists, rehabilitation nurses, and other rehabilitation experts. The stroke survivors considered for using this innovation are those who get treated in a hospital facility for their acute stroke and are discharged home after being medically stabilized for their acute stroke at the hospital. The intervention consists of two key components: (1) ReWin Stroke Survivor app and (2) ReWin Therapist app. Both apps will have the capability to communicate with each other.

ReWin Stroke Survivor App

This is a patient-specific app that would provide educational information and guide stroke survivors to understand stroke and their functional problems, seek uninterrupted, organized stroke care from stroke experts based at the hospital, and set realistic goals that could help them meet their poststroke rehabilitation needs based at home. The intervention includes the following components:

1. Information on stroke: a video-based education for caregivers and stroke survivors on stroke such as what is stroke, how a stroke occurs, common symptoms of stroke, and warning signs of stroke in regional languages.

2. Self-care assessment: a self-care assessment is designed to assess and evaluate the participation of stroke survivors in basic ADL using a standardized assessment of ADL. All the questions are developed using the modified Barthel index assessment for ADL as the core logic. This assessment is completed by the stroke survivors or their caregivers themselves.

3. Functional goal-setting: the patient app will suggest functional goals to the patient based on the results of the self-care assessment. Patients can select short-term functional goals in areas where they want to see improvement in their ADL.

4. Therapeutic expert consultation: these goals will be shared digitally with the stroke experts using a single point-of-access triage facilitator in the hospital for further rehabilitation and care planning (web-based consultations, goal planning, and follow-up) for the stroke survivors based at their homes.

5. Home-based self-management or caregiver-supported management of the physical disability: this is the core therapeutic component of the ReWin innovation. It consists of 4 critical domains for stroke rehabilitation. They are (1) home-based therapeutic exercises, (2) functional skills or preparation for daily living, (3) ADL, and (4) assistive devices. The content of all these domains is stored in the server of ReWin. This content can be reviewed and recommended to stroke survivors by the therapists through their app. Following this, the recommendations will be automatically available for the users through their patient app.

i. Home-based therapeutic exercises: in this section, self or caregiver-mediated home-based training with support using a customized exercise program as prescribed by their expert therapist can be performed. Stroke survivors and caregivers would be asked to follow the exercises provided in the app based on expert guidance. Home-based therapeutic exercises will be provided on 3 platforms. Each platform has its uniqueness.

   - Guided 3D video-based therapeutic exercises: in this platform, ReWin offers 3D animated videos that will guide and train stroke survivors and caregivers on how to do their daily therapeutic exercises as prescribed by their expert therapist. The therapeutic exercise library will have a wide selection of passive, active-assisted, and active exercises (Figure 3).

   - Wireless bio-feedback sensors: bio-feedback sensors combined with a mobile app will help to coach, track, and remotely monitor patients to enhance and improve their rehab experience. These sensors are nonhazardous and can track the range of motion, time taken to complete a task, and movement smoothness. All these data will be monitored and shown in the expert app dashboard. A wide range of passive, active-assisted, and active exercises will be available on this platform (Figure 4).

   - VR therapeutic games: innovative, immersive, therapeutic applications that address a wide variety of active range of motion exercises focused on ADL through virtual reality games. Each game is uniquely designed and curated for a particular active range of motion exercise. The purpose of this intervention is to provide immersive, engaging, safe, and higher dosage interventions in a home or clinical setting for patients with stroke (Figure 5).

ii. Functional skills or preparation for daily living: a virtual reality–based education of stroke survivors and caregivers on ways to perform their functional activities, such as positioning themselves in bed and chair, bed mobility, mobilizing in bed, chair, and wheelchair, and transfers, will be available for viewing and performing under expert guidance.

iii. ADL: a virtual reality–based education of stroke survivors and caregivers on ways to perform their functional activities such as brushing, grooming, bathing, dressing, and walking will be available for viewing and performing under expert guidance.

iv. Assistive devices: a virtual reality–based education of stroke survivors and caregivers on assistive devices that can help with their ADL, details of the device, how to wear them, and perform their day-to-day activities is provided.

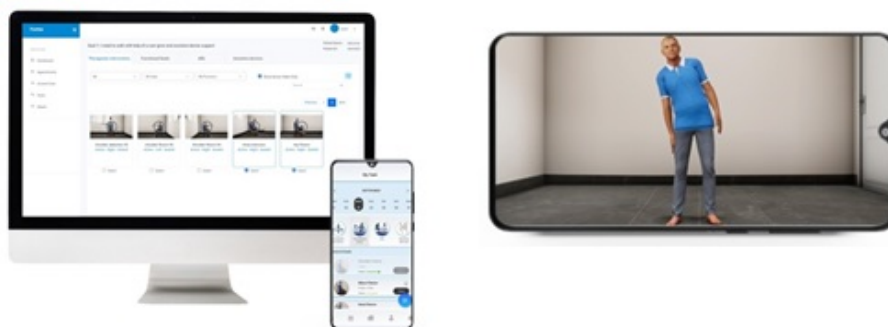**Figure 3.** Mobile-based therapeutic videos.

Figure 4. Wireless sensor for active, active-assisted, and passive therapeutic exercise.

Figure 5. Headset of the head-mounted display for stroke rehabilitation.

ReWin Stroke Expert App

The ReWin stroke expert app is specifically designed to enable stroke care experts in a hospital facility to ensure a continuum of care by engaging with stroke survivors who are discharged from the hospital and are living at home digitally in real-time. This app is designed to serve the following purposes:

1. Web-based consulting: this app enables stroke rehabilitation experts to consult with a stroke survivor virtually rather than consulting at the hospital. The experts can provide

appointments for specific time durations and could organize care for their patients who have already been discharged and keep track of them.

2. Stroke severity assessment: the app has an inbuilt NIHSS. This standardized assessment will enable expert clinicians to assess and evaluate the stroke severity, and disabilities or impairments due to stroke. The assessment consists of structured questions to evaluate physical, visual, cognitive, speech, and sensory deficits and is modeled on the NIHSS. The outcome of the assessment will reflect the severity of

the stroke. This assessment is done face-to-face with the present pilot.

3. Digital goal-setting: stroke expert clinicians using this app can view the goals set by their patients and can consult to set realistic goals together with the patient and keep track of them. This could serve the purpose of both achieving it with optimum resources and ensuring the prognosis is documented and patient progress is objectively guided.

4. Web-based supervision of therapy: based on the goals set for a particular patient, the therapist can set the therapeutic interventions mentioned in the survivor's app, such as therapeutic exercises, functional skills, ADL, and assistive devices, as per the needs of the patient and ask their patients to understand how it is done and practice it at home under their supervision. Under the therapeutic exercises section of the app, the therapist can select the exercises and repetitions or dosages on a week or fortnight basis for their patients and track real-time progress objectively. Our platform also has the capability to recommend exercises as per the patient's goals, but the final decision will be taken by the concerned expert clinician.

5. Web-based follow-up: similar to consultation and supervision, the app will enable expert clinicians to conduct web-based follow-ups of their patients who have been discharged from hospital-based rehabilitation and care but who have been using the patient app for this intervention

and are being cared for by the expert clinicians irrespective of the patient's living location globally.

ReWin Stroke Telerehabilitation App Technological Flow

The ReWin stroke survivor app and the therapist app are designed to communicate with each other to provide continuous support to the therapist and stroke survivor. A summary of the workings of the app is detailed below and in Figure 6.

- A stroke survivor logs into the app and performs a self-care assessment. Goals are suggested to the patients based on their assessment outcomes.
- Stroke survivors and caregivers select goals that they want to see improved in their daily lives.
- The goal outcome is communicated to a therapist.
- The therapist performs a stroke severity and disability assessment on the stroke survivor, and the therapist, stroke survivors, and caregivers consult and finalize their goals for improvement.
- The therapist prescribes intervention based on the modified goals on a weekly or fortnightly basis.
- Therapeutic intervention is sent to the ReWin stroke survivor app for daily usage.
- Stroke survivors and therapists communicate digitally using the app at their discretion to achieve therapeutic goals and experience a continuum of care.

Figure 6. The operational flow of the intervention in terms of synchronized patient and clinician applications.
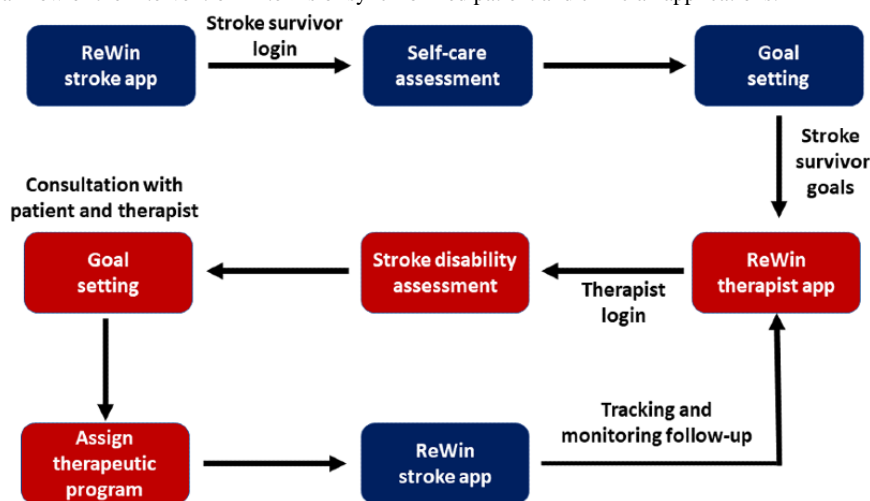
Discussion

Principal Findings

Globally, telerehabilitation has been widely accepted and promoted in stroke care [16]. Several innovations have been developed worldwide and tested for their feasibility and effectiveness [17]. Telerehabilitation for stroke includes a wide range of innovations targeting the diverse aspects of stroke care, ranging from lifestyle coaching to reducing various types of impairments as well as functional rehabilitation [18]. It is evident that telerehabilitation for stroke care can be a very useful adjunct to conventional stroke care at rehabilitation centers and hospitals and in situations where there is no other option [18]. There is also evidence to suggest that telerehabilitation

interventions have either better or equal salutary effects on physical, psychological, and cognitive impairments compared with conventional face-to-face therapy [17]. Although there is evidence for the feasibility of such innovations, the strategy used in these innovations to promote a continuum of care is still unclear [16-19]. Technological innovations for stroke care targeting the posthospital discharge period have not been shown to reduce impairments, improve independence in ADL, or improve quality of life [16]. This is especially true because telerehabilitation innovations targeting continuum care are hardly developed and evaluated, particularly in low- and middle-income countries such as India [20].

ReWin innovation targets a continuum of care for stroke survivors that is effective, safe, and of good quality. Patients

who seek treatment for stroke in a hospital get comprehensive treatment for acute stroke, and they get discharged home as soon as they are medically stable [21]. Poststroke disability is poorly understood and managed because we do not have a continuum of care outside the hospital setting in a country such as India [22]. This is true even from the government's health care perspective. The ReWin innovation bridges this important gap.

First, it enables the continuum of care for stroke survivors after hospital discharge at their home (patient app). Second, it enables the hospitals to organize their services systematically in the community for their patients and strengthen their service provision outside the hospital and have a follow-up of their patients even after they leave the hospital facility through this innovative technology-driven intervention. Systematic development cannot make the intervention scalable [8]. The intervention needs to be evaluated for its feasibility, acceptability, and effectiveness [23-25].

The key limitation of this viewpoint paper is that it does not provide the results of the feasibility assessment with sufficient data in detail. This is especially because the pilot study is currently in progress. However, once it is complete, we will ensure we report the results of the evaluation as a separate publication. Currently, ReWin is being evaluated for its feasibility and acceptability. It will be subsequently evaluated for its effectiveness too. Given our experience in developing the ReWin intervention, we foresee that affordability (costs) as well as the digital literacy of the users, particularly those who are older adults, will be key barriers to implementation that must be evaluated. The evaluation of ReWin will provide an opportunity to develop a scalable solution for empowering therapists and persons with disabilities, in general, to objectively self-manage their treatment. Findings from this study will also provide valuable information about the resources required to deliver such interventions in resource-constrained settings such as India.

Conclusions

Technology-based innovations for stroke care are absolutely essential to bridge the gaps in access to rehabilitation and to enhance recovery following stroke, particularly after hospital discharge. Innovations such as the ReWin are warranted for development as well as systematic evaluation. The innovation must connect stroke care providers in hospitals and rehabilitation centers to stroke survivors and their families in the community. The development of innovations without a strategy to ensure a continuum of care can only be efficacious in the ideal environment and might not be a scalable solution to ensure effective community-based stroke care, particularly in a country such as India.

Authors' Contributions

SK and VK contributed to the conceptualization of the innovation, and SK, RN, VK, and ABK contributed to the development and review of the manuscript. SK and VK finalized the manuscript.

Conflicts of Interest

Two authors, VK and ABK, have been the CEO and technical expert for TNQ InGage. All authors declare no other competing interests.

References

1. Liu F, Huang K, Lu X. Lifetime risk of stroke in the global burden of disease study. N Engl J Med 2019 Apr 04;380(14):1377. [doi: 10.1056/NEJMc1900607] [Medline: 30943347]

2. Iosa M, Hesse S, Oliviero A, Paolucci S. New technologies for stroke rehabilitation. Stroke Res Treat 2013;2013:815814 [FREE Full text] [doi: 10.1155/2013/815814] [Medline: 23401849]

3. Clark WE, Sivan M, O'Connor RJ. Evaluating the use of robotic and virtual reality rehabilitation technologies to improve function in stroke survivors: a narrative review. J Rehabil Assist Technol Eng 2019;6:2055668319863557 [FREE Full text] [doi: 10.1177/2055668319863557] [Medline: 31763052]

4. Rodriguez-Prunotto L, Cano-de-la-Cuerda R. [Mobile applications related to stroke: a systematic review]. Rev Neurol 2018 Apr 01;66(7):213-229 [FREE Full text] [Medline: 29557547]

5. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ 2021 Sep 30;374:n2061 [FREE Full text] [doi: 10.1136/bmj.n2061] [Medline: 34593508]

6. Burns SP, Terblanche M, Perea J, Lillard H, DeLaPena C, Grinage N, et al. mHealth intervention applications for adults living with the effects of stroke: a scoping review. Arch Rehabil Res Clin Transl 2021 Mar;3(1):100095 [FREE Full text] [doi: 10.1016/j.arrct.2020.100095] [Medline: 33778470]

7.   Deutschbein J, Grittner U, Schneider A, Schenk L. Community care coordination for stroke survivors: results of a complex intervention study. BMC Health Serv Res 2020 Dec 19;20(1):1143 [FREE Full text] [doi: 10.1186/s12913-020-05993-x] [Medline: 33341112]

8.   Kamalakannan S, Gudlavalleti Venkata M, Prost A, Natarajan S, Pant H, Chitalurri N, et al. Rehabilitation needs of stroke survivors after discharge from hospital in India. Arch Phys Med Rehabil 2016 Sep;97(9):1526-1532.e9 [FREE Full text] [doi: 10.1016/j.apmr.2016.02.008] [Medline: 26944710]

9.   Sureshkumar K, Murthy GVS, Kuper H. Protocol for a randomised controlled trial to evaluate the effectiveness of the 'care for stroke' intervention in India: a smartphone-enabled, carer-supported, educational intervention for management of disabilities following stroke. BMJ Open 2018 May 09;8(5):e020098 [FREE Full text] [doi: 10.1136/bmjopen-2017-020098] [Medline: 29743322]

10.   Adeoye O, Nyström KV, Yavagal DR, Luciano J, Nogueira RG, Zorowitz RD, et al. Recommendations for the establishment of stroke systems of care: a 2019 update. Stroke 2019 Jul;50(7):e187-e210 [FREE Full text] [doi: 10.1161/STR.0000000000000173] [Medline: 31104615]

11.   Vargus-Adams JN, Majnemer A. International Classification of Functioning, Disability and Health (ICF) as a framework for change: revolutionizing rehabilitation. J Child Neurol 2014 Aug;29(8):1030-1035. [doi: 10.1177/0883073814533595] [Medline: 24850572]

12.   Dandona R, Pandey A, George S, Kumar G, Dandona L. India's disability estimates: limitations and way forward. PLoS One 2019;14(9):e0222159 [FREE Full text] [doi: 10.1371/journal.pone.0222159] [Medline: 31491011]

13.   Pati M, Swaroop N, Kar A, Aggarwal P, Jayanna K, Damme WV. A narrative review of gaps in the provision of integrated care for noncommunicable diseases in India. Public Health Rev 2020;41:8 [FREE Full text] [doi: 10.1186/s40985-020-00128-3] [Medline: 32435518]

14.   Kamalakannan S, Chockalingam M. The National Commission for Allied and Health Care Professions Bill 2020: implications for occupational therapists and the AIOTA. Indian J Occup Ther 2020 Oct 23;52(3):104-107 [FREE Full text] [doi: 10.4103/ijoth.ijoth_40_20] [Medline: 34898824]

15.   Grills N, Singh L, Pant H, Varghese J, Murthy G, Hoq M, et al. Access to services and barriers faced by people with disabilities: a quantitative survey. DCID 2017 Aug 22;28(2):23 [FREE Full text] [doi: 10.5463/dcid.v28i2.615]

16.   Laver KE, Adey-Wakeling Z, Crotty M, Lannin NA, George S, Sherrington C. Telerehabilitation services for stroke. Cochrane Database Syst Rev 2020 Jan 31;1:CD010255 [FREE Full text] [doi: 10.1002/14651858.CD010255.pub3] [Medline: 32002991]

17.   Sarfo FS, Ulasavets U, Opare-Sem OK, Ovbiagele B. Tele-rehabilitation after stroke: an updated systematic review of the literature. J Stroke Cerebrovasc Dis 2018 Sep;27(9):2306-2318 [FREE Full text] [doi: 10.1016/j.jstrokecerebrovasdis.2018.05.013] [Medline: 29880211]

18.   Caughlin S, Mehta S, Corriveau H, Eng JJ, Eskes G, Kairy D, et al. Implementing telerehabilitation after stroke: lessons learned from Canadian trials. Telemed J E Health 2020 Jun;26(6):710-719. [doi: 10.1089/tmj.2019.0097] [Medline: 31633454]

19.   French B, Day E, Watkins C, McLoughlin A, Fitzgerald J, Leathley M, et al. The challenges of implementing a telestroke network: a systematic review and case study. BMC Med Inform Decis Mak 2013 Nov 14;13:125 [FREE Full text] [doi: 10.1186/1472-6947-13-125] [Medline: 24229343]

20.   Hartford W, Lear S, Nimmon L. Stroke survivors' experiences of team support along their recovery continuum. BMC Health Serv Res 2019 Oct 21;19(1):723 [FREE Full text] [doi: 10.1186/s12913-019-4533-z] [Medline: 31638959]

21.   Srivastava A, Swaminathan A, Chockalingam M, Srinivasan MK, Surya N, Ray P, Indian Federation of Neurorehabilitation (IFNR) Research Task Force. Tele-neurorehabilitation during the COVID-19 pandemic: implications for practice in low- and middle-income countries. Front Neurol 2021;12:667925 [FREE Full text] [doi: 10.3389/fneur.2021.667925] [Medline: 34690907]

22.   Camicia M, Lutz BJ, Harvath TA, Joseph JG. Using the preparedness assessment for the transition home after stroke instrument to identify stroke caregiver concerns predischarge: uncertainty, anticipation, and cues to action. Rehabil Nurs 2021;46(1):33-42. [doi: 10.1097/rnj.0000000000000267] [Medline: 32404680]

23.   Milat A, Lee K, Conte K, Grunseit A, Wolfenden L, van Nassau F, et al. Intervention scalability assessment tool: a decision support tool for health policy makers and implementers. Health Res Policy Syst 2020 Jan 03;18(1):1 [FREE Full text] [doi: 10.1186/s12961-019-0494-2] [Medline: 31900230]

24.   World Health Organization. Nine Steps For Developing A Scaling-up Strategy. Geneva: WHO ExpandNet; 2010.

25.   Patel V, Chesmore A, Legner CM, Pandey S. Trends in workplace wearable technologies and connected‐worker solutions for next‐generation occupational safety, health, and productivity. Advanced Intelligent Systems 2021 Sep 23;4(1):2100099 [FREE Full text] [doi: 10.1002/aisy.202100099]

Abbreviations

ADL: activities of daily living
NIHSS: National Institute of Health Stroke Scale

XSL•FO

RenderX

Original Paper

Understanding the Technology Acceptance and Usability of a New Device for Hand Therapy: Qualitative Descriptive Study

Adriana M Rios Rincon[1*], PhD; Christine Guptill[2*], PhD; Juan David Guevara Salamanca[1], BSc; Yilina Liubaoerjijin[1*], BSc; Mathieu Figeys[1*], PhD; Geoff Gregson[3], PhD; Antonio Miguel-Cruz[1*], PhD

[1]Department of Occupational Therapy, University of Alberta, Edmonton, AB, Canada

[2]Department of Occupational Therapy, Faculté des Sciences de la Santé, Université d'Ottawa, Ottawa, ON, Canada

[3]Department Glenrose Rehabilitation Research, Innovation & Technology, Glenrose Rehabilitation Hospital, Edmonton, AB, Canada

[*]these authors contributed equally

Corresponding Author:
Antonio Miguel-Cruz, PhD
Department of Occupational Therapy
University of Alberta
116 St & 85 Ave
Edmonton, AB, T6G 2R3
Canada
Phone: 1 7802246641
Email: miguelcr@ualberta.ca

Abstract

Background: Upper extremity function plays a critical role in completing activities of daily living, employment, and participating in recreational activities. The FEPSim device is a medical device for hand and wrist rehabilitation that can be adjusted according to the patient's requirements in rehabilitation. Furthermore, the FEPSim can be used to assess the patient's strength and range of motion of the forearm, wrist, and hand. At present, the acceptance and usability of the FEPSim have not been tested in a clinical setting, with limited perspectives from rehabilitation-providing clinicians.

Objective: This study aims to understand the factors related to the acceptance and usability of the FEPSim device. Upper limb disorders are prevalent across populations. The impact of upper limb disorders, both acute and chronic, puts a significant burden on the Canadian health care system.

Methods: A qualitative descriptive study was conducted that involved face-to-face semistructured interviews with hand therapists from hand therapy services who used the FEPSim device. We used purposive sampling to recruit 10 participants over a period of 14 months. Semistructured interview questions (topic-guided) examined the technology acceptance and usability of the FEPSim device.

Results: We found 6 factors to be critical aspects of the acceptance and usability of the FEPSim device. These factors were (1) useful for therapy, (2) effortlessness, (3) environmental conditions, (4) internal encouragement, (5) technological aesthetics, and (6) use.

Conclusions: The FEPSim device was widely accepted by the therapists. The use of the FEPSim device is a feasible alternative for supporting hand therapy.

Trial Registration: ISRCTN Registry ISRCTN13656014; https://www.isrctn.com/ISRCTN13656014

KEYWORDS

usability; technology acceptance; hand therapy, rehabilitation, disability; medical device; limb disorder; chronic disorder; health care system

XSL•FO
RenderX

Introduction

Upper extremity function plays a critical role in completing activities of daily living, employment, and participating in recreational activities [1]. Upper extremity functions can be detrimentally impacted by numerous disorders, thus having a deleterious impact on health and well-being [1-4].

Upper limb disorders are prevalent across populations [5,6]. There is significant variability surrounding the operational definition of upper limb disorders with differing underlying etiologies, as well as significant heterogeneity [7]. Therefore, a wide prevalence of estimates of upper limb disorders between 1.6% and 53% has been reported [7].

The impact of upper limb disorders, both acute and chronic, puts a significant burden on the Canadian health care system. One of the most prevalent etiologies resulting in upper limb impairment is arthritis; nearly 1 in 5 Canadians are living with arthritis, resulting in a yearly health care expenditure of CAD $6.4 billion [8,9]. Another common cause is cerebrovascular accidents, with an incidence rate of approximately 62,000 cases per year, costing the health care system US $3.6 billion annually [10]. Nearly 714,000 cases of injuries specific to the wrist and hand were reported during 1 year, as reported by the Canadian Community Health Survey [11]. Focusing further on wrist fractures, nearly 47,000 cases per year are reported in Canada, resulting in over CAD $100 million in acute care costs alone [12]. Finally, people with spinal cord injury may also experience impaired hand function; 86,000 Canadians are living with spinal cord injury, resulting in CAD $2.7 billion of health care costs per year [13]. Together, etiologies resulting in upper limb disorders impact millions of Canadians and are associated with an annual health care expenditure in the tens of billions of dollars in Canada alone.

With this immense prevalence and impact of upper limb disorders, rehabilitative approaches play a pivotal role in compensation for, or restoration of function after, these impairments. The increasing emphasis on rehabilitation technologies to promote activities of daily living while increasing therapy efficiency, accessibility, and practicality has resulted in various technological and robotic devices targeting upper limb therapy [14-17]. Indeed, rehabilitation strategies can improve upper limb function, although compliance and technology acceptance and adoption can pose significant challenges [15]. Additional factors associated with conventional therapy approaches such as resistance balls and putties can quickly lead to a lack of engagement from the patient, which ultimately impacts performance and compliance. Robotic rehabilitative technologies have begun to address this issue, although often at a logistical or financial cost [15,17].

Current devices specific to upper limb rehabilitation can be categorized into low-cost and portable, high-cost and portable, or high-cost and nonportable [18]. Although many low-cost devices exist as part of routine clinical care, to the authors' knowledge, none are capable of allowing a therapist to obtain performance metrics such as forearm, wrist, and hand strength; range of motion; or dexterity during functional hand movements (eg, wrist pronation/supination and flexion/extension) and grasp patterns (eg, the lateral grip, which is the grasp pattern used when grasping and turning a key to open a door).

The FEPSim (flexion, extension, pronation, and supination), developed by Karma Medical Products, is a medical device for hand and wrist rehabilitation that can be adjusted according to the patient's requirements in rehabilitation. Furthermore, the FEPSim can be used to assess the patient's strength and range of motion of the forearm, wrist, and hand. To measure range of motion, the device has features that allow the therapist to determine the degrees of movement of any given joint. The FEPSim also counts the number of repetitions of an exercise that the patient performs, which is an indicator of the patient's endurance. The customizability of the FEPSim allows for adjustments during rehabilitation progression and targeted therapeutic goals. This is achieved by the ability to adjust the strength and dexterity that the patient requires during therapy. The adjustment of dexterity is achieved by using a variety of accessories for exercising different grasp patterns such as disk grasp, power grasp, spherical grasp, and lateral grip.

Although rehabilitative devices may be efficacious, there are factors behind technology acceptance, usability, and compliance that may ultimately impact the final adoption of these technologies. For instance, in a recent randomized controlled trial investigating neurorehabilitation technology with occupational therapy–delivered hand rehabilitation compared with occupational therapy alone, over one-third of the participants in the neurotechnology and therapy group dropped out of the study due to noncompliance [19]. Rates of nonadherence to rehabilitation interventions as high as 50% have been reported [20]. This puts further stressors on the individual, the therapist, and an overburdened health care system [20]. Therapists are critical stakeholders in the adoption of rehabilitation technologies. To facilitate adoption by therapists, factors including perceived technological effectiveness (ie, usefulness because technology helps to achieve the therapeutic goals), therapeutic effort to implement the device, and patient acceptance are fundamental [21].

Together, the FEPSim's available features allow rehabilitation practitioners to optimize therapy, make informed decisions, and conduct objective measurements of rehabilitative progress specific to the upper limbs. At present, the acceptance and usability of the FEPSim have not been tested in a clinical setting, with limited perspectives from rehabilitation-providing clinicians. Therefore, the purpose of this study was to understand what factors affect the technology acceptance and usability of the FEPSim device for hand therapy by therapists at 2 hospitals in Canada.

Methods

Design

This study is part of a comprehensive study that aimed to determine the clinical effectiveness of adding the FEPSim device to standard care for patients with injuries and clinical conditions of the forearm, wrist, and hand. A comprehensive study protocol can be found in [18]. For the qualitative component of the study, we used a qualitative description design [22] to understand what

factors are related to the acceptance and usability of the FEPSim device. Qualitative description is appropriate when seeking to provide a descriptive summary of the experiences and opinions of a group of people in relation to a phenomenon [23,24].

Setting

This study was conducted in 2 health care facilities located in Edmonton, Alberta, Canada, namely the Royal Alexandra Hospital Outpatient Clinic and Glenrose Rehabilitation Hospital Specialized Rehabilitation Outpatient Program Hand Class.

Participants, Sample Size, and Recruitment

A purposive sampling method was used in this study. Hand therapists from hand therapy services that used the FEPSim device were recruited, as they could provide insight into what factors have an influence on the acceptance and usability of the FEPSim device. To ensure we reflected the diversity of experiences appropriately, we intentionally recruited hand therapists from the 2 clinical sites. All the participants were required to have used the FEPSim device. A total of 10 interviews were conducted, 1 with each participant. Hand therapists did not receive any incentive for participating in this study.

Ethical Considerations

Ethics approval was obtained from the University of Alberta Research Ethics Board and in accordance with the Declaration of Helsinki (study protocol and approval number: Pro00095587). Written informed consent was obtained from the participants prior to their participation in this study [25]. This study is part of a larger study registered at the International Registered Report Identifier (IRRID).

Data Collection Procedures

We used semistructured interviews to ensure that we collected a broad range of perspectives [22,26] regarding the technology acceptance and usability of the device. The semistructured interviews had 16 questions. During the semistructured interviews, hand therapists responded to questions such as the following: Was the FEPSim useful? Was learning to use the FEPSim easy? Was using the FEPSim well-suited to your needs? Do people who are important to you think that you should use the FEPSim? Do you plan to use the FEPSim in the near future?

They also described actual use of the FEPSim, if applicable. The semistructured interviews allowed the respondents to express themselves in their own manner and pace [27]. The interviews were conducted face-to-face.

The project coordinator (YL) conducted 10 face-to-face semistructured interviews over the course of 14 months. Each interview began with the project coordinator presenting the

study's background and purpose. The interviews were completed in a range from a minimum of 15 minutes to a maximum of 45 minutes.

The semistructured interview questions (topic-guided) examined the technology acceptance and usability of the FEPSim device. The semistructured interview questions were developed, and their face validity was determined by obtaining feedback from 2 co-authors (AMC and AMRR) who had expertise in usability and technology acceptance research [28,29].

To verify the preliminary results with the participants [30], the participants were asked to read their interview transcripts for consistency. This was done to allow the participants to correct any misunderstandings, to further expand on their ideas, and to add comments regarding the technology acceptance of the FEPSim device if any had been missed.

Data Analysis

The semistructured interviews were audio recorded and transcribed verbatim by a professional transcription service. The transcripts were read and reviewed multiple times to ensure accuracy [31]. Content analysis [32] guided our data analysis. The transcripts were annotated and coded based on their content. The codes were then organized into subcategories. After analyzing each semistructured interview, we compared the findings between the different participants. A conceptually clustered matrix was used to compare and contrast the responses. The data from each semistructured interview were summarized in a table and cross referenced. In order to achieve saturation, we used a data saturation model (ie, relates to the degree to which new data repeat what was expressed in previous data). Microsoft Excel software was used to conduct the data analysis.

In this study, we adopted verification strategies such as methodological coherence, sampling adequacy, concurrent data collection and analysis, and theoretical thinking in order to be more rigorous during the data collection and analysis [33]. We also adopted the verification strategies proposed by Morse et al [33] to enhance rigor during data collection and analysis. We supplemented these with aspects of trustworthiness strategies such as verifying data accuracy, peer debriefing, and keeping an audit trail [34].

Results

Participants

Table 1 shows the participants' demographics. The sample comprised 10 therapists from the Royal Alexandra Hospital Outpatient Clinic (n=5) and the Glenrose Rehabilitation Hospital Specialized Rehabilitation Outpatient Program Hand Class (n=5).

Table 1. Participant characteristics (n=10).

Variable	Therapists' results
Age (years), mean (SD)	40.20 (6.63)
Years providing hand therapy, mean (SD)	13.10 (6.95)
Sex, n (%)	
Male	0 (0)
Female	10 (100)
Background education, n (%)	
Occupational therapy	7 (70)
Physical therapy	0 (0)
Other	3 (30)
Highest level of education, n (%)	
Bachelor's degree	6 (60)
Master's degree	2 (20)
Diploma	2 (20)

Factors Affecting the Technology Acceptance and Usability of the FEPSim Device

The data generated 6 categories (hereafter, factors) as being critical aspects of the acceptance and usability of the FEPSim device. These factors were useful for therapy, effortlessness, environmental conditions, internal encouragement, technological aesthetics, and use. Each factor was further divided into subcategories as described in the following sections (see Figure 1 for more details).

XSL•FO
RenderX

Figure 1. Factors that affects acceptance and usability of the FEPSim device.
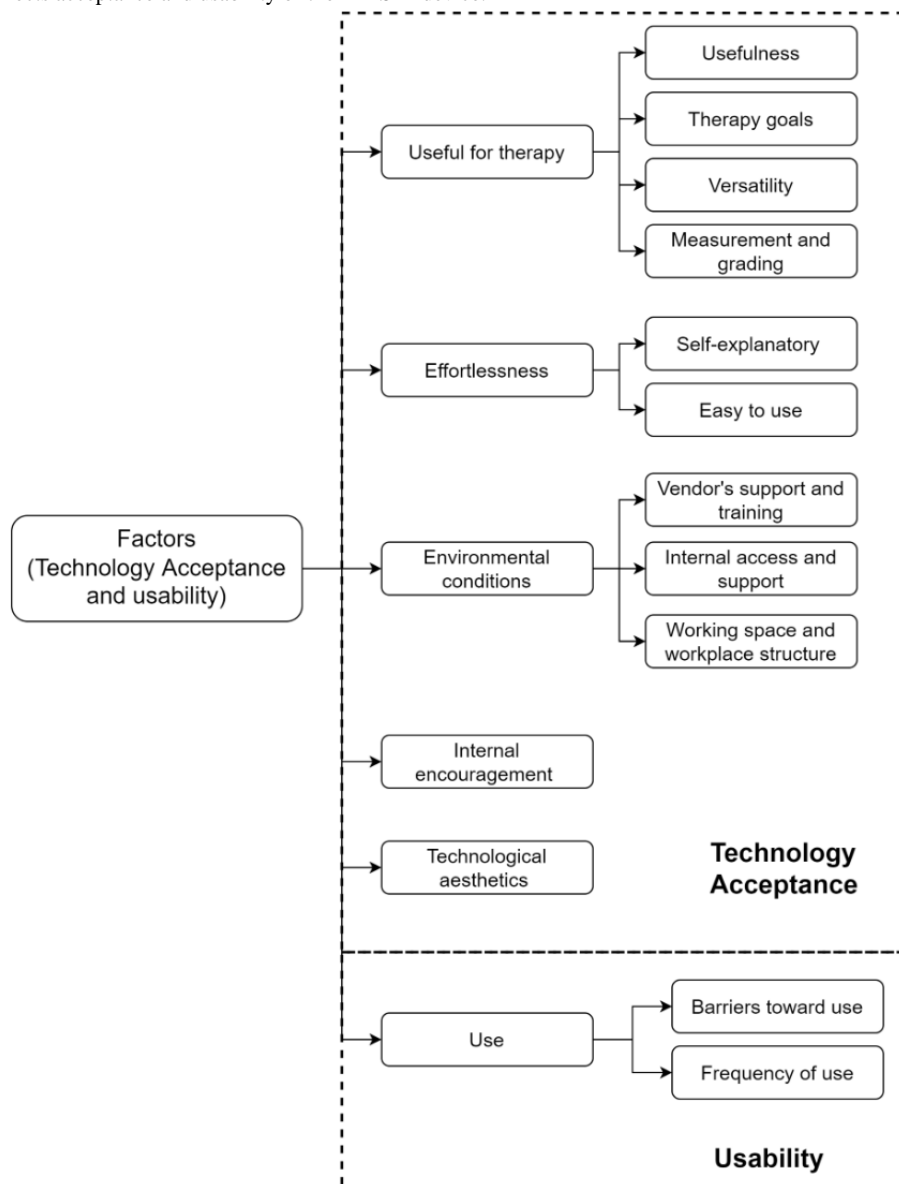
Useful for Therapy

One aspect of the device that was useful for therapy was described by the therapists as how its features facilitated therapy sessions with patients and helped to achieve their therapeutic goals. Subcategories of this included usefulness, therapy goals, versatility, and measurement and grading.

Usefulness is related to how the features of the FEPSim device can be used in combination with other strategies and modalities to facilitate the provision of hand therapy to patients who have a lower-level arm injury or disorder and who have moderate to high functioning. The participants highlighted that using the FEPSim device may provide patients with independence during therapy, as the therapist can teach them how to change tools independently or the patients will know what repetitions they have done of a given exercise, which will facilitate the provision of therapy to groups (eg, hand classes). The participants also found it useful that the FEPSim device allows daily activities to be simulated.

Like, the number is there in front of people. So, they can see how many times they've turned the tool. And the ways that you adjust the resistance on it is more precise, and so I think it's more effective and more professional than the older tool. [P8]

I find it's useful because a lot of the tools on it are—simulate, kind of, every day functional things they do, like the doorknob and the twisting. [P7]

Therapy goals were described in terms of how the FEPSim device helps therapists work on patients' strength and endurance building, range of motion, grasp and release or grip and pitch, and functional goals. However, one participant commented that the device is not useful for manipulation goals.

I think I used it if I wanted to get a certain work on a certain movement pattern. So, if there was, you know, the knob or the lever or the key grasp or, you know, any of the other sort of grasps that I felt like, you know, I wanted to target, it was good. It was good in that respect... Yes. I felt like, like I said, I used it

to achieve certain movement patterns and for getting in the strength and endurance that I needed. [P9]

I don't tend to use it for manipulation goals, because you're not really manipulating, you're grabbing and releasing or pinching and releasing, you're not having to pick up and manipulate stuff within your fingertips, so. [P4]

Versatility is related to specific features that make the FEPSim device a single tool that provides many different options and attachments that can be used for several therapeutic goals with patients. For example, the device can be adjusted for resistance, it has several attachments that allow different grasp and grip patterns to be worked on, it counts the number of repetitions, and it is slick. The participants also used descriptors such as the FEPSim is an "all-in-one device," thus highlighting that neither the patients nor the therapists have to walk around to use different tools, but rather, the FEPSim provides everything they need in one device.

I think the adjustability is good in terms of, you know, being able to use one thing for many usages. [P9]

I like the versatility with all the different, like, attachments and heads that you can use. And the fact that you can have a great range of adjustability for resistance. [P8]

It was useful because then I could track and I could plan to make increases and to increase the program and the resistance to reach goals of, you know, increased strength and that type of thing. [P7]

Measurement and grading are related to the device's features that allow different aspects of the treatment to be counted, graded, measured, and monitored over time. The participants highlighted as positive features that the FEPSim counts the repetitions of the exercises and allows the therapist to grade the resistance, the amount of rotation, and the difficulty of different grasps and grips using the real-life attachments; thus, the therapist controls the strength, range of motion, and hand patterns the patient needs to use during a session. All of these features allow the therapists to use objective data and provide feedback to the patients, which helps with the transferability of skills gained from the device to the use of real-world objects.

What I really like is the counter. So, the patients get direct feedback. They don't have to rely on counting the repetitions. For traditional pieces of equipment, they don't have that visual feedback. So, I like that. As they're doing it, they can see the counter, so I can say stop at 20. [P10]

I like that it counts the reps and that you can increase the strength. [P1]

Effortlessness

Effortlessness within the context of this study was defined as how easy it is to learn to use the device. The participants identified that the FEPSim device was self-explanatory and easy to use.

The self-explanatory aspect was related to how easy it was to learn or figure out how to use the device. The participants

highlighted that learning how to use the device was easy and self-explanatory and that they were able to figure out on their own how to use it by asking their colleagues a few questions.

Yeah. Learning is pretty straightforward. Like, you look at it, and it's fairly intuitive in how you set it up. Like, you pull the pin. You can see how the attachments only attach in a certain way. Yeah. And then the device got improved when you could do the—when you could push down the suction to get it off [to remove it from the table], because before the suction used to be really hard to get off. [P10]

The easy-to-use aspect includes how easy it is for the device to be used, cleaned, set up, and transported, as well as how easy it is to teach patients how to use it. In general, most of participants commented that the FEPSim device is easy to use.

I don't think setting it up takes a lot of effort. Sometimes, like, taking it off the table as I just described is a little bit more effortful. [P8]

It's pretty straightforward to use, pretty easy to clean. [P4]

It's useful in that it's easy to transport and just have it sit at one station, and they can do a number of things without having to move around the room. [P7]

Environmental Conditions

Environmental conditions were described in terms of how supportive the environment is with regard to using the FEPSim device. The participants commented on the support and training provided by the FEPSim device's vendor and the institutional access and support.

The participants identified the vendor's support and training as being an important element for using the device's features in full. The participants felt that they had not had formal training or direct contact with the vendor. One participant commented on having only a little in-service. It seems that formal training on how to use the device was not provided by the vendor, so the therapists had diverse experiences with their training. Discrepancies in training might affect how much the therapists used all the device's features.

But I thought that it was—like, I was able to figure it out. Maybe I didn't figure out everything, but I thought I got it to do what I wanted... Maybe I didn't know that you could do it (supination and pronation) with that machine. [P9]

I feel like the majority of the training that happens with the tool is just kind of from staff member to staff member. [P8]

I think it would be a good idea if, moving forward, that there is a legend or an exercise sheet or—that shows different ways of using the tools in order to target different things. Because as it stands, I think everything was left just to me to try and put things together in order to reach the goals that I wanted. [P7]

Institutional access and support are related to how much support from the hospitals was provided to use the FEPSim device and

how available the device was for use during therapeutic sessions. The participants felt, in general, that the hospitals supported the use of the FEPSim device. The therapists commented that the device was available in general, although some barriers were identified regarding its complete accessibility such as the FEPSim sometimes being located in an intervention room different from the one used to provide treatment. The participants also commented that they learned how to use the device mainly from their colleagues and that they did not have direct contact with the vendor when they had an issue with the device. The contact was through technology leaders who are therapists whose duties include promoting technology adoption at one of the hospitals.

> *Oh, see I've never dealt with [the vendor], it was always our technology leader that kind of would go to it, and I've never had a problem that I had to problem-solve with, but then it was kind of self-evident how to work the FEPS, so.* [P4]

> *I guess it'd be whether or not we're treating in our room that has the FEPS. Because right now, we have two [FEPSim] in SROP [the outpatient service], but we have treatment spaces all over the hospital. So, if there's no FEPS there, then I wouldn't—or I couldn't book the area with the FEPS and that would be a barrier.* [P10]

Internal Encouragement

Internal encouragement is related to the attitudes of people in the therapists' human environment toward them using the FEPSim device as part of their treatment. The participants commented on feeling encouraged by their managers, supervisors, and colleagues to use the FEPSim device but that they were able to make the decision about whether to use it or not with their patients.

> *They're good at encouraging us to and providing the education and then allowing us to have that therapeutic decision making if we use it or not.* [P5]

> *They [managers, supervisors, colleagues] encourage it [the FEPSim device], like the therapists do the assessments and they'll add that on the treatment plan, or we can add it too, and that happens regularly.* [P1]

Technological Aesthetics

Technological aesthetics was described in terms of how the FEPSim device's appearance contributed to its acceptance. The participants commented on how cool, innovative, and high-tech the device looked, which motivated the patients to engage during sessions when it was used.

> *I mean, the FEPS looks good. It does. It looks pretty sleek. And I think patients get impressed by the look. Actually, my patient really wanted to—the one that was in the control—wanted to use it. So, I think that might be a motivating factor for patients.* [P9]

> *...if I talk about like how it's made, people are always, think it's really cool, because it's on a 3D printer. So, the patients get excited about it, because they just*

> *think that it's cool and they like the way it looks. [laugh] Yeah.* [P10]

Use

Use, in the context of this study, is related to the factors that influence the actual use of the device during therapeutic sessions. The subcategories identified by the participants are related to the barriers regarding use and frequency of use.

The barriers against the actual use of the FEPSim device included (1) COVID-19–related restrictions, (2) patient conditions, and (3) therapeutic goals that were clearly focused on functional outcomes. The participants commented on how the COVID-19 pandemic had been having a huge impact on the use of the device, as the measures to control the spread of the virus changed the frequency of the therapeutic sessions and the mode of delivery (eg, from in-person to telerehab). The therapists commented that, if the device was available at home, the patients could use it on a regular basis. However, as this was not the case, during the sessions at the hospital, the therapists opted to teach activities and exercises that the patients could practice with the resources they had at home. Lack of active movement of the wrist, lack of grip, pain, and cognitive issues were identified as factors related to the patients' conditions that limited the therapists from incorporating the FEPSim device during the treatment sessions. One participant commented that the FEPSim was "abstract" for patients with cognitive issues whose sessions needed to focus on actual functional tasks (eg, getting dressed or doing up their zipper), which are not possible with the device. Having patients with cognitive issues was an example of how the device was not appropriate for use with cases for whom the therapeutic goals needed to be strongly focused on functional, real-world outcomes.

> *Well, because COVID, I don't know what my near future looks like, but right now I've been doing a lot in outpatients, right now my whole caseload is on Zoom.* [P5]

Frequency of use is related to how frequently the therapists used the FEPSim device. The participants commented on how they used the device fairly frequently but not in every single session with the patients. Frequency of use depended on the patients' needs, the availability of the device, and how the session turned out.

> *I think it's been used fairly frequently but not on everybody—depending on the patient.* [P10]

Discussion

Principal Findings

In this study, we aimed to understand what factors affect the technology acceptance and usability of the FEPSim device for hand therapy by therapists at 2 hospitals in Alberta, Canada. In doing so, by using a qualitative description design, we analyzed data from 10 semistructured interviews conducted with hand therapists that used the FEPSim. Overall, 6 factors were found to be critical aspects of the acceptance and usability of the FEPSim device. These factors were useful for therapy,

effortlessness, environmental conditions, internal encouragement, technological aesthetics, and use.

Our findings revealed that the FEPSim device was useful for hand therapy. The usefulness of the FEPSim device lies in the fact that it is a versatile tool with a variety of measurement and grading systems that allow therapists to tailor their treatment plans to achieve their clients' hand therapy goals. This finding is consistent with the results of previous studies about technology acceptance and usability in mobile health, health, and rehabilitation and assistive technologies [28,35-37]. For example, the study by Liu et al [35] aimed to explore the technology acceptance and usability of GPS technology among persons living with dementia and family caregivers; they found that usefulness had a significant influence on the acceptance of GPS. In the study, GPS technology provided peace of mind for caregivers and more independence for people living with dementia [35]. In another study, Liu et al [28] reported that usefulness was the most significant factor in the acceptance of new rehabilitation technologies. In other words, how rehabilitation technologies can help therapists to achieve their therapeutic goals with clients was the most important factor in determining therapists' acceptance and use of these new rehabilitation technologies [28].

It is important to note that the versatility of the FEPSim is added value for the device that allows therapy to be achieved. In other words, the therapists acknowledged that the FEPSim device has a relative advantage over traditional devices (including old FEPS models [ie, wood-based devices]) that therapists had been using. Relative advantage is understood to be the degree to which using the FEPSim device is perceived as being better than using its precursor or other devices [38]. The relative advantage of the FEPSim accounts for a device that is more usable and functional for therapy. This finding reassures rehabilitation technology designers that they should hear the voices of therapists before embarking on designing and creating these technologies. In other words, the use and implementation of co-design and co-creation strategies should be paramount for rehabilitation technology designers.

We found that using the FEPSim device was effortless. The FEPSim device is self-explanatory and easy to use not only for therapists but also for patients. By having a device that is self-explanatory, therapists meant that the FEPSim is very intuitive to use and that it is easy to remember how to use it. Simply put, the FEPSim device is memorable. The scholarly literature defines memorability as a feature of a technology that is easy to remember, so that the casual user is able to return to use the technology after some period of not having used it, without having to learn everything all over again [39]. On the other hand, ease of use is understood to be the degree to which a person believes that using a technology would be free of effort [38]. The scholarly literature in the field of technology acceptance and usability of mobile applications for health, health, and rehabilitation and assistive technologies shows that ease of use is becoming a less important factor with regard to technology acceptance as long as the technology shows signs of usefulness in achieving therapeutic goals. For example, one study found that therapists were not influenced by the degree of difficulty of using new rehabilitation technologies [28]. The same is true for another study that assessed the technology acceptance of a mobile application that was intended to support the workflow of health care aides who provided services to older adults residing in a care facility [37]. More surprisingly, a further study found that the ease of use of a GPS technology mattered inversely to its technology acceptance. In other words, contrary to what many technology acceptance theories predict (eg, [38]), while the users perceived that the GPS was hard to use, they would still have continued to use the device if they were able to do so [35]. Since our study was a qualitative study, it was impossible for us to determine how important effortless was in comparison to the other factors. Therefore, it would be worth exploring through a quantitative study whether the FEPSim's ease of use is a salient factor with regard to technological acceptance and the specific weight of this factor compared with usefulness, for example.

The therapists believed that they had created all the conditions to use the FEPSim device. Environmental conditions included the vendors' support and training, internal access to the device and support, and working space and workplace structure. Environmental conditions, also known as facilitating conditions in some technology adoption theories such as the Unified Theory of Acceptance and Use of Technology (UTAUT), are defined as the degree to which an individual believes that all the conditions exist to support the use of a technology [38]. This result did not surprise us, as there is an extensive body of literature in the field of technology acceptance and use that points toward facilitating conditions as a salient factor in technology acceptance and use [40].

The aesthetics of the FEPSim device motivated its use. In other words, the patients liked the way the FEPSim device looks and the way the device was made (eg, 3D-printed). This finding is consistent with the scholarly literature and, at the same time, is interesting because it has some implications. For example, a recent study aimed to identify what factors are related to the acceptance and usability of locator devices that are important to individuals with dementia and other stakeholders. The study found that aesthetic appeal was a factor in technology acceptance [29]. The implication of our finding lies in the fact that aesthetic appeal might have been a motivating factor for the patients to use the device, which in turn might have influenced the therapists' decision to adopt the FEPSim technology. In other words, the clients drove the therapists' decision to adopt the technology. Motivation, which is more formally called hedonic motivation in some technology acceptance theories (eg, UTAUT2) and which is defined as the fun or pleasure derived from using a technology [41], has been shown to be an important determinant in technology acceptance and use [42]. Other scholars have found similar results regarding "positive feedback" that influenced mutual technology acceptance between dyads of users. For example, in one study, caregivers and clients living with dementia encouraged each other to use GPS devices in order to address the burden on caregivers that is associated with anxiety about their clients getting lost [35]. From a research perspective, it would be worth studying the phenomenon of technological acceptance further, following a dyadic approach rather than exploring individual perspectives and beliefs.

Limitations

This study has one important limitation. The data were collected from participants who were therapists from 2 health care institutions in the public sector only. This limited the potential for generalizing the results, for example, to therapists from other provinces or the private health care sector in Canada or in other countries. Regardless of this limitation, the findings can be used to understand the technology acceptance and usability of the FEPSim device. They also serve as a starting point for future research, specifically quantitative and mixed methods research.

Conclusions

Overall, our findings suggest that the factors useful for therapy, namely effortlessness, environmental conditions, internal encouragement, technological aesthetics, and use, affected the technology acceptance and usability of the FEPSim device for hand therapy by therapists. In conclusion, the FEPSim device was widely accepted by therapists. The use of the FEPSim device is a feasible alternative for supporting hand therapy.

Acknowledgments

Conflicts of Interest

None declared.

References

1. Lamers I, Feys P. Assessing upper limb function in multiple sclerosis. Mult Scler 2014 Jun 24;20(7):775-784. [doi: 10.1177/1352458514525677] [Medline: 24664300]

2. Kaymaz D, Candemir İ, Ergün P, Demir N, Taşdemir F, Demir P. Relation between upper-limb muscle strength with exercise capacity, quality of life and dyspnea in patients with severe chronic obstructive pulmonary disease. Clin Respir J 2018 Mar 22;12(3):1257-1263. [doi: 10.1111/crj.12659] [Medline: 28618190]

3. Lieshout ECCV, van de Port IG, Dijkhuizen RM, Visser-Meily JMA. Does upper limb strength play a prominent role in health-related quality of life in stroke patients discharged from inpatient rehabilitation? Top Stroke Rehabil 2020 Oct 09;27(7):525-533. [doi: 10.1080/10749357.2020.1738662] [Medline: 32148183]

4. Damms NA, McCallum LM, Sarrigiannis PG, Zis P. Pain as a determinant of health-related quality of life in patients with carpal tunnel syndrome; a case-controlled study. Postgrad Med 2020 Jan 30;132(1):52-55. [doi: 10.1080/00325481.2019.1694840] [Medline: 31736403]

5. Walker-Bone K, Palmer KT, Reading I, Coggon D, Cooper C. Prevalence and impact of musculoskeletal disorders of the upper limb in the general population. Arthritis Rheum 2004 Aug 15;51(4):642-651 [FREE Full text] [doi: 10.1002/art.20535] [Medline: 15334439]

6. Dutta D, Sen S, Aruchamy S, Mandal S. Prevalence of post-stroke upper extremity paresis in developing countries and significance of m-Health for rehabilitation after stroke - A review. Smart Health 2022 Mar;23:100264. [doi: 10.1016/j.smhl.2022.100264]

7. Huisstede BM, Bierma-Zeinstra SM, Koes BW, Verhaar JA. Incidence and prevalence of upper-extremity musculoskeletal disorders. A systematic appraisal of the literature. BMC Musculoskelet Disord 2006 Jan 31;7(1):7 [FREE Full text] [doi: 10.1186/1471-2474-7-7] [Medline: 16448572]

8. Butler-Jones D. The Chief Public Health Officer's Report on The State of Public Health in Canada 2010 – Growing older: Adding life to years. Government of Canada. 2010. URL: https://www.canada.ca/en/public-health/corporate/publications/chief-public-health-officer-reports-state-public-health-canada/annual-report-on-state-public-health-canada-2010.html [accessed 2022-10-27]

9. Badley EM, Goulart CM, Millstone DB, Perruccio AV. An update on arthritis in Canada - National and provincial data regarding the past, present, and future. J Rheumatol 2019 Jun 15;46(6):579-586. [doi: 10.3899/jrheum.180147] [Medline: 30770501]

10. (Dis)connected: How unseen links are putting us at risk. Heart and Stroke Canada. 2019. URL: https://www.heartandstroke.ca/-/media/pdf-files/canada/2019-report/heartandstrokereport2019.ashx [accessed 2022-10-27]

11. Billette JM, Janz T. Injuries in Canada: Insights from the Canadian Community Health Survey. Statistics Canada. URL: https://www150.statcan.gc.ca/n1/pub/82-624-x/2011001/article/11506-eng.htm [accessed 2022-10-27]

12. Fracture incidence and costs by province. Osteoporosis Canada. 2013. URL: https://fls.osteoporosis.ca/wp-content/uploads/FLS-TOOLKIT-App-B.pdf [accessed 2022-10-27]

13. Noonan VK, Fingas M, Farry A, Baxter D, Singh A, Fehlings MG, et al. Incidence and prevalence of spinal cord injury in Canada: a national perspective. Neuroepidemiology 2012 Apr 27;38(4):219-226 [FREE Full text] [doi: 10.1159/000336014] [Medline: 22555590]

14. Loureiro RCV, Harwin WS, Nagai K, Johnson M. Advances in upper limb stroke rehabilitation: a technology push. Med Biol Eng Comput 2011 Oct 20;49(10):1103-1118. [doi: 10.1007/s11517-011-0797-0] [Medline: 21773806]

XSL·FO

RenderX

15. Kowalczewski J, Prochazka A. Technology improves upper extremity rehabilitation. Prog Brain Res 2011;192:147-159. [doi: 10.1016/B978-0-444-53355-5.00010-5] [Medline: 21763524]

16. Maceira-Elvira P, Popa T, Schmid A, Hummel FC. Wearable technology in stroke rehabilitation: towards improved diagnosis and treatment of upper-limb motor impairment. J Neuroeng Rehabil 2019 Nov 19;16(1):142 [FREE Full text] [doi: 10.1186/s12984-019-0612-y] [Medline: 31744553]

17. Qassim HM, Wan Hasan WZ. A review on upper limb rehabilitation robots. Applied Sciences 2020 Oct 06;10(19):6976. [doi: 10.3390/app10196976]

18. Miguel-Cruz A, Guptill C, Gregson G, Ladurner A, Holmes C, Yeung D, et al. Determining the effectiveness of a new device for hand therapy (the FEPSim device): feasibility protocol for a randomized controlled trial study. JMIR Res Protoc 2021 May 27;10(5):e22145 [FREE Full text] [doi: 10.2196/22145] [Medline: 34042597]

19. Waliño-Paniagua CN, Gómez-Calero C, Jiménez-Trujillo MI, Aguirre-Tejedor L, Bermejo-Franco A, Ortiz-Gutiérrez RM, et al. Effects of a game-based virtual reality video capture training program plus occupational therapy on manual Dexterity in Patients with Multiple Sclerosis: a randomized controlled trial. J Healthc Eng 2019;2019:9780587 [FREE Full text] [doi: 10.1155/2019/9780587] [Medline: 31178989]

20. Argent R, Daly A, Caulfield B. Patient involvement with home-based exercise programs: can connected health interventions influence adherence? JMIR Mhealth Uhealth 2018 Mar 01;6(3):e47 [FREE Full text] [doi: 10.2196/mhealth.8518] [Medline: 29496655]

21. Morrow CM, Johnson E, Simpson KN, Seo NJ. Determining factors that influence adoption of new post-stroke sensorimotor rehabilitation devices in the USA. IEEE Trans. Neural Syst. Rehabil. Eng 2021;29:1213-1222. [doi: 10.1109/tnsre.2021.3090571]

22. Sandelowski M. Whatever happened to qualitative description? Res. Nurs. Health 2000 Aug;23(4):334-340. [doi: 10.1002/1098-240x(200008)23:4<334::aid-nur9>3.0.co;2-g]

23. Kim H, Sefcik JS, Bradway C. Characteristics of qualitative descriptive studies: a systematic review. Res Nurs Health 2017 Feb 30;40(1):23-42 [FREE Full text] [doi: 10.1002/nur.21768] [Medline: 27686751]

24. Neergaard MA, Olesen F, Andersen RS, Sondergaard J. Qualitative description - the poor cousin of health research? BMC Med Res Methodol 2009 Jul 16;9(1):52 [FREE Full text] [doi: 10.1186/1471-2288-9-52] [Medline: 19607668]

25. Determining the effectiveness of the FEPSim™ device for hand therapy. ISRCTN Registry. URL: https://www.isrctn.com/ISRCTN13656014 [accessed 2022-10-27]

26. Lam SKY, Chau JPC, Lo SHS, Siow EKC, Lee VWY, Shum EWC, et al. User engagement in the development of a home-based virtual multidisciplinary stroke care clinic for stroke survivors and caregivers: a qualitative descriptive study. Disabil Rehabil 2022 Oct 23;44(20):5983-5989. [doi: 10.1080/09638288.2021.1955305] [Medline: 34297647]

27. Jamshed S. Qualitative research method-interviewing and observation. J Basic Clin Pharm 2014 Sep;5(4):87-88 [FREE Full text] [doi: 10.4103/0976-0105.141942] [Medline: 25316987]

28. Liu L, Miguel Cruz A, Rios Rincon A, Buttar V, Ranson Q, Goertzen D. What factors determine therapists' acceptance of new technologies for rehabilitation – a study using the Unified Theory of Acceptance and Use of Technology (UTAUT). Disabil Rehabil 2015 Jun 05;37(5):447-455. [doi: 10.3109/09638288.2014.923529] [Medline: 24901351]

29. Neubauer N, Spenrath C, Philip S, Daum C, Liu L, Miguel-Cruz A. Identifying adoption and usability factors of locator devices for persons living with dementia. Dementia (London) 2022 Apr 29;21(3):862-881 [FREE Full text] [doi: 10.1177/14713012211065381] [Medline: 34964391]

30. Guba EG. Criteria for assessing the trustworthiness of naturalistic inquiries. ECTJ 1981 Jun;29(2):1. [doi: 10.1007/bf02766777]

31. Poland BD. Transcription quality as an aspect of rigor in qualitative research. Qualitative Inquiry 2016 Jun 29;1(3):290-310. [doi: 10.1177/107780049500100302]

32. Hsieh H, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res 2005 Nov 01;15(9):1277-1288. [doi: 10.1177/1049732305276687] [Medline: 16204405]

33. Morse JM, Barrett M, Mayan M, Olson K, Spiers J. Verification strategies for establishing reliability and validity in qualitative research. International Journal of Qualitative Methods 2016 Nov 30;1(2):13-22. [doi: 10.1177/160940690200100202]

34. Lincoln YS, Guba EG, Pilotta JJ. Naturalistic inquiry. International Journal of Intercultural Relations 1985 Jan;9(4):438-439. [doi: 10.1016/0147-1767(85)90062-8]

35. Liu L, Miguel Cruz A, Ruptash T, Barnard S, Juzwishin D. Acceptance of global positioning system (GPS) technology among dementia clients and family caregivers. Journal of Technology in Human Services 2017 Jan 17;35(2):99-119. [doi: 10.1080/15228835.2016.1266724]

36. Lim H, Dunn A, Muhammad Firdaus Ooi S, Teo CH, Abdullah A, Woo WJ, et al. mHealth adoption among primary care physicians in Malaysia and its associated factors: a cross-sectional study. Fam Pract 2021 Jun 17;38(3):210-217. [doi: 10.1093/fampra/cmaa103] [Medline: 32968795]

37. Miguel Cruz A, Lopez Portillo HP, Daum C, Rutledge E, King S, Liu L. Technology acceptance and usability of a mobile app to support the workflow of health care aides who provide services to older adults: pilot mixed methods study. JMIR Aging 2022 May 18;5(2):e37521 [FREE Full text] [doi: 10.2196/37521] [Medline: 35583930]

38.   Venkatesh V, Morris MG, Davis GB, Davis FD. User acceptance of information technology: toward a unified view. MIS Quarterly 2003;27(3):425. [doi: 10.2307/30036540]
39.   Nielsen J. Usability engineering. Mountain View, CA: Morgan Kaufmann; 1993.
40.   Miguel Cruz A, Daum C, Comeau A, Salamanca JDG, McLennan L, Neubauer N, et al. Acceptance, adoption, and usability of information and communication technologies for people living with dementia and their care partners: a systematic review. Disabil Rehabil Assist Technol 2020 Dec 30:1-15. [doi: 10.1080/17483107.2020.1864671] [Medline: 33378627]
41.   Venkatesh V, Thong JYL, Xu X. Consumer acceptance and use of information technology: extending the unified theory of acceptance and use of technology. MIS Quarterly 2012;36(1):157. [doi: 10.2307/41410412]
42.   Brown SA, Venkatesh V. Model of adoption of technology in households: a baseline model test and extension incorporating household life cycle. MIS Quarterly 2005;29(3):399. [doi: 10.2307/25148690]

Abbreviations

AICE: Accelerating Innovation Into Care
IRRID: International Registered Report Identifier
UTAUT: Unified Theory of Acceptance and Use of Technology

XSL•FO
RenderX

The Effects of an Individualized Smartphone-Based Exercise Program on Self-defined Motor Tasks in Parkinson Disease: Pilot Interventional Study

Heiko Gaßner[1,2], DPhil; Jana Friedrich[1], BA; Alisa Masuch[1], MD; Jelena Jukic[1], MD; Sabine Stallforth[1,3], MD; Martin Regensburger[1], MD; Franz Marxreiter[1], MD; Jürgen Winkler[1], MD; Jochen Klucken[1,2,3,4,5,6], MD

[1]Department of Molecular Neurology, University Hospital Erlangen, Erlangen, Germany

[2]Digital Health Systems, Fraunhofer Institute for Integrated Circuits (IIS), Erlangen, Germany

[3]Medical Valley, Digital Health Application Center GmbH, Bamberg, Germany

[4]Digital Medicine Group, Luxembourg Centre for Systems Biomedicine (LCSB), University of Luxembourg, Esch-sur-Alzette, Luxembourg

[5]Digital Medicine Group, Department of Precision Health, Luxembourg Institute of Health (LIH), Strassen, Luxembourg

[6]Digital Medicine Group, Centre Hospitalier de Luxembourg (CHL), Luxembourg, Luxembourg

Corresponding Author:
Heiko Gaßner, DPhil
Department of Molecular Neurology
University Hospital Erlangen
Schwabachanlage 6
Erlangen, 91054
Germany
Phone: 49 913185 ext 39324
Email: Heiko.Gassner@uk-erlangen.de

Abstract

Background: Bradykinesia and rigidity are prototypical motor impairments of Parkinson disease (PD) highly influencing everyday life. Exercise training is an effective treatment alternative for motor symptoms, complementing dopaminergic medication. High frequency training is necessary to yield clinically relevant improvements. Exercise programs need to be tailored to individual symptoms and integrated in patients' everyday life. Due to the COVID-19 pandemic, exercise groups in outpatient setting were largely reduced. Developing remotely supervised solutions is therefore of significant importance.

Objective: This pilot study aimed to evaluate the feasibility of a digital, home-based, high-frequency exercise program for patients with PD.

Methods: In this pilot interventional study, patients diagnosed with PD received 4 weeks of personalized exercise at home using a smartphone app, remotely supervised by specialized therapists. Exercises were chosen based on the patient-defined motor impairment and depending on the patients' individual capacity (therapists defined 3-5 short training sequences for each participant). In a first education session, the tailored exercise program was explained and demonstrated to each participant and they were thoroughly introduced to the smartphone app. Intervention effects were evaluated using the Unified Parkinson Disease Rating Scale, part III; standardized sensor-based gait analysis; Timed Up and Go Test; 2-minute walk test; quality of life assessed by the Parkinson Disease Questionnaire; and patient-defined motor tasks of daily living. Usability of the smartphone app was assessed by the System Usability Scale. All participants gave written informed consent before initiation of the study.

Results: In total, 15 individuals with PD completed the intervention phase without any withdrawals or dropouts. The System Usability Scale reached an average score of 72.2 (SD 6.5) indicating good usability of the smartphone app. Patient-defined motor tasks of daily living significantly improved by 40% on average in 87% (13/15) of the patients. There was no significant impact on the quality of life as assessed by the Parkinson Disease Questionnaire (but the subsections regarding mobility and social support improved by 14% from 25 to 21 and 19% from 15 to 13, respectively). Motor symptoms rated by Unified Parkinson Disease Rating Scale, part III, did not improve significantly but a descriptive improvement of 14% from 18 to 16 could be observed. Clinically relevant changes in Timed Up and Go test, 2-minute walk test, and sensor-based gait parameters or functional gait tests were not observed.

XSL•FO
RenderX

Conclusions: This pilot interventional study presented that a tailored, digital, home-based, and high-frequency exercise program over 4 weeks was feasible and improved patient-defined motor activities of daily life based on a self-developed patient-defined impairment score indicating that digital exercise concepts may have the potential to beneficially impact motor symptoms of daily living. Future studies should investigate sustainability effects in controlled study designs conducted over a longer period.

Introduction

Motor impairment in everyday life is highly affected by prototypical symptoms of Parkinson disease (PD) including bradykinesia and rigidity reflected by slow and reduced amplitude of movements and limited automaticity [1]. Exercise and physical therapy are increasingly recognized as both effective and complementary—to dopaminergic medication—treatment of motor symptoms in PD [2].

High-Frequency and Home-Based Training

There is evidence that high-frequency training (approximately 4 times per week) is necessary to gain lasting improvement in motor symptoms in individuals with PD [3,4]. This is a major limitation for typical outpatient settings owing to the high organizational burden for patients and therapists. Furthermore, quarantine-related isolation and canceled physical therapy sessions, owing to the global COVID-19 pandemic, have made a huge impact on patients with chronic diseases [5-8]. Therefore, new solutions in the form of remotely supervised, home-based exercise programs have been developed, and the COVID-19 pandemic has accelerated the acceptance of these telemedical solutions [8,9]. Several studies have shown evidence that prescribed home-based exercise improved motor symptoms in patients with PD [4,10-15].

Previous studies assessing the benefit of home-based exercise have included mild to moderate disease stages of PD (Hoehn and Yahr stages I-III) with no cognitive impairment, stable medication, and an average age >60 years [10-12,14-17]. Exercises performed (treadmill walking [16], cycling [12], and balance training [10,13]) as well as the type of presentation (personal visit, paper sheet, smartphone app, and instructional DVD) varied. All studies were, to a certain degree, supervised by a therapist and exercises were prescribed by a specialized therapist beforehand. The duration of intervention ranged between 4 weeks and 6 months [10-12,14-17]. Overall, these studies observed improvements by exercise programs in gait and mobility [4,10,14,15]. Studies that assessed the Unified Parkinson Disease Rating Scale, part III (UPDRS-III) score reported fewer motor symptoms after the intervention period, especially when compared with a control group without intervention [13,18]. One study reported an increased quality of life (QoL) [16].

A meta-analysis, including studies mentioned previously, showed that a minimum training frequency of 150 minutes per week for at least 6 weeks yielded considerably higher benefits than a lower training frequency. Furthermore, it reported a lack of sustainable effects, stating that benefits only lasted shortly after the end of the intervention [4], consequently confirming that a sustainable long-term solution is undeniably needed.

Telehealth Solutions and Smartphone-Based Exercise

Exercise needs to be consistent, less supervised, and more personalized to reach full potential and become a sustainable long-term solution [4,19]. Telemedicine and new digital patient-centered technologies seem to be a promising solution to those problems, making exercise and feedback data more accessible [20,21]. We therefore developed a smartphone app to enable the home-based exercise program for patients with PD. Apps can provide the user with easy access and allow for remote supervision. As the content of an app can be modified rather easily, it allows for more personalization and an exercise program tailored to the individual requirements of patients.

Recent research showed that most patients with PD have access to mobile phones and internet and are comfortable with using these technologies [22]. Smartphone apps have already successfully been used in various studies within patients with PD [23-25]. One study in particular should be highlighted [12]. This study included 130 patients (Hoehn and Yahr stages under II) mildly affected by PD, aged 30 to 75 years with stable dopaminergic medication, being split into an intervention group performing 30 to 45 minutes of cycling on a virtual reality–enhanced home trainer at least 3 times a week for 6 months and a control group doing stretching exercises at the same frequency [12]. All participants received coaching instructions at the beginning of the intervention and a follow-up phone call every fortnight. The intervention included a motivational app that provided training instructions and tips, gave instant feedback, and monitored progress [12]. Outcomes were significantly lower UPDRS-III scores and an improvement in physical fitness; however, the benefits were only present during medical "off" state testing.

Patient-Reported Outcome Measures

Patient-reported outcome measures (PROMs) describe how patients individually perceive the outcome of measures such as an intervention on their symptoms, functional status, or QoL [26,27]. As exercise programs aim to complement pharmacological therapies and to improve motor performance of patients with PD in everyday life, PROMs are of huge interest as they can be used as a measure of relevant intervention effects for individuals. Patient-defined outcomes are even more relevant in a patient-centered approach.

Despite the fact that the engagement of patients and the additive value of patient-reported outcomes has rapidly gained relevance, there is a lack of home-based exercise studies focusing on the

individualized approach. This approach in particular might benefit substantially from using a modifiable smartphone app.

Therefore, the aim of this pilot study was to investigate the feasibility of a home-based, high-frequency exercise program for patients with PD in Germany, as a smartphone app–supported training program tailored to the individual patient requirements. In addition, we exploratory investigated possible improvements of motor symptoms associated with participating in the exercise program. Therefore, we included a structured evaluation of patient-defined outcomes such as individually relevant motor activities of daily living. These results need to be interpreted cautiously owing to the pilot design of this study but will serve as a valuable starting point for future high-quality hypotheses testing studies of our exercise program.

Methods

Study Design and Cohort

In this pilot interventional study, we focused on the feasibility of the digital intervention program. Individuals diagnosed with PD as defined by the Guidelines of the German Association for Neurology similar to the United Kingdom PD Society Brain Bank criteria [28] were included. They were recruited from regular visits at the Movement Disorder Outpatient Unit at the Department of Molecular Neurology, University Hospital Erlangen, Germany, in the time frame between March 2020 and October 2020. Patients aged >18 years with a Hoehn and Yahr disease stage between I and III were included. In addition to meeting the inclusion criteria, participants were required to use a smartphone to use the digital training app. Patients who reported motor fluctuations or dyskinesia were excluded. Patients continued their normal medication, exercise, and therapy throughout the study.

Ethics Approval

This study was approved by the local ethics committee (reference number: 72_20 B, Medical Faculty, FAU Erlangen-Nürnberg, Germany) and participants gave written informed consent. This study was conducted in accordance with the Declaration of Helsinki.

Assessments

Outcomes of the study were the scores or values of the outcomes of the parameters for System Usability Scale (SUS), Parkinson Disease Questionnaire (PDQ-39), patient-defined motor symptoms in everyday life, UPDRS-III, Timed Up and Go (TUG) test, 2-minute walking test, and sensor-based gait analysis. Each of these outcomes are explained in detail in the following sections.

The SUS was used to evaluate the usability of the app, in particular, if the app provides a clear and easy-to-use structure, if the system is consistent, and if participants feel comfortable using the app [29]. Usability is considered as good as indicated by a total score >68 [30]. PROMs consisted of patients' self-perceived QoL (PDQ-39) [31] as well as patients' reports on their personal motor symptoms and limitations to everyday tasks—defined by patients with support of a therapist. These motor tasks were documented on a scale between 0 and 10,

where 0 represented no restrictions and 10 represented maximal restrictions in everyday life. Clinical assessments included the UPDRS-III [32] and the Montreal Cognitive Assessment [33].

Furthermore, sensor-based gait analysis was conducted including a standardized 4×10-m walk test, TUG, and a 2-minute walking test [34]. We used 2 wearable SHIMMER2 sensors (Shimmer Research Ltd) that were attached to the outer rear side of each shoe. Sensor signals were recorded within a (triaxial) accelerometer range of –6 to +6 g (sensitivity 300 mV/g), a gyroscope range of –500 to +500 degrees per second (sensitivity 2 mV/degree/sec), and a sampling rate of 102.4 Hz. The sensors were connected to a tablet via Bluetooth and the data were stored in the tablet [35]. A machine learning algorithm processed the stored data and calculated clinically relevant spatiotemporal gait parameters such as stride length and gait velocity [36,37]. This system has been proven to be technically valid [38]. More details on sensor-based gait analysis were presented in previous work [35-37,39,40].

Development of a Smartphone-Based Exercise Program at Home

For this study, an interdisciplinary team of movement scientists, therapists, clinicians, and patients with PD developed an individualized and remotely supervised exercise program that was configured in the medical product smartphone app "PatientConcept" developed by NeuroSys GmbH, Germany. Data safety was based on the General Data Protection Regulation guidelines. The app provided digitally instructed personalized training videos to support self-sufficient training at home over a period of 4 weeks. At baseline, patients with PD reported between 4 and 7 individual motor impairments that hindered them in everyday life tasks (eg, "I have problems closing the buttons of my shirt. I would like to improve on that."). On the basis of their impairment, PD-specialized therapists identified suitable training tasks. The individualized physical activity tasks were selected from eight categories (flexibility, strength training, gait, balance and posture, coordination and rhythm, large amplitude movements, finger and hand movements, and stretching). In total, 50 movement tasks in different levels of difficulty were available (eg, finger tapping improves fine finger motor skills that are needed for tasks such as closing buttons). Therapists defined 3 to 5 short training sequences, depending on the patients' individual capacity, that were then configured in the patients' app. In total, participants performed approximately 20 minutes of daily exercise training in their home environment using these 3 to 5 video sequences from the 8 categories. In general, approximately 15 repetitions per task (and if left-right-dependent per side) were required for each training session. For example, trunk stretching combined with arms lifting in a maximal stretched standing position was performed 15 times without using additional devices.

Patient Education and Remote Support

In an initial education session for each patient at the University Hospital Erlangen, the training sequences were explained and demonstrated by a therapist. Patients were also thoroughly introduced to the smartphone app. Furthermore, to support the communication between the patient and (remote) therapist, we implemented a diary to document self-perceived general

condition, mood, gait stability, and management of training sessions into the app. Using the diary as an interface, the therapist was able to directly supervise the progress of the patients. The app registered patients' viewing of an exercise video and was thus able to monitor participation and adherence. Participants had the opportunity to directly contact their therapist via the smartphone app if they had questions or needed support. The smartphone app interface is illustrated in Figure 1.

Figure 1. App interface (in German): home screen with a personal diary where participants gave feedback, the exercise button with personalized training videos, and a documentation sheet of the training progress (left); page for each exercise is presented—an instructional video, a short description, and the individually adjustable number of exercise runs (middle); and personal diary directly transmitted to the therapist (right).
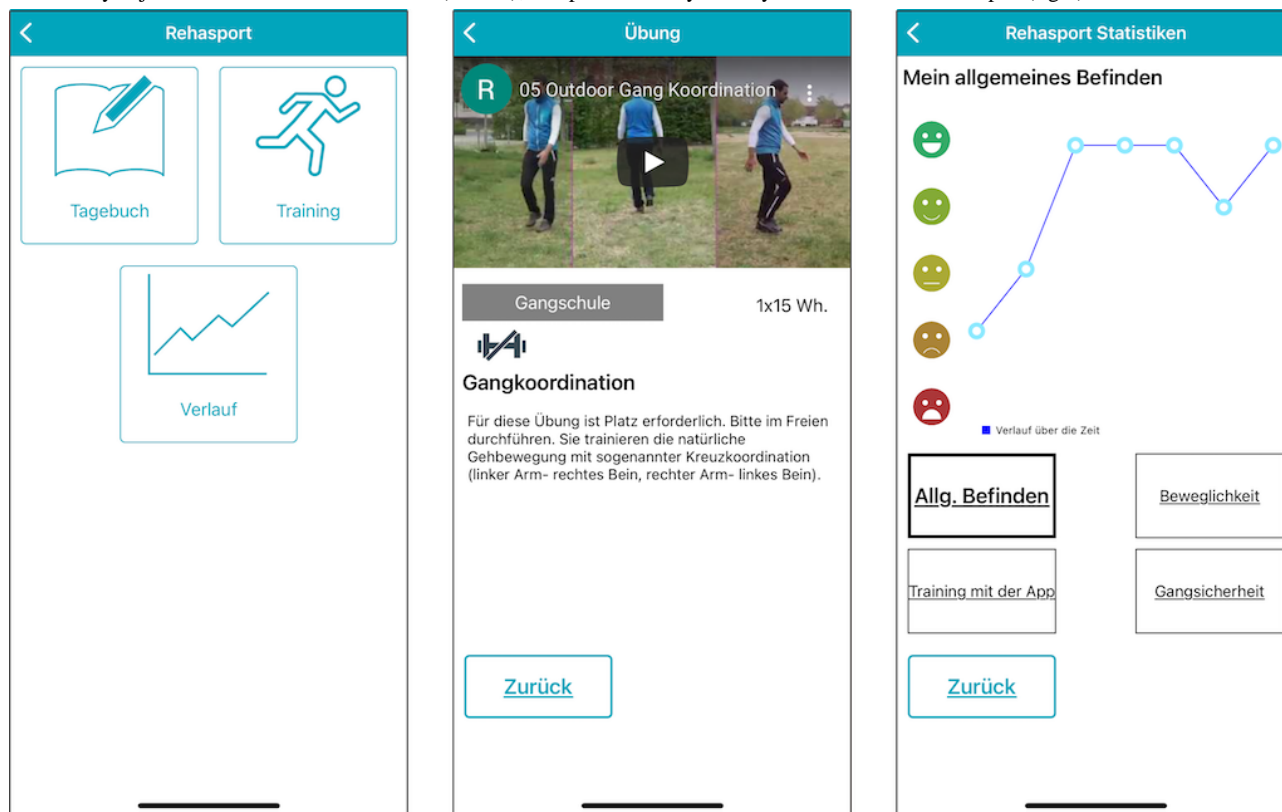
Patients with PD were instructed to complete their short exercise program every day. At the midpoint of the study (14 days), a re-evaluation was scheduled. Depending on the preferences and training success of the patient, their schedule of exercise was updated, and some exercises were changed. At the end of the exercise intervention period, patients were asked to evaluate the applicability of the whole system including the smartphone app using the SUS.

Statistical Analysis

Normality of data was tested by Shapiro-Wilk test and variance homogeneity by Levene test. As several parameters were not normally distributed, a conservative approach was used and nonparametric analysis was performed for all parameters. Repeated measures statistics (paired Wilcoxon test) was applied to analyze differences between baseline and follow-up visit. To minimize the effect of multiple comparisons among potentially related spatiotemporal gait parameters, significance level was adapted and P values of $<.004$ were considered as significantly different ($P=.05/13$; gait parameters=.004). For clinical assessments and PROMs, a significance level of $P<.05$ was used. All statistical analyses were performed using SPSS software package (version 24.0.0.2; IBM Corp).

Results

Study Cohort

Detailed information on the study participants is given in Table 1. In total, 15 participants completed the exercise sessions and final assessments. Adherence throughout the study was 100% as all participants completed the intervention program and performed their exercises reliably without any withdrawals or dropouts. All patients with PD (10 men and 5 women) were highly motivated to complete all training sessions within the time frame of 4 weeks. No adverse events were observed. The system usability score reached 72.2 (SD 6.5; 95% CI 68.5-75.8). Table 2 shows detailed results of each SUS question.

Table 1. Characteristics of patients with Parkinson disease at baseline (N=15).

Characteristics	Smartphone-based exercise at home	
	Mean (SD)	Range
Age (years)	66 (6.2)	55-79
Height (cm)	176 (7.9)	163-190
Weight (kg)	86 (17.7)	68-144
BMI (kg/m^2)	28 (6.1)	21-46
Disease duration (years)	9 (5.7)	1-21
LEDD[a] (mg/day)	566 (369.6)	105-1688
UPDRS-III[b]	18 (10.4)	4-43
MoCA[c] (n=14)	28 (2.5)	22-30

[a]LEDD: levodopa equivalent daily dose.

[b]UPDRS-III: Unified Parkinson Disease Rating Scale, part III (motor score).

[c]MoCA: Montreal Cognitive Assessment.

Table 2. Overview of System Usability Scale (SUS) scores of all participants.

Patient	SUS 1	SUS 2	SUS 3	SUS 4	SUS 5	SUS 6	SUS 7	SUS 8	SUS 9	SUS 10	SUS score
Mean (SD)	4 (1)	2 (1)	4 (1)	2 (1)	4 (1)	2 (1)	4 (1)	1 (1)	4 (1)	2 (1)	72 (7)
#1	3	1	2	1	5	2	5	1	5	1	65
#2	5	1	5	1	5	1	2	1	5	1	67.5
#3	4	3	4	3	4	2	3	2	4	2	77.5
#4	3	1	2	1	1	4	3	3	4	1	57.5
#5	4	1	4	2	4	1	5	2	4	2	72.5
#6	4	2	5	1	4	1	4	1	4	1	67.5
#7	5	2	3	3	5	3	5	1	4	2	82.5
#8	4	2	4	1	4	3	5	1	4	2	75
#9	3	2	3	2	3	3	4	2	3	3	70
#10	5	3	5	1	4	2	5	1	5	1	80
#11	4	1	4	2	3	2	5	2	4	2	72.5
#12	5	1	5	1	5	1	2	1	5	1	67.5
#13	5	1	5	1	5	1	4	1	5	1	72.5
#14	5	1	5	2	5	1	5	1	5	1	77.5
#15	5	1	4	1	4	4	5	1	5	1	77.5

Patient-Reported QoL

Participants completed the PDQ-39 questionnaire at baseline and follow-up to evaluate self-perceived QoL. The PDQ-39 total score as well as all subscores did not change significantly from baseline (mean 25, SD 12.7 points) to follow-up visit (mean 24, SD 13.3 points; P=.78). A descriptive improvement could be observed in mobility-related QoL by 14% (baseline: mean 25, SD 17.9 points; follow-up: mean 21, SD 16.9 points)

and QoL regarding social support by 19% (baseline: mean 15, SD 16.5 points; follow-up: mean 13, SD 14.5 points).

QoL with regard to everyday life activities (washing, cutting food, or writing) and emotional well-being (feeling depressive or anxious) remained stable between baseline (mean 25, SD 13.5 points for everyday activities and mean 22, SD 13.0 points for emotional well-being) and follow-up (mean 26, SD 18.6 and mean 21, SD 16 points, respectively). Table 3 shows all data regarding QoL.

XSL•FO

RenderX

Table 3. Parkinson Disease Questionnaire (PDQ-39) scores for baseline (B) and posttest (P) subscores (N=15).

	SUS score		
	Mean (SD)	Range	Percentile, median (IQR)
PDQ-39			
B	24.60 (12.72)	1-38	30.00 (13.00-35.00)
P	24.07 (13.34)	3-49	28.00 (13.00-32.00)
PDQ-39 mobility			
B	24.80 (17.93)	0-50	30.00 (5.00-42.00)
P	21.27 (16.86)	2-55	22.00 (5.00-32.00)
PDQ-39 everyday			
B	24.67 (13.49)	0-45	25.00 (16.00-33.00)
P	26.40 (18.64)	0-66	25.00 (8.00-37.00))
PDQ-39 emotion			
B	22.07 (12.98)	0-41	20.00 (12.00-33.00)
P	20.60 (16.23)	0-50	25.00 (4.00-33.00)
PDQ-39 SocialSupp			
B	15.40 (16.46)	0-41	8.00 (0.00-33.00)
P	12.53 (14.54)	0-41	8.00 (0.00-25.00)

Patient-Defined Impairment During Everyday Motor Tasks

Before the intervention, participants documented individual motor tasks in everyday life in which they recognized impairment (4-7 tasks were mentioned, such as limited trunk rotation, problems with buttoning up a shirt, or morning stiffness) and rated these deficits on a scale ranging from 0 (no impairment) to 10 (maximal impairment). After 4 weeks of daily personalized exercise, patients were asked to rate the same tasks again, without seeing their initial rating. Improvement or decrease in the activity was measured by comparing the areas outlined by the curves. The areas were calculated as consecutive triangles using the formula, , wherein x represents the values stated by the patients, and the angle g is obtained by dividing 2π by i (the number of points measured). Overall, this resulted in a significant improvement by 38 (SD 31.5) units of area (approximately 40% on average; $P<.001$). Only one participant experienced an aggravation of 27% (13.5 units of area) owing to lower back pain that was unrelated to the intervention. Another patient remained stable. Figure 2 shows the individual everyday tasks each patient rated at baseline (dark dashed) and posttest period (grey drawn) as well as the resulting areas. As all patients additionally continued their normal therapy schedules during the intervention, a ceiling effect could be observed in two participants (participant #1 and #13).

Figure 2. Radar plots of rated daily activity of all 15 patients. Dark dashed line represents Baseline, grey drawn through line represents Post Test.
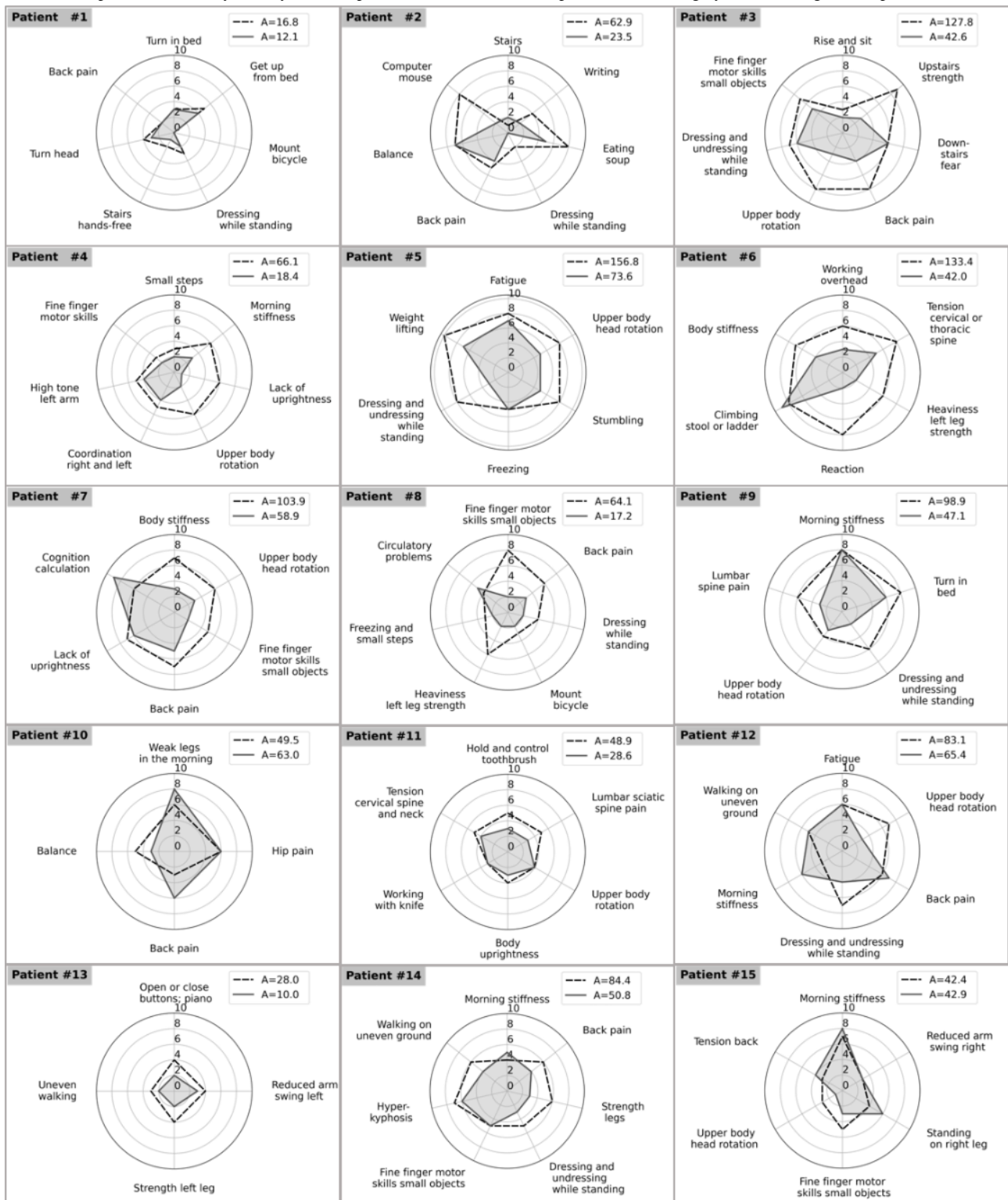
Clinical Motor Symptoms, TUG, 2-Minute Walk, and Gait Parameters

Motor impairment of patients with PD rated by a trained examiner using the UPDRS-III did not yield significant changes (P=.20) but descriptively decreased by 14% from 18 (SD 10.7) points at baseline to 16 (SD 6.7) points at follow-up. The conducted sensor-based gait analysis showed no change in TUG test, 2-minute walk test, or any of the measured gait parameters. A detailed comparison of these parameters between baseline and follow-up is presented in Table 4.

Table 4. Clinical scores and gait parameters at baseline (B) and posttest (P) period (N=15).

Parameters	Clinical score		
	Mean (SD)	Range	Percentile, median (IQR)
UPDRS-III[a]			
B	18.13 (10.74)	4 to 43	19.00 (9.00 to 25.00)
P	15.60 (6.70)	6 to 29	16.00 (10.00 to 20.00)
TUG[b] **(s)**			
B	11.05 (2.61)	7.8 to 16.2	10.10 (9.00 to 13.90)
P	10.08 (1.58)	7.6 to 13.1	9.55 (9.18 to 10.96)
2-minute walk (min)			
B	166.00 (31.88)	112 to 215	162.00 (150.00 to 190.00)
P	165.57 (24.38)	118 to 202	160.50 (149.75 to 191.00)
Stride time (s)			
B	1.09 (0.09)	0.96 to 1.25	1.08 (1.03 to 1.15)
P	1.09 (0.07)	1 to 1.24	1.08 (1.04 to 1.12)
Swing time (%)			
B	36.27 (1.61)	32.78 to 38.73	36.33 (35.60 to 37.61)
P	35.95 (1.75)	32.92 to 38.52	35.83 (34.49 to 37.65)
Strance time (%)			
B	63.73 (1.61)	61.27 to 67.22	62.67 (62.39 to 64.40)
P	64.05 (1.75)	61.48 to 37.08	64.17 (62.35 to 65.51)
Stride length (cm)			
B	133.19 (15.33)	108.68 to 157.5	135.31 (120.04 to 145.16)
P	132.67 (14.96)	106.24 to 158.9	135.00 (119.66 to 140.72)
Gait velocity (m/s)			
B	1.24 (0.18)	0.91 to 1.45	1.28 (1.06 to 1.41)
P	1.23 (0.17)	0.86 to 1.49	1.24 (1.12 to 1.36))
TO[c] **angle (degrees)**			
B	−71.08 (8.10)	−83.12 to −56.24	−71.48 (−78.69 to −64.96)
P	−70.91 (7.72)	−82.56 to −60.44	−70.42 (−79.28 to −64.98)
HS[d] **angle (degrees)**			
B	12.94 (7.93)	−5.24 to 31.42	13.07 (8.61 to 16.06)
P	14.11 (5.55)	1.86 to 27.42	14.15 (10.90 to 17.58)
Maximum toe clearance (cm)			
B	6.62 (2.04)	2.88 to 11.29	7.01 (5.58 to 7.70)
P	7.38 (2.04)	3.74 to 11.49	7.03 (6.45 to 8.50)
Stride time CV[e] **(%)**			
B	4.07 (1.20)	2.09 to 6.4	4.08 (4.08 to 4.66)
P	4.10 (1.34)	1.84 to 6.84	3.99 (3.26 to 5.14)
Swing time CV (%)			
B	5.53 (2.13)	2.84 to 11.21	5.40 (5.40 to 6.26)
P	4.58 (1.33)	2.23 to 7.07	4.39 (4.39 to 5.56)
Strance time CV (%)			

Parameters	Clinical score		
	Mean (SD)	Range	Percentile, median (IQR)
B	3.15 (1.24)	1.41 to 6.54	3.09 (2.53 to 3.57)
P	2.61 (0.92)	1.23 to 4.39	2.47 (2.47 to 3.47)
Stride length CV (cm)			
B	6.82 (1.91)	5.08 to 12.3	6.32 (6.32 to 7.18)
P	5.89 (1.19)	4.06 to 8.28	6.08 (4.94 to 6.73)
Gait velocity CV (m/s)			
B	7.78 (1.93)	6.11 to 12.84	7.39 (6.21 to 8.10)
P	7.32 (1.62)	5.61 to 11.17	7.22 (7.2 to 8.40)

[a]UPDRS-III: Unified Parkinson Disease Rating Scale, part III (motor score).

[b]TUG: Timed Up and Go.

[c]TO: toe-off.

[d]HS: heel strike.

[e]CV: coefficient of variance.

Discussion

Principal Findings

The aim of this pilot study was to investigate the feasibility of a home-based, high-frequency exercise program for patients with PD in Germany, as a smartphone app–supported training program tailored to the individual patient requirements. We exploratory investigated possible improvements of motor symptoms in a structured evaluation of patient-defined outcomes using individually relevant motor activities of daily living. The main finding of this study was that personalized home-based, high-frequency, digital exercise with remote supervision was feasible. In addition, the tailored exercise program was able to improve individual motor tasks regarding mobility and everyday life based on a self-developed patient-reported impairment score in this pilot study.

Usability of App and Adherence

With an average SUS score of 72 (SD 6.5, 95% CI 68.5-75.8), the usability of the app used was considered good according to the commonly used averaged cutoff score of 68 [30]. In approximately 500 evaluation studies, the average SUS score was 68, implying that any score higher than that yields results above average. Even though there were a few technical difficulties, none resulted in dropouts or discontinuation of the training. We observed a very high adherence throughout the study. However, this high adherence has to be interpreted cautiously as the intervention period was limited to 4 weeks in this study. Whether this high adherence level is sustainable over a longer period, needs to be determined in future research. Similar apps for detection of speech impairment and sleep, motor, and emotional symptoms provide evidence that these digital tools beneficially complement the clinical diagnostics in patients with PD [41-43]. Consequently, digital health apps should be considered as a usable and relevant method in future research.

PROMs: QoL Measures

Overall, we did not observe improvements in QoL measures (PDQ-39 total score). Previous studies presented contrary findings with regard to this aspect. Although some studies report increased QoL owing to exercise programs [16,44], others do not support the same [4,45]. There is evidence that motor symptoms rated by UPDRS-III and mobility have a smaller influence on QoL than nonmotor impairments such as mood or depression [46,47]. Exercise-related studies as this study or the ones mentioned in this paper mostly target on motor functions. Possible changes in QoL might therefore be overcovered by stronger influencing factors. However, when looking at the determined subscores of the PDQ-39 questionnaire, we observed a certain increase in mobility-related QoL, without reaching significance level in this pilot study. This underlines the improvements in self-defined motor tasks as previously described. Furthermore, there is a descriptive increase in social support–related QoL potentially indicating that patients felt supported by their therapists, even when solely digitally connected. QoL measures were already being implemented in several studies but have yet to improve care from a patients' point of view [26]. Acknowledging the controversial results that have been reported with regard to QoL, further research is needed to understand the various aspects that influence QoL in patients with PD and which of them may be addressed by digital exercise programs.

Patient-Defined Outcome Measures: Daily Motor Activities

A previous study investigated occupational therapy in patients with PD using a very similar PROM method and asked patients to list 3 to 5 daily tasks they aimed to improve and rated them on a scale from 1 to 10. Similar to our study, significant improvements in individually chosen motor tasks were observed while secondary outcomes such as UPDRS-III remained stable [48]. Another study has shown improvements in general self-reported mobility but did not specify the methods used [15]. PROMs gain in importance and priority as needs of patients with PD are being increasingly communicated and more

recognized. For self-determination in patients with PD, the possibility to put emphasis on specific symptoms and decide which deficits they aim to focus on is very important for each individuals' motivation [22]. Integrating patients and their needs into study designs is a crucial step to shape and develop a satisfying tailored approach [26]. As confirmed by these studies, by implementing their individual needs, patients with PD substantially benefit from exercise programs, even though clinical scores that were conventionally used to determine the effect of an intervention, such as the UPDRS-III, did not show significant improvements in this pilot study. PROMs may help managing and monitoring the progression of long-term medical conditions in PD [49]. Especially in the current change in health care and the rapid shift toward telemedicine that has been thriving throughout the COVID-19 pandemic, PROMs play a major role [9,27]. In summary, we highlight the importance of implementing PROMs (considered as patient-defined outcomes) into clinical studies and health care.

UPDRS and Sensor-Based Gait Analysis

This study revealed descriptive improvements in UPDRS-III after a 4-week long home-based exercise intervention. We used a cutoff score of a 5-point difference in UPDRS-III between baseline and follow-up as the minimal clinically important change as is common for Hoehn and Yahr stages I to III [47]. Compared with other studies with comparable exercise interventions that yielded a significant difference in UPDRS-III, it is noticeable that these interventions lasted longer (8 weeks or 6 months) [12,13]. Considering that we observed a trend toward lower scores during follow-up testing in this pilot study, this suggests that the intervention period of our study was potentially too short for clinically relevant changes in UPDRS-III. However, our exercise program might be beneficial when conducted over a longer period. This theory is supported by a meta-analysis of different home-based exercise studies indicating that duration and frequency have a high impact on the outcome [4]. As our frequency was comparable with the suggested 150 minutes per week [4], a follow-up study with a longer intervention period might reveal potential improvements in UPDRS-III.

With regard to sensor-based gait parameters, a few studies observed improvements in some [10] or even on all aspects of gait (though the latter study used Nordic walking, focusing solely on gait and fitness and is therefore not directly comparable with our intervention) [44], when pooling different home-based studies, no significant long-term effect was observed [4]. This is in line with our findings and indicates that standardized gait tests in the hospital might not be the appropriate method to detect exercise intervention effects. Continuous home-based measures over a longer period may more precisely reflect the impact of therapy [50], as a broader picture of motor symptoms is drawn in comparison with snapshot measures on a certain time point of the day.

Limitations

First, as this pilot study mainly focused on the feasibility of the intervention and the smartphone app, results were not yet compared with a control group. To fully evaluate the benefits of this intervention, future studies should include a control group matched for age, gender, and severity of PD-related symptoms. Consequently, this study was unblinded as assessors were aware that all participants received training. Second, owing to the low number of participants, the statistical power of the results of this study is rather low. Therefore, results presented in this study should be interpreted with caution. In this context, it should be considered that nonsignificant findings presented in the study may be either because of the actual absence of true effects of the intervention or because the statistical power was too low to detect true effects. Therefore, the results should be mainly considered as exploratory. Future studies with an active control group, randomized design, and blinded assessors should increase sample size and furthermore need to be conducted over a longer period to investigate whether this approach yields sustainable effects.

Conclusions

In conclusion, this pilot study presented that an individualized, digital, home-based, and high-frequency exercise program over 4 weeks is feasible in patients with PD as indicated by a total SUS score of 72. The exercise program showed beneficial effects on individual patient-defined motor impairment in daily life activities (improvement of 40% on average). These results indicate that digital exercise concepts remotely supported by therapists have the potential to complement at-site exercise sessions and serve as additional stimuli in everyday life for patients with PD. This study also showed the relevance of a personalized exercise approach identified by individual, patient-defined outcomes. Future high-quality studies should investigate this digital intervention in more depth, evaluate potential gender-related effects, and whether clinically relevant effects are sustainable over longer periods.

XSL·FO

RenderX

Data Availability

The data sets used and analyzed during this study are available from the corresponding authors on request.

Authors' Contributions

HG and JK led the conception and design of the study. HG, FM, JK, JJ, SS, and MR executed the study. HG, AM, and JF performed the statistical analysis. HG and JF prepared the first draft of the manuscript. AM, FM, JJ, SS, MR, JW, and JK reviewed the manuscript and suggested changes.

Conflicts of Interest

JW reports personal fees outside of the submitted work from Desitin Arzneimittel GmbH and Biogen GmbH. JK received an Attract fellow grant (Digital Health Pathways in PD) by the Fraunhofer Gesellschaft. JK holds ownerships of Portabiles HealthCare Technologies GmbH and Portabiles GmbH and received compensation and honoraria in the last 5 years from serving on scientific advisory boards for RoxHealth GmbH and Als Digital-Medizinisches Anwendungs-Centrum GmbH as well as from lecturing from Ever Neuro Pharma GmbH. HG, MR, and JW received an institutional research grant by the Federal Ministry of Education and Research (project: treatHSP, 01GM1905B). HG further received support by the Medical Research Foundation at the University Hospital Erlangen and the Förderverein für HSP-Forschung e.V. outside of the submitted work. HG and FM received an institutional research grant by the Huntington-Stiftung of the Deutsche Huntington Hilfe e.V. MR and FM are supported by the Interdisciplinary Center for Clinical Research of the FAU, Clinician Scientist program.

References

1. Mirelman A, Bonato P, Camicioli R, Ellis TD, Giladi N, Hamilton JL, et al. Gait impairments in Parkinson's disease. Lancet Neurol 2019 Jul;18(7):697-708. [doi: 10.1016/S1474-4422(19)30044-4] [Medline: 30975519]
2. Mak MK, Wong-Yu IS, Shen X, Chung CL. Long-term effects of exercise and physical therapy in people with Parkinson disease. Nat Rev Neurol 2017 Nov;13(11):689-703. [doi: 10.1038/nrneurol.2017.128] [Medline: 29027544]
3. Ebersbach G, Grust U, Ebersbach A, Wegner B, Gandor F, Kühn AA. Amplitude-oriented exercise in Parkinson's disease: a randomized study comparing LSVT-BIG and a short training protocol. J Neural Transm (Vienna) 2015 Feb;122(2):253-256. [doi: 10.1007/s00702-014-1245-8] [Medline: 24872078]
4. Flynn A, Allen NE, Dennis S, Canning CG, Preston E. Home-based prescribed exercise improves balance-related activities in people with Parkinson's disease and has benefits similar to centre-based exercise: a systematic review. J Physiother 2019 Oct;65(4):189-199 [FREE Full text] [doi: 10.1016/j.jphys.2019.08.003] [Medline: 31521554]
5. van de Venis L, van de Warrenburg BP, Weerdesteyn V, van Lith BJ, Geurts AC, Nonnekes J. COVID-19 reveals influence of physical activity on symptom severity in hereditary spastic paraplegia. J Neurol 2020 Dec;267(12):3462-3464 [FREE Full text] [doi: 10.1007/s00415-020-10016-0] [Medline: 32638108]
6. Boldrini P, Garcea M, Brichetto G, Reale N, Tonolo S, Falabella V, et al. Living with a disability during the pandemic. "Instant paper from the field" on rehabilitation answers to the COVID-19 emergency. Eur J Phys Rehabil Med 2020 Jun;56(3):331-334 [FREE Full text] [doi: 10.23736/S1973-9087.20.06373-X] [Medline: 32406226]
7. Carda S, Invernizzi M, Bavikatte G, Bensmaïl D, Bianchi F, Deltombe T, et al. The role of physical and rehabilitation medicine in the COVID-19 pandemic: the clinician's view. Ann Phys Rehabil Med 2020 Nov;63(6):554-556 [FREE Full text] [doi: 10.1016/j.rehab.2020.04.001] [Medline: 32315802]
8. Langer A, Gassner L, Flotz A, Hasenauer S, Gruber J, Wizany L, et al. How COVID-19 will boost remote exercise-based treatment in Parkinson's disease: a narrative review. NPJ Parkinsons Dis 2021 Mar 08;7(1):25 [FREE Full text] [doi: 10.1038/s41531-021-00160-3] [Medline: 33686074]
9. Dorsey ER, Okun MS, Bloem BR. Care, convenience, comfort, confidentiality, and contagion: the 5 C's that will shape the future of telemedicine. J Parkinsons Dis 2020;10(3):893-897. [doi: 10.3233/JPD-202109] [Medline: 32538870]
10. Atterbury EM, Welman KE. Balance training in individuals with Parkinson's disease: therapist-supervised vs. home-based exercise programme. Gait Posture 2017 Jun;55:138-144. [doi: 10.1016/j.gaitpost.2017.04.006] [Medline: 28445854]
11. King LA, Wilhelm J, Chen Y, Blehm R, Nutt J, Chen Z, et al. Effects of group, individual, and home exercise in persons with Parkinson disease: a randomized clinical trial. J Neurol Phys Ther 2015 Oct;39(4):204-212 [FREE Full text] [doi: 10.1097/NPT.0000000000000101] [Medline: 26308937]
12. van der Kolk NM, de Vries NM, Kessels RP, Joosten H, Zwinderman AH, Post B, et al. Effectiveness of home-based and remotely supervised aerobic exercise in Parkinson's disease: a double-blind, randomised controlled trial. Lancet Neurol 2019 Nov;18(11):998-1008. [doi: 10.1016/S1474-4422(19)30285-6] [Medline: 31521532]

13. Khalil H, Busse M, Quinn L, Nazzal M, Batyha W, Alkhazaleh S, et al. A pilot study of a minimally supervised home exercise and walking program for people with Parkinson's disease in Jordan. Neurodegener Dis Manag 2017 Feb;7(1):73-84. [doi: 10.2217/nmt-2016-0041] [Medline: 28097926]

14. Caglar AT, Gurses HN, Mutluay FK, Kiziltan G. Effects of home exercises on motor performance in patients with Parkinson's disease. Clin Rehabil 2005 Dec;19(8):870-877. [doi: 10.1191/0269215505cr924oa] [Medline: 16323386]

15. Song J, Paul SS, Caetano MJ, Smith S, Dibble LE, Love R, et al. Home-based step training using videogame technology in people with Parkinson's disease: a single-blinded randomised controlled trial. Clin Rehabil 2018 Mar;32(3):299-311. [doi: 10.1177/0269215517721593] [Medline: 28745063]

16. Canning CG, Allen NE, Dean CM, Goh L, Fung VS. Home-based treadmill training for individuals with Parkinson's disease: a randomized controlled pilot trial. Clin Rehabil 2012 Sep;26(9):817-826. [doi: 10.1177/0269215511432652] [Medline: 22257506]

17. Morris ME, Taylor NF, Watts JJ, Evans A, Horne M, Kempster P, et al. A home program of strength training, movement strategy training and education did not prevent falls in people with Parkinson's disease: a randomised trial. J Physiother 2017 Apr;63(2):94-100 [FREE Full text] [doi: 10.1016/j.jphys.2017.02.015] [Medline: 28342682]

18. Dobkin BH. A Rehabilitation-Internet-of-Things in the home to augment motor skills and exercise training. Neurorehabil Neural Repair 2017 Mar;31(3):217-227 [FREE Full text] [doi: 10.1177/1545968316680490] [Medline: 27885161]

19. Ellis T, Rochester L. Mobilizing Parkinson's disease: the future of exercise. J Parkinsons Dis 2018;8(s1):S95-100 [FREE Full text] [doi: 10.3233/JPD-181489] [Medline: 30584167]

20. Eskofier BM, Lee SI, Baron M, Simon A, Martindale CF, Gaßner H, et al. An overview of smart shoes in the Internet of health things: gait and mobility assessment in health promotion and disease monitoring. Appl Sci 2017 Sep 25;7(10):986. [doi: 10.3390/app7100986]

21. Pasluosta CF, Gassner H, Winkler J, Klucken J, Eskofier BM. An emerging era in the management of Parkinson's disease: wearable technologies and the Internet of Things. IEEE J Biomed Health Inform 2015 Nov;19(6):1873-1881. [doi: 10.1109/JBHI.2015.2461555] [Medline: 26241979]

22. Riggare S, Stamford J, Hägglund M. A long way to go: patient perspectives on digital health for Parkinson's disease. J Parkinsons Dis 2021;11(s1):S5-10 [FREE Full text] [doi: 10.3233/JPD-202408] [Medline: 33682728]

23. Bayés À, Samá A, Prats A, Pérez-López C, Crespo-Maraver M, Moreno JM, et al. A "HOLTER" for Parkinson's disease: validation of the ability to detect on-off states using the REMPARK system. Gait Posture 2018 Jan;59:1-6. [doi: 10.1016/j.gaitpost.2017.09.031] [Medline: 28963889]

24. Dorsey ER, Yvonne Chan YF, McConnell MV, Shaw SY, Trister AD, Friend SH. The use of smartphones for health research. Acad Med 2017 Feb;92(2):157-160. [doi: 10.1097/ACM.0000000000001205] [Medline: 27119325]

25. Silva de Lima AL, Hahn T, de Vries NM, Cohen E, Bataille L, Little MA, et al. Large-scale wearable sensor deployment in Parkinson's patients: the Parkinson@home study protocol. JMIR Res Protoc 2016 Aug 26;5(3):e172 [FREE Full text] [doi: 10.2196/resprot.5990] [Medline: 27565186]

26. Nelson EC, Eftimovska E, Lind C, Hager A, Wasson JH, Lindblad S. Patient reported outcome measures in practice. BMJ 2015 Feb 10;350:g7818. [doi: 10.1136/bmj.g7818] [Medline: 25670183]

27. Black N. Patient reported outcome measures could help transform healthcare. BMJ 2013 Jan 28;346:f167. [doi: 10.1136/bmj.f167] [Medline: 23358487]

28. Hughes AJ, Daniel SE, Kilford L, Lees AJ. Accuracy of clinical diagnosis of idiopathic Parkinson's disease: a clinico-pathological study of 100 cases. J Neurol Neurosurg Psychiatry 1992 Mar;55(3):181-184 [FREE Full text] [doi: 10.1136/jnnp.55.3.181] [Medline: 1564476]

29. Brooke J. SUS: a 'quick and dirty' usability scale. In: Jordan PW, Thomas B, McClelland IL, Weerdmeester B, editors. Usability Evaluation in Industry. London, UK: CRC Press; 1996:189-194.

30. Sauro J. A Practical Guide to the System Usability Scale: Background, Benchmarks & Best Practices. Denver, CO, USA: Measuring U; 2011.

31. Jenkinson C, Fitzpatrick R, Peto V, Greenhall R, Hyman N. The Parkinson's Disease Questionnaire (PDQ-39): development and validation of a Parkinson's disease summary index score. Age Ageing 1997 Sep;26(5):353-357. [doi: 10.1093/ageing/26.5.353] [Medline: 9351479]

32. Goetz CG, Fahn S, Martinez-Martin P, Poewe W, Sampaio C, Stebbins GT, et al. Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): process, format, and clinimetric testing plan. Mov Disord 2007 Jan;22(1):41-47. [doi: 10.1002/mds.21198] [Medline: 17115387]

33. Nasreddine ZS, Phillips NA, Bédirian V, Charbonneau S, Whitehead V, Collin I, et al. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. J Am Geriatr Soc 2005 Apr;53(4):695-699. [doi: 10.1111/j.1532-5415.2005.53221.x] [Medline: 15817019]

34. Gaßner H, Jensen D, Marxreiter F, Kletsch A, Bohlen S, Schubert R, et al. Gait variability as digital biomarker of disease severity in Huntington's disease. J Neurol 2020 Jun;267(6):1594-1601 [FREE Full text] [doi: 10.1007/s00415-020-09725-3] [Medline: 32048014]

35. Klucken J, Barth J, Kugler P, Schlachetzki J, Henze T, Marxreiter F, et al. Unbiased and mobile gait analysis detects motor impairment in Parkinson's disease. PLoS One 2013 Feb 19;8(2):e56956 [FREE Full text] [doi: 10.1371/journal.pone.0056956] [Medline: 23431395]

36. Barth J, Oberndorfer C, Pasluosta C, Schülein S, Gassner H, Reinfelder S, et al. Stride segmentation during free walk movements using multi-dimensional subsequence dynamic time warping on inertial sensor data. Sensors (Basel) 2015 Mar 17;15(3):6419-6440 [FREE Full text] [doi: 10.3390/s150306419] [Medline: 25789489]

37. Rampp A, Barth J, Schülein S, Gaßmann KG, Klucken J, Eskofier BM. Inertial sensor-based stride parameter calculation from gait sequences in geriatric patients. IEEE Trans Biomed Eng 2015 Apr;62(4):1089-1097. [doi: 10.1109/TBME.2014.2368211] [Medline: 25389237]

38. Kluge F, Gaßner H, Hannink J, Pasluosta C, Klucken J, Eskofier BM. Towards mobile gait analysis: concurrent validity and test-retest reliability of an inertial measurement system for the assessment of spatio-temporal gait parameters. Sensors (Basel) 2017 Jun 28;17(7):1522 [FREE Full text] [doi: 10.3390/s17071522] [Medline: 28657587]

39. Gaßner H, Raccagni C, Eskofier B, Klucken J, Wenning GK. The diagnostic scope of sensor-based gait analysis in atypical Parkinsonism: further observations. Front Neurol 2019 Jan 22;10:5 [FREE Full text] [doi: 10.3389/fneur.2019.00005] [Medline: 30723450]

40. Gaßner H, Marxreiter F, Steib S, Kohl Z, Schlachetzki JC, Adler W, et al. Gait and cognition in Parkinson's disease: cognitive impairment is inadequately reflected by gait performance during dual task. Front Neurol 2017 Oct 26;8:550 [FREE Full text] [doi: 10.3389/fneur.2017.00550] [Medline: 29123499]

41. Lauraitis A, Maskeliūnas R, Damaševičius R, Krilavičius T. Detection of speech impairments using cepstrum, auditory spectrogram and wavelet time scattering domain features. IEEE Access 2020 May 19;8:96162-96172. [doi: 10.1109/access.2020.2995737]

42. Mascheroni A, Choe EK, Luo Y, Marazza M, Ferlito C, Caverzasio S, et al. The SleepFit tablet application for home-based clinical data collection in Parkinson disease: user-centric development and usability study. JMIR Mhealth Uhealth 2021 Jun 08;9(6):e16304 [FREE Full text] [doi: 10.2196/16304] [Medline: 34100767]

43. Zhan A, Mohan S, Tarolli C, Schneider RB, Adams JL, Sharma S, et al. Using smartphones and machine learning to quantify Parkinson disease severity: the mobile Parkinson disease score. JAMA Neurol 2018 Jul 01;75(7):876-880 [FREE Full text] [doi: 10.1001/jamaneurol.2018.0809] [Medline: 29582075]

44. Szefler-Derela J, Arkuszewski M, Knapik A, Wasiuk-Zowada D, Gorzkowska A, Krzystanek E. Effectiveness of 6-week Nordic walking training on functional performance, gait quality, and quality of life in Parkinson's disease. Medicina (Kaunas) 2020 Jul 17;56(7):356 [FREE Full text] [doi: 10.3390/medicina56070356] [Medline: 32708938]

45. Schenkman M, Hall DA, Barón AE, Schwartz RS, Mettler P, Kohrt WM. Exercise for people in early- or mid-stage Parkinson disease: a 16-month randomized controlled trial. Phys Ther 2012 Nov;92(11):1395-1410 [FREE Full text] [doi: 10.2522/ptj.20110472] [Medline: 22822237]

46. Schrag A, Jahanshahi M, Quinn N. What contributes to quality of life in patients with Parkinson's disease? J Neurol Neurosurg Psychiatry 2000 Sep;69(3):308-312 [FREE Full text] [doi: 10.1136/jnnp.69.3.308] [Medline: 10945804]

47. Schrag A, Sampaio C, Counsell N, Poewe W. Minimal clinically important change on the unified Parkinson's disease rating scale. Mov Disord 2006 Aug;21(8):1200-1207. [doi: 10.1002/mds.20914] [Medline: 16673410]

48. Sturkenboom IH, Graff MJ, Hendriks JC, Veenhuizen Y, Munneke M, Bloem BR, OTiP study group. Efficacy of occupational therapy for patients with Parkinson's disease: a randomised controlled trial. Lancet Neurol 2014 Jun;13(6):557-566. [doi: 10.1016/S1474-4422(14)70055-9] [Medline: 24726066]

49. Damman OC, Jani A, de Jong BA, Becker A, Metz MJ, de Bruijne MC, et al. The use of PROMs and shared decision-making in medical encounters with patients: an opportunity to deliver value-based health care to patients. J Eval Clin Pract 2020 Apr;26(2):524-540 [FREE Full text] [doi: 10.1111/jep.13321] [Medline: 31840346]

50. Del Din S, Godfrey A, Mazzà C, Lord S, Rochester L. Free-living monitoring of Parkinson's disease: lessons from the field. Mov Disord 2016 Sep;31(9):1293-1313. [doi: 10.1002/mds.26718] [Medline: 27452964]

Abbreviations

PD: Parkinson disease
PDQ: Parkinson Disease Questionnaire
PROM: patient-reported outcome measure
QoL: quality of life
SUS: System Usability Scale
TUG: Timed Up and Go
UPDRS-III: Motor Score of the Unified Parkinson Disease Rating Scale, part III

XSL•FO
RenderX

Review

Telehealth and Remote Interventions for Children With Cerebral Palsy: Scoping Review

Marina Pagaki-Skaliora[1*], BSc, MBBS; Eileen Morrow[1,2*], BSc, MSc; Tim Theologis[1,2*], MSc, PhD

[1]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, United Kingdom

[2]Oxford University Hospitals National Health Service Foundation Trust, Oxford, United Kingdom

[*]all authors contributed equally

Corresponding Author:
Eileen Morrow, BSc, MSc
Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
University of Oxford
Botnar Centre
Windmill Road
Oxford, OX3 7LE
United Kingdom
Phone: 44 1865227607
Email: eileen.morrow@ouh.nhs.uk

Abstract

Background: Remote treatment, or telehealth, has shown promise for children with cerebral palsy (CP) prior to 2020; however, the beginning of the global COVID-19 pandemic limiting access to hospitals for face-to-face treatments has driven the need for telehealth and led to a surge in its development. Due to the recent developments, there has been limited synthesis of the available evidence of telehealth for children with CP.

Objective: This study aimed to analyze and summarize the existing evidence for telehealth interventions for the treatment of children with CP and identify any areas requiring further research.

Methods: A scoping review was performed. A systematic search of available literature in MEDLINE and PubMed was performed during July 2021. Inclusion criteria for articles were primary research and systematic reviews that investigated telehealth, included children with CP, were published between 2010-2021, and were written in English. Exclusion criteria were secondary research other than systematic reviews; interventions that did not meet the World Health Organization definition of telehealth; or studies where all participants were aged >18 years, children's results were not reported separately, or there were no results reported for children with CP. A scoping review was chosen due to the expected heterogeneity of the participants, as well as the expected small sample sizes and inconsistency of measured outcomes; therefore, a narrative reporting of the results was considered appropriate.

Results: In all, 5 papers were identified, which included the results of 11 studies—2 of the included articles were systematic reviews, which included the results of 3 studies each. These 6 studies, together with 5 primary research articles, were included in this scoping review. The existing evidence is of low methodological quality, primarily consisting of case series. There is some evidence that the requirements of telehealth differ depending on the children's developmental stage and functional level. Telehealth is reported to reduce caregiver burden. There is mixed evidence on children's compliance with telehealth. Overall, the results of telehealth interventions for the treatment of children with CP were positive, indicating either comparable or improved results compared with children receiving usual face-to-face care.

Conclusions: The evidence base is lacking in breadth and methodological quality to provide robust clinical recommendations. Most studies investigated hand function only, indicating the limited scope of existing research. However, this review shows that telehealth has demonstrated potential to improve function for children with CP while making health care services more accessible and reducing caregiver burden. Areas requiring further research include telehealth interventions for the lower limb, postural management, and pain control and the barriers to implementing telehealth.

Introduction

Background

Cerebral palsy (CP) is an umbrella term for neurological and movement disorders caused by nonprogressive disturbance to the developing fetal or infant brain [1,2].

CP affects approximately 1 in 400 children in the United Kingdom and represents a lifetime disability with substantial socioeconomic consequences [2]. Functional mobility is best classified by the Gross Motor Function Classification System (GMFCS) [3], an international standard based on the severity of motor disability. GMFCS has been produced to allocate patients aged 6-18 years to 1 of 5 functional levels from "walking without limitations" (GMFCS level I) to "transported in a manual wheelchair" (GMFCS level V), which assist in defining the management plan. This system can be used by all health care professionals in the multidisciplinary team including dietitians, doctors, occupational therapists, orthotists, physiotherapists, psychologists, and speech and language therapists [4]. CP is also classified according to affected body areas as unilateral (hemiplegia) or bilateral (diplegia or quadriplegia, affecting predominantly lower limbs or all 4 limbs, respectively).

CP can be further classified by neurological pattern as dystonic, dyskinetic, ataxic, and mixed [3]. In 70% of cases, CP predominantly causes spasticity—increased muscle tone or tightness due to prolonged contraction. The increased muscle tone leads to progressive stiffness and deficient longitudinal muscle growth, which, in turn, causes secondary joint contracture, bone deformity, and pain. Dyskinetic CP is an extrapyramidal type and results from damage in the basal ganglia (BG). This area of the brain is damaged in Parkinson disease and as such, CP lesions in the BG can have a Parkinsonian presentation. Dystonic CP mostly occurs later in the antenatal period at 38-40 weeks of gestation, where metabolic demands of the BG area in the fetal brain lead to movement disorders such as dystonia. The BG can also be damaged due to hyperbilirubinemia as by-products from bilirubin metabolism are deposited in the brain and lead to dyskinesia. Children with dystonic CP present with dystonia and chorea [2,5]. Ataxic CP is another extrapyramidal type causing balance issues. The damage is in the involuntary motor neurons that affect coordination and gait. Children with ataxic CP often present with hypotonia, intention tremor, nystagmus, trunk ataxia, and balance problems [2].

Treatment

CP affects many aspects of a person's activities of daily living including movement and posture, speech and communication, and swallowing (eating and drinking) and causes a range of health problems such as osteopenia, excess saliva, pain and discomfort, stress and anxiety, depression, and sleep disturbances. Therefore, the treatment options and requirements are vast.

Modern clinical management has evolved to allow clinicians a greater variety of treatment options and offers patients more tailored treatment for their needs. Telehealth (TH) and remote interventions to facilitate the use of TH are at the forefront of this evolution. The World Health Organization (WHO) defines TH as "the delivery of healthcare services, where patients and providers are separated by distance. TH uses information and communication technologies for the exchange of information for the diagnosis and treatment of diseases and injuries, research and evaluation, and for the continuing education of health." [6].

TH has shown promise for patients with CP prior to 2020 [7,8]. However, the beginning of the global COVID-19 pandemic limiting access to hospitals for face-to-face treatments has driven the need for remote treatments including TH and led to a surge in its development [9].

Study Aims

The aim of this scoping review was to analyze and summarize the existing evidence for TH interventions for the treatment of children with CP and identify any areas requiring further research.

This review is timely due to the ongoing COVID-19 pandemic increasing the need for and development of TH interventions. This study will contribute to the current evidence base as despite 2 previous systematic reviews having been conducted in this area, neither was specific to children with CP, and 1 focused only on therapy for the upper extremity [10,11].

Methods

Study Design

A scoping review was chosen as the appropriate methodology, as the substantial heterogeneity of the participants, small sample sizes, and an inconsistency of measured outcomes were expected. Therefore, narrative synthesis and reporting were considered the most appropriate. A scoping review also allowed a broad research question to highlight gaps in the literature and provide recommendations for TH as a method to assist children with CP in their ongoing treatment. The methods for the scoping review are summarized in Figure 1. The steps of a scoping review were followed and the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) checklist completed (see Multimedia Appendix 1 [12]).

XSL•FO

RenderX

Figure 1. Scoping review methodology flowchart.
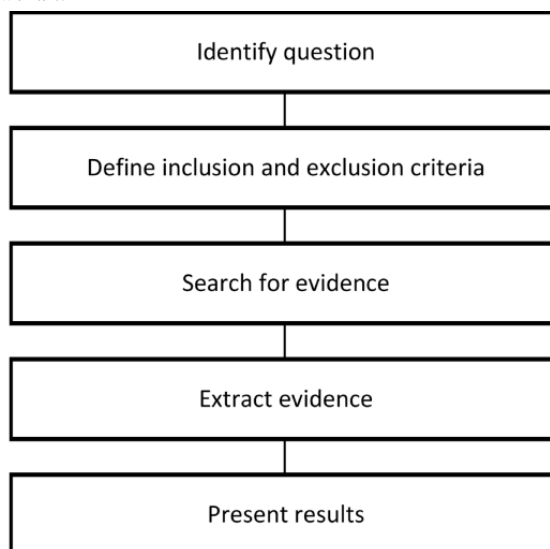
Search Strategy

For the purpose of this paper, we used the definition of TH described by the WHO [6] as discussed in the introduction. Children were defined as aged 0-18 years.

A database search was conducted in the MEDLINE and PubMed databases. The MEDLINE search was completed using the OvidSP search platform, and the website-specific search engine was used to search the PubMed database. The search strategy used in the MEDLINE database is included in Table 1.

The International Journal of Rehabilitation Research was also manually searched for further articles that met the eligibility criteria, as it was identified a priori as having published several important papers in TH for people with CP. Backward reference searching was also conducted on all papers identified for inclusion through the previous search strategies. Authors were not contacted for further data.

The management of children with CP is multidisciplinary and includes a variety of aspects of their complex disability. For the purpose of this study, we did not limit the definition of "treatment" to 1 or more of the disciplines but rather considered children's management globally, including all relevant disciplines involved in their care.

Table 1. The database search strategy with the number of articles for the MEDLINE database.

Number	Search term	Article, n
1	Cerebral palsy	23,791
2	Assistive tech*	2431
3	Treatment*	4,925,573
4	Software*	197,274
5	Application*	1,365,926
6	2 OR 4 OR 5	1,538,901
7	1 AND 3 AND 6	231

Eligibility Criteria

Inclusion criteria for articles were primary research, systematic reviews, and meta-analyses that investigated TH, included children with CP either as all participants or results reported as a subgroup, were published between 2010-2021, and were peer-reviewed articles reporting results that are available and written in the English language.

Exclusion criteria were secondary research other than systematic reviews and meta-analyses; interventions that did not meet the WHO definition of TH; animal studies; or studies where the participants were aged >18 years, children's results were not reported as a separate subgroup, or there were no results reported for individuals with CP.

These criteria were assigned due to resource and funding constraints of this scoping review. Due to the recent advances in TH, it was considered that research completed before 2010 would be outdated.

Abstracts identified by the search strategy were screened by 2 investigators (MPS and TT) for eligibility using the above criteria. If it was unclear from the abstract whether the article met the eligibility criteria, the full article was retrieved for assessment.

The search strategy is represented in Figure 2.

Figure 2. A flowchart of paper selection for inclusion in this review. CP: cerebral palsy.

```
┌─────────────────────────────────┐
│  Titles and abstracts identified │
│      and screened (n= 231)       │
└─────────────────────────────────┘
                 │
                 │         ┌──────────────────────────────────────┐
                 │         │  Excluded from abstract (n=214; reason:│
                 ├────────▶│   duplicates, animal studies, adult    │
                 │         │  participants, and neuromuscular       │
                 │         │  disorders other than CP)              │
                 │         └──────────────────────────────────────┘
                 │
┌─────────────────────────────────┐
│  Full article text retrieved and │
│    assessed for eligibility      │
│             (n=17)               │
└─────────────────────────────────┘
                 │
                 │         ┌──────────────────────────────────────┐
                 │         │  Excluded from text (n= 13; resason:  │
                 ├────────▶│  duplicates, animal studies, adult     │
                 │         │  participants, neuromuscular disorders │
                 │         │  other than CP)                        │
                 │         └──────────────────────────────────────┘
                 │
┌──────────────────────────┐       │
│ Included from backward    │       │
│  reference searching (n=1)│───────┤
└──────────────────────────┘       │
                 │
┌─────────────────────────────────┐
│  Articles included in review      │
│             (n=5)                 │
└─────────────────────────────────┘
```

Results

Search Results

The search was conducted on July 2, 2021. The systematic search strategy produced 231 abstracts. After reviewing the titles and abstracts, 214 articles were excluded as they were duplicates or did not meet the eligibility criteria. After reviewing the full text of 17 articles, 13 were excluded as they did not meet the eligibility criteria. From the backward reference searching of the 4 eligible articles, 1 further article was included. Therefore, 5 articles were included in this scoping review. Additionally, 2 of the included articles were systematic reviews, which included the results of 3 relevant studies each. Therefore, the results of 11 studies were included in this review [7,10,11,13-20] (Table 2). The findings of the included studies are summarized in Table 3.

Table 2. A summary of studies included in the scoping review.

Number	Main author	Study methodology	Study objectives
1	Preston et al [13]	Pilot study	Gaming technology on arm function
2	Hung and Fong [11]	Systematic review	Effects of telerehabilitation in occupational therapy practice
3	Ferre et al [17]	Randomized control trial	Caregiver-directed home-based intensive bimanual training
4	Golomb et al [7]	Pilot study	In-home virtual reality in telerehabilitation of adolescents with hemiplegic CP[a]
5	Reifenberg et al [16]	Case report	Pediatric game-based neurorehabilitation using TH[b] technologies
6	Staszuk et al [15]	Pilot study	Image processing to create a "TeleReh application"
7	Tanner et al [14]	Quality improvement project	Comparing outcomes of traditional in-person therapy and TH therapy
8	Camden et al [10]	Systematic review	Telerehabilitation for children with disabilities
9	Mitchell et al [19]	Randomized control trial	Web-based intervention of a 30-minute training program
10	James et al [18]	Randomized control trial	Web-based multimodal therapy for unilateral CP
11	Chen et al [20]	Meta-analysis	Virtual reality for function

[a]CP: cerebral palsy.

[b]TH: telehealth.

Table 3. Findings of all included papers within the scoping review.

Number	Main author	Outcomes
1	Preston et al [13]	No outcome showing a clinically important difference in arm function improvement with gaming technology
2	Hung and Fong [11]	TH[a] is a feasible approach for hand therapy for children, demonstrating increased motivation and hand function and reduced parental stress
3	Ferre et al [17]	Home-based therapy improved dexterity and the performance of functional goals, but not bimanual performance
4	Golomb et al [7]	Positive functional outcomes using virtual reality video game with improved hand function
5	Reifenberg et al [16]	Positive functional outcomes
6	Staszuk et al [15]	TH has the potential to assist health care services and patients in making health care more accessible, personalized, and available to all
7	Tanner et al [14]	Positive clinical utility, and COMP[b] could accurately assess functional goals and measure change in the patient's functional ability after receiving telerehabilitation sessions over 4 months
8	Camden et al [10]	No significant differences with web-based therapy compared to conventional face-to-face therapy, with virtual reality potentially being more effective in younger children
9	Mitchell et al [19]	Significant improvement in 6-minute walk test distance and functional strength, although no differences were noted in activity performance
10	James et al [18]	No clinically significant differences in a web-based hand therapy treatment (Move it to improve it; Mitti) when compared to usual treatment
11	Chen et al [20]	Virtual reality improves outcomes for children with CP[c] with a strong effect size

[a]TH: telehealth.

[b]COMP: Canadian Occupational Performance Measure.

[c]CP: cerebral palsy.

Gaming Technology

Preston et al [13] investigated gaming technology on the arm function of children with spastic CP who had recently received botulinum toxin injections. This study was a pilot and was underpowered, with 58 participants required to demonstrate a generalizable difference, but only 15 were included. The outcomes were measured with the Canadian Occupational Performance Measure (COPM), which measures patient ability, functional impairment, and satisfaction with function [14], and ABILHAND-kids, which is a parent-completed questionnaire grading the child's ability to complete tasks. Children were randomized to usual care or the intervention, which consisted of a noncompetitive and noncollaborative computer-based game,

customized for arm rehabilitation for children with CP. This intervention was provided within 1 week of the botulinum toxin injections. The results showed that the gaming system was used on average for only 7 minutes per day, despite the recommended usage being 30 minutes per day. No outcome showed a clinically important difference; however, the low recruitment numbers and the low usage of this system means that the results contribute little to the understanding of the effectiveness of computer-based gaming systems on remote rehabilitation [13].

Hung and Fong [11] published a systematic review in 2019 on the effects of TH in occupational therapy practice. The review included 15 studies, 3 of which included children with CP [7,16,17]. These studies investigated hand function training through teleconsultation and telemonitoring [16,17] and a virtual reality video game home program [7]. Ferre et al [17] trained caregivers to take standardized assessments with the patients; Golomb et al [7] and Reifenberg et al [16] used occupational therapist–measured outcomes remotely and in clinic. Together, the studies demonstrated that TH was a feasible approach for hand therapy for children with CP and demonstrated increased motivation [16] and hand function [7,16] and reduced parental stress [16].

Image Processing

Staszuk et al [15] investigated a system of TH as it applied to children with CP while also including adults with stroke. The proposed system involved (1) a central database where all patient information, medical tests, results, and images were stored; (2) a network of rehabilitation centers, laboratories, and hospitals that were involved in patients' care; (3) a web service that connected the stored data from the database with all the health care professionals involved, through a secure internet connection; and (4) a computer or other electronic device (tablet, smartwatch, or smartphone) in the child's home that could send relevant data and information to the central database, thus creating a health record for each patient that was concise enough to allow health care professionals to monitor their health and recovery sufficiently [15].

The TH process used cameras to look at the patient's hand movements and a "TeleReh" application [15] where a predefined standard of movements was set for the child to practice and perfect. Each time they managed to complete the movement, the software detected it and moved onto the next step of the rehabilitation process. These steps formed a training program and used rehabilitation techniques remotely, without the need of a health care professional to be physically present, although they could be present over the web to watch and assist the rehabilitation process [15].

The main technology behind this system was image processing. The proposed stages included (1) processing the video into picture frames and (2) using local thresholding to identify homogenous areas, which led to (3) hand detection based on hand texture, colors, and shapes. This research concluded that TH has potential to assist health care services and children in making health care more accessible, personalized, and available to all [15].

Teleconsultations and Virtual Therapies

Tanner et al [14] compared the outcomes of conventional in-person therapy and TH therapy as a quality improvement project following a forced change to TH during the COVID-19 pandemic. In their study, they used COPM to set personalized goals for children by identifying the individual challenges they encountered and measured the outcomes of the telerehabilitation process. The TH therapy was delivered through videoconferencing, and all therapists had previously been trained specifically in pediatric patients. Tanner et al [14] conducted 3 cycles in which they (1) identified what measure to use, (2) assessed if it was a feasible measure to use, and (3) looked into the therapists' perceptions of its use [14]. The results were promising, showing that there was a positive clinical utility and COPM could accurately assess functional goals and measure change in the child's functional ability after receiving telerehabilitation sessions over a period of 4 months [14].

A further systematic review was conducted in 2020 by Camden et al [10], investigating telerehabilitation for children with disabilities; 3 included studies involved participants who were children with CP and were randomized controlled trials of web-based games and a meta-analysis of virtual reality training [18-20].

A paper by James et al [18] was included in this systematic review, which showed that there were no clinically significant differences in a web-based hand therapy treatment (Move it to improve it; Mitti) when compared to usual treatment, indicating that this program is a viable therapy tool. The outcomes measured were primarily focused on hand function, including the Assessment of Motor and Process Skills and COPM [18].

This systematic review also included the only study that investigated a full-body intervention. All other included studies investigated interventions for the hand only. Mitchell et al [19] conducted a randomized control trial on an individualized web-based intervention, which allowed participants to undertake a daily program of 30 minutes of training. This study included a mix of repetitive body weight exercises and interactive games. This intervention indicated significant improvement in the 6-minute walk test and functional strength, although no differences were noted in activity performance [19].

Finally, Chen et al [20] meta-analyzed 14 articles, which indicated that virtual reality improved outcomes for children with CP with a strong effect size. However, it was noted that the poor quality of the studies meant that further high-quality research was required to reach a firm recommendation. A subgroup analysis indicated that virtual reality may be more effective for younger children [20].

Discussion

The aim of this scoping review was to analyze and summarize the existing evidence for TH interventions for the treatment of children with CP and identify any areas requiring further research.

Principal Findings

We have found the existing evidence for TH interventions for the treatment of children with CP to be scarce and of poor quality, primarily comprising of underpowered pilot studies. There was reasonable consistency in the domains of outcomes measured, with most studies investigating activity, participation, and patient and parent satisfaction. However, most studies measured these domains using different tools; therefore, result comparison across studies was limited. Most studies did not include an adequate description of participants and often lacked CP neurological type or GMFCS level; therefore, the results were difficult to interpret for clinical application.

The scope of the research into TH was often broad, whereas patient recruitment was limited, leading to underpowered results. Difficulties in assessing the efficiency and efficacy of these devices and services, as well as the broad definitions, make it difficult to directly compare their outcomes and combine results.

However, in the aggregate, the results of TH interventions for the treatment of children with CP were positive, indicating either comparable results with children receiving usual face-to-face care or in some domains, the results were improved. Notably, there is some evidence that TH may increase participant motivation with therapy, reduce caregiver stress, increase functional abilities, and may improve the accessibility of health services. These findings are supported by previous reviews, which have found that assistive technologies for children with physical disabilities increase motivation and reduce caregiver burden [21].

The only study that did not demonstrate any promising results was the study by Preston et al [13], who investigated the ability of a customized computer-based gaming system to improve the arm function of children with spastic CP. However, the children were not compliant with the treatment, averaging only 7 minutes of game play per day, which was significantly lower than the recommended 30 minutes. This finding contrasts with other studies included in this review, which tested home gaming systems; Golomb et al [7], Reifenberg et al [16], and Chen et al [20] reported positive functional outcomes and noted minimal difficulties with compliance. However, it should be noted that the paper by Reifenberg et al[16] is a single case report. Given the functional improvements noted by the other 3 studies, it is possible that the game proposed by Preston et al [13] was less compelling or that a nonrepresentative sample was recruited for the study leading to type II error. This finding emphasizes the uncertainties in interpreting results presented by an underpowered study.

The results for TH without a computer-based or web-based game aspect also showed potential for functional improvements in children with unilateral spastic CP. Ferre et al [17] taught caregivers via TH, child-friendly, and home-based activities designed to improve bimanual hand use, including board games, clay modeling, and page turning. This approach encouraged family-centered care, placing caregivers rather than therapists at the center of the child's care and allowing intense therapy without the additional caregiver burden of hospital travel and appointments conflicting with work schedules. However, it should be noted that there was high attrition from the study,

with 40% of participants not completing the intervention. Further research should be conducted to established if this result was due to a flaw in study or intervention design. Importantly, this study also showed no significant differences between the therapist-measured baseline and caregiver-measured baseline, indicating that the Assisting Hand Assessment and Box and Blocks Test can be appropriately measured by caregivers remotely at baseline [17].

Although these results are promising for TH as an intervention for the hand in children with CP, it should be noted that there is insufficient evidence on TH interventions for other areas of the body, including the lower limbs or body posture. Mitchell et al [19] conducted the only study included in this scoping review that investigated a full-body intervention. This intervention included body weight exercises and interactive games that participants undertook at home under the guidance and supervision of remote therapists. Although the results of this study were promising, showing excellent adherence to the program and improved functional measures, they did not translate into significant differences in activity-based outcome measures [19]. However, this finding is not uncommon for this patient group, and the ceiling effects of training can also be seen in face-to-face therapy [22]. Therefore, the findings may be considered as showing promise for TH as a full-body intervention for children with CP [19].

Importantly, we have not identified any investigation on pain management through TH. This TH type is particularly important as more than half (67.1%) of children with CP report acute pain [23], and this pain appears to have increased through the lack of intervention during the COVID-19 pandemic [24].

Future Directions

Of critical and immediate importance to improving the existing evidence base for TH for children with CP is the development of studies with good methodological quality and a sufficient cohort to draw appropriately powered conclusions. The majority of the included studies in this scoping review were case series, which notably complicates the interpretation of results, as where results conflict, it is difficult to assess whether this conflict is due to intervention differences, problems with study methodology, or type II error.

There is some evidence that the requirements of TH vary depending on developmental stage [25] and GMFCS level [26]. It is likely that different neurological types of CP (dyskinetic, dystonic, or ataxic) will have different requirements of TH and require adaptions to accommodate different movements. For example, mathematical models have been developed to improve the layout of touchscreen communication devices for children with dyskinetic CP with different motor requirements, with good results [27]. However, this adaptation has not been adequately investigated to suggest what forms of TH are effective for different children with CP, partially due to small study sizes but also due to the poor definition of participants in studies. Therefore, future work would benefit from clearly defining the participant inclusion criteria, descriptive statistics, and subgroup analysis stratification by GMFCS level, age, and CP neurological type. This definition will increase the understanding of the effectiveness of TH for different groups

of children with CP and allow greater potential for meta-analysis.

There is also limited evidence of the barriers to TH implementation, particularly in the longer term. Most of the existing evidence is anecdotal or a short description of the reasons for attrition from studies. A larger qualitative study, investigating the reasons for dropout from TH studies or noncompliance with TH necessarily implemented during the COVID-19 pandemic, would provide a much greater understanding of the barriers to TH uptake.

Future work would benefit from focusing on outcomes that are important to children with CP. Considering outcomes, such as pain and spasticity, that have been shown to have deteriorated through the lack of in-person treatment during the COVID-19 pandemic would also be useful. Parent-reported outcome measures were commonly gathered across TH studies, allowing the collection of data remotely. The most commonly used outcome measure was the COPM. However, it should be noted that the COPM has only been validated for children with spastic CP. Further work would be required to validate its appropriateness for children with ataxic and dyskinetic CP [28]. The validation of the COPM in larger patient groups will likely be beneficial to this area of research. However, as most therapists agree, this validation should be applicable within a reasonable length of time, and functional goals should be identified [14].

Finally, more evidence is required to support the use of TH in the treatment of the lower limb or postural control for children with CP. The existing evidence is strongly focused on the upper limb. It is possible that retrospective studies of routinely collected clinical outcomes during the COVID-19 pandemic may provide some valuable insight into this area of TH.

Limitations

This scoping review included the results of 11 studies—a small number despite the broad eligibility criteria, which included any therapy, study aims, and outcomes measured. There are limited trials that have been conducted in this area despite the drastic increase in TH consultations reported through the COVID-19 pandemic. Retrospective research using routinely collected outcome measures in this patient group gathered throughout the COVID-19 pandemic may add important findings and context for the potential benefits of ongoing TH consultations. We would recommend the publication of any data gathered by health care professionals on their changing interventions in this time. As COVID-19 has affected the need for more TH, this subject is likely to expand exponentially in

the future and more reviews similar to this paper will be needed for further assessment.

Second, the substantial heterogeneity of participants made comparison of outcomes between studies challenging. To reduce the heterogeneity, classifications systems such as the GMFCS have been used. However, the GMFCS levels or CP neurological type were not consistently reported; therefore, it is unclear if the results are generalizable to the population or comparable to other forms of TH. This result has limited our drawing of clinical recommendations on TH for the treatment of children with CP, but it has helped identify limitations in the literature as a whole and addressed a key issue that needs careful consideration in future primary research investigating CP treatment.

Third, due to the heterogeneity of participants and the inconsistency in outcome measures used, it was not possible to directly compare the results of studies through meta-analysis. Therefore, we were unable to directly compare the quantitative results of the studies and examine statistically and clinically significant differences across smaller studies, which has affected our efforts to chart data and directly visualize results quantitatively. As the technological advancements increase and the quality of the research improves, we hope that in the future, there will be more quantitative data to enable direct analysis and comparison, which will inform clinical recommendations for TH.

Finally, due to time and resource constraints, we were unable to perform a formal critical appraisal of the included studies, which may mean that the results are unduly influenced by research with poor methodology. We have tried to identify notable areas of concern with research methodology within the narrative review, as a less formal critical review. However, future work in this area should consider a formal critical review.

Conclusions

This scoping review provided for the first time an up-to-date account of the current evidence on TH for children with CP. The evidence has been shown to be lacking due to poor study design or underpowered results; therefore, clinical recommendations were not possible. However, this scoping review has shown that TH has demonstrated its potential to improve hand function while making health care services more accessible. TH interventions have shown similar or improved results compared to face-to-face treatment. To understand precisely how this technology will benefit children with CP, further research is required, with a focus on the lower limb, postural control, and quite importantly, pain—a substantial barrier to interventions being accepted by children. Further work to identify barriers to TH implementation is also required.

Authors' Contributions

MPS contributed to the development of methodology, data collection, data analysis, and writing the original draft. EM contributed to data collection, data analysis, writing review and editing, and project administration. TT contributed to conceptualization, data analysis, writing review and editing, and project supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Completed PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) checklist.
[DOCX File , 108 KB - rehab_v9i4e36842_app1.docx]

References

1. Bax M, Goldstein M, Rosenbaum P, Leviton A, Paneth N, Dan B, Executive Committee for the Definition of Cerebral Palsy. Proposed definition and classification of cerebral palsy, April 2005. Dev Med Child Neurol 2005 Aug;47(8):571-576 [FREE Full text] [doi: 10.1017/s001216220500112x] [Medline: 16108461]
2. Cerebral palsy. BMJ Best Practice. URL: https://bestpractice.bmj.com/topics/en-gb/674/aetiology [accessed 2021-07-21]
3. Rethlefsen SA, Ryan DD, Kay RM. Classification systems in cerebral palsy. Orthop Clin North Am 2010 Oct;41(4):457-467. [doi: 10.1016/j.ocl.2010.06.005] [Medline: 20868878]
4. Morris C, Bartlett D. Gross motor function classification system: impact and utility. Dev Med Child Neurol 2004 Jan;46(1):60-65 [FREE Full text] [doi: 10.1017/s0012162204000118] [Medline: 14974650]
5. Spasticity in under 19s: management clinical guideline. National Institute for Health Care Excellence. 2012 Jul 25. URL: https://www.nice.org.uk/guidance/cg145 [accessed 2022-09-02]
6. Telemedicine: opportunities and developments in member states: report on the second global survey on eHealth. World Health Organization. 2010. URL: https://apps.who.int/iris/handle/10665/44497 [accessed 2021-07-21]
7. Golomb MR, McDonald BC, Warden SJ, Yonkman J, Saykin AJ, Shirley B, et al. In-home virtual reality videogame telerehabilitation in adolescents with hemiplegic cerebral palsy. Arch Phys Med Rehabil 2010 Jan;91(1):1-8.e1. [doi: 10.1016/j.apmr.2009.08.153] [Medline: 20103390]
8. Edirippulige S, Reyno J, Armfield NR, Bambling M, Lloyd O, McNevin E. Availability, spatial accessibility, utilisation and the role of telehealth for multi-disciplinary paediatric cerebral palsy services in Queensland. J Telemed Telecare 2016 Oct;22(7):391-396. [doi: 10.1177/1357633X15610720] [Medline: 26519377]
9. Doraiswamy S, Abraham A, Mamtani R, Cheema S. Use of telehealth during the COVID-19 pandemic: scoping review. J Med Internet Res 2020 Dec 01;22(12):e24087 [FREE Full text] [doi: 10.2196/24087] [Medline: 33147166]
10. Camden C, Pratte G, Fallon F, Couture M, Berbari J, Tousignant M. Diversity of practices in telerehabilitation for children with disabilities and effective intervention characteristics: results from a systematic review. Disabil Rehabil 2020 Dec;42(24):3424-3436. [doi: 10.1080/09638288.2019.1595750] [Medline: 30978110]
11. Hung Kn G, Fong KN. Effects of telerehabilitation in occupational therapy practice: a systematic review. Hong Kong J Occup Ther 2019 Jun;32(1):3-21 [FREE Full text] [doi: 10.1177/1569186119849119] [Medline: 31217758]
12. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): checklist and explanation. Ann Intern Med 2018 Oct 02;169(7):467-473 [FREE Full text] [doi: 10.7326/M18-0850] [Medline: 30178033]
13. Preston N, Weightman A, Gallagher J, Levesley M, Mon-Williams M, Clarke M, et al. A pilot single-blind multicentre randomized controlled trial to evaluate the potential benefits of computer-assisted arm rehabilitation gaming technology on the arm function of children with spastic cerebral palsy. Clin Rehabil 2016 Oct;30(10):1004-1015. [doi: 10.1177/0269215515604699] [Medline: 26370148]
14. Tanner LR, Grinde K, McCormick C. The Canadian Occupational Performance Measure: a feasible multidisciplinary outcome measure for pediatric telerehabilitation. Int J Telerehabil 2021 Jun 21;13(1):e6372 [FREE Full text] [doi: 10.5195/ijt.2021.6372] [Medline: 34345346]
15. Staszuk A, Wiatrak B, Tadeusiewicz R, Karuga-Kuźniewska E, Rybak Z. Telerehabilitation approach for patients with hand impairment. Acta Bioeng Biomech 2016;18(4):55-62. [Medline: 28133379]
16. Reifenberg G, Gabrosek G, Tanner K, Harpster K, Proffitt R, Persch A. Feasibility of pediatric game-based neurorehabilitation using telehealth technologies: a case report. Am J Occup Ther 2017 May;71(3):7103190040p1-7103190040p8. [doi: 10.5014/ajot.2017.024976] [Medline: 28422630]
17. Ferre CL, Brandão M, Surana B, Dew AP, Moreau NG, Gordon AM. Caregiver-directed home-based intensive bimanual training in young children with unilateral spastic cerebral palsy: a randomized trial. Dev Med Child Neurol 2017 May;59(5):497-504 [FREE Full text] [doi: 10.1111/dmcn.13330] [Medline: 27864822]

XSL·FO
RenderX

18.   James S, Ziviani J, Ware RS, Boyd RN. Randomized controlled trial of web-based multimodal therapy for unilateral cerebral palsy to improve occupational performance. Dev Med Child Neurol 2015 Jun;57(6):530-538 [FREE Full text] [doi: 10.1111/dmcn.12705] [Medline: 25955443]

19.   Mitchell LE, Ziviani J, Boyd RN. A randomized controlled trial of web-based training to increase activity in children with cerebral palsy. Dev Med Child Neurol 2016 Jul;58(7):767-773 [FREE Full text] [doi: 10.1111/dmcn.13065] [Medline: 26877078]

20.   Chen Y, Lee S, Howard AM. Effect of virtual reality on upper extremity function in children with cerebral palsy: a meta-analysis. Pediatr Phys Ther 2014;26(3):289-300. [doi: 10.1097/PEP.0000000000000046] [Medline: 24819682]

21.   Nicolson A, Moir L, Millsteed J. Impact of assistive technology on family caregivers of children with physical disabilities: a systematic review. Disabil Rehabil Assist Technol 2012 Sep;7(5):345-349. [doi: 10.3109/17483107.2012.667194] [Medline: 22436000]

22.   Smits DW, Gorter JW, van Schie PE, Dallmeijer AJ, Ketelaar M, PERRIN+ study group. How do changes in motor capacity, motor capability, and motor performance relate in children and adolescents with cerebral palsy? Arch Phys Med Rehabil 2014 Aug;95(8):1577-1584. [doi: 10.1016/j.apmr.2014.04.013] [Medline: 24792140]

23.   Ostojic K, Paget S, Kyriagis M, Morrow A. Acute and chronic pain in children and adolescents with cerebral palsy: prevalence, interference, and management. Arch Phys Med Rehabil 2020 Feb;101(2):213-219. [doi: 10.1016/j.apmr.2019.08.475] [Medline: 31521713]

24.   Karatekin BD, İcagasioglu A, Sahin SN, Kacar G, Bayram F. How did the lockdown imposed due to COVID-19 affect patients with cerebral palsy? Pediatr Phys Ther 2021 Oct 01;33(4):246-249 [FREE Full text] [doi: 10.1097/PEP.0000000000000818] [Medline: 34323865]

25.   Huang IC, Sugden D, Beveridge S. Assistive devices and cerebral palsy: the use of assistive devices at school by children with cerebral palsy. Child Care Health Dev 2009 Sep;35(5):698-708. [doi: 10.1111/j.1365-2214.2009.00968.x] [Medline: 19323669]

26.   Ostensjø S, Carlberg EB, Vøllestad NK. The use and impact of assistive devices and other environmental modifications on everyday activities and care in young children with cerebral palsy. Disabil Rehabil 2005 Jul 22;27(14):849-861. [doi: 10.1080/09638280400018619] [Medline: 16096237]

27.   Bertucco M, Sanger TD. A model to estimate the optimal layout for assistive communication touchscreen devices in children with dyskinetic cerebral palsy. IEEE Trans Neural Syst Rehabil Eng 2018 Jul;26(7):1371-1380 [FREE Full text] [doi: 10.1109/TNSRE.2018.2840445] [Medline: 29985146]

28.   Cusick A, Lannin NA, Lowe K. Adapting the Canadian Occupational Performance Measure for use in a paediatric clinical trial. Disabil Rehabil 2007 May 30;29(10):761-766. [doi: 10.1080/09638280600929201] [Medline: 17457734]

Abbreviations

BG: basal ganglia
COPM: Canadian Occupation Performance Measure
CP: cerebral palsy
GMFCS: Gross Motor Function Classification System
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews
TH: telehealth
WHO: World Health Organization

<u>Original Paper</u>

The Impact of COVID-19 Lockdown Restrictions on Exercise Behavior Among People With Multiple Sclerosis Enrolled in an Exercise Trial: Qualitative Interview Study

Louise C Palmer[1], BSc, MA; Whitney N Neal[2], BA, MA; Robert W Motl[3], BSc, PhD; Deborah Backus[1], PT, PhD

[1]Crawford Research Institute, Shepherd Center, Atlanta, GA, United States

[2]Department of Health Behavior, University of Alabama at Birmingham, Birmingham, AL, United States

[3]Department of Kinesiology and Nutrition, University of Illinois Chicago, Chicago, IL, United States

Corresponding Author:
Louise C Palmer, BSc, MA
Crawford Research Institute, Shepherd Center
2020 Peachtree Rd NW
Atlanta, GA, 30309
United States
Phone: 1 404 350 7513
Email: louise.palmer@shepherd.org

Abstract

Background: During spring and summer 2020, US states implemented COVID-19 pandemic restrictions, resulting in the closure of rehabilitation facilities and, with them, some of the clinical trials that were taking place. One such trial was the Supervised Versus Telerehabilitation Exercise Program for Multiple Sclerosis ("STEP for MS") comparative effectiveness multiple sclerosis (MS) exercise trial. Although 1 study arm was implemented via telerehabilitation, the comparative arm took place in rehabilitation facilities nationwide and was subsequently closed during this time frame. The experience of the STEP for MS participants provides insights into the impact of lockdown restrictions on exercise behavior by mode of exercise delivery (telerehabilitation vs conventional facility based).

Objective: This study sought to understand the impact of COVID-19 lockdown restrictions on exercise behavior among people with MS enrolled in an exercise trial at the time of the restrictions.

Methods: Semistructured phone and video interviews were conducted with a convenience sample of 8 participants representing both arms of the exercise trial. We applied reflexive thematic analysis to identify, analyze, and interpret common themes in the data.

Results: We identified 7 main themes and 2 different narratives describing the exercise experiences during lockdown restrictions. Although the telerehabilitation participants continued exercising without interruption, facility-based participants experienced a range of barriers that impeded their ability to exercise. In particular, the loss of perceived social support gained from exercising in a facility with exercise coaches and other people with MS eroded both the accountability and motivation to exercise. Aerobic exercises via walking were the most impacted, with participants pointing to the need for at-home treadmills.

Conclusions: The unprecedented disruption of COVID-19 lockdown restrictions in spring and summer 2020 impacted the ability of facility-based STEP for MS exercise trial participants to exercise in adherence to the intervention protocol. By contrast, the participants in the telerehabilitation-delivered exercise arm continued exercising without interruption and reported positive impacts of the intervention during this time. Telerehabilitation exercise programs may hold promise for overcoming barriers to exercise for people with MS during COVID-19 lockdown restrictions, and potentially other lockdown scenarios, if the participation in telerehabilitation has already been established.

KEYWORDS

XSL•FO
RenderX

Introduction

Background

COVID-19 was declared a global health emergency in January 2020 and a pandemic in March 2020 [1]. Governments worldwide, including in the United States, subsequently implemented public health emergency measures, including legally enforced closures and limitations on the maximum capacity of places where people congregate (ie, schools, stores, and recreational facilities), physical distancing, mask wearing, limitations on nonessential domestic and international travel, and self-isolation or quarantine requirements [2]. These measures disrupted participation in work, education, travel, recreation, exercise, and physical activity (PA), with potentially significant physical and mental health implications, especially for people with disabilities, including multiple sclerosis (MS). Indeed, 2 years after the lockdown restrictions were lifted, research indicates that vulnerable populations, including people with MS, experienced heightened social isolation, increased depression and anxiety [3,4], and a lack of access to health services [5-7].

MS is a chronic neurological disease of the central nervous system with prevalence among nearly 1 million adults in the United States and 2.5 million adults worldwide [8]. Damage within the central nervous system yields the myriad of symptoms experienced by people with MS, resulting in functional limitations, cognitive dysfunction, and reduced quality of life (QOL) [9]. PA and exercise can improve walking, balance, fatigue, depression, and QOL for people with MS [10]. However, people with MS are more inactive than the general population [11] and experience many barriers to exercise, including a lack of MS-adapted exercise protocols [12].

Objective

Both facility-based and telerehabilitation (telerehab) exercise training have yielded positive results in people with MS. However, the facility-based and telerehab modes of delivering exercise have not been compared head to head. Comparing the outcomes of delivering the same exercise intervention in a facility (facility based) and in the home or community using a telerehab approach would be an important step toward informing people with MS about their exercise options. The Supervised Versus Telerehabilitation Exercise Program for Multiple Sclerosis (STEP for MS) comparative effectiveness trial was designed to address this knowledge gap by assessing the effectiveness of the *Guidelines for Exercise in People With Multiple Sclerosis (GEMS)* exercise protocol [13,14] for people with MS delivered via telerehab compared with in a conventional facility setting. The primary research question of the STEP for MS study was as follows: "In people with MS, does an evidence-based individualized exercise program delivered via telerehab yield comparable benefits for improving walking, mobility, participation, and QOL when compared with delivery via a conventional, facility-based approach?" By the beginning of March 2020, the STEP for MS trial had enrolled 217 participants across 8 study sites throughout the United States.

In the United States, governors implemented pandemic restrictions on a state-by-state basis; however, by the end of March 2020, all STEP for MS study sites were temporarily closed to in-person research activities. Studies indicate that the full or partial closure of fitness and rehabilitation facilities and parks and the continuation of self-isolation directives for medically vulnerable persons through early summer 2020 decreased the PA levels among people with MS [15,16]. Indeed, 1 study estimated that almost half of the people with MS decreased their PAs during the COVID-19 pandemic [15]. Studies assessing the impact of COVID-19 restrictions on PA and exercise among people with MS use a cross-sectional research design and survey methodology, which do not delve into the unique perceptions and experiences of people with MS [15-18]. A deeper understanding of these issues can inform the development of programs that will more effectively address the unique needs of people with MS. To address this gap, this study used a qualitative research design and explored the impact of COVID-19 lockdown restrictions on exercise behavior among a small convenience sample of adults with MS enrolled in STEP for MS. The study further explored whether participants' experiences during lockdown restrictions had implications for the design and implementation of future exercise trials. Specifically, our study sought to answer the research question, "What impact, if any, has the COVID-19 pandemic had on the exercise behaviors of people participating in the STEP for MS trial?"

Methods

Study Setting and Design

This research was an ancillary qualitative study conducted as part of the larger STEP for MS multisite trial (NCT03468868). The STEP for MS trial compares the effectiveness of a 16-week evidence-based, individualized exercise training program (GEMS) delivered via telerehab with that of the same program delivered in a facility among people with MS who have walking dysfunction and mobility disability (assumed to be due to their MS) [19]. The STEP for MS trial began recruitment in September 2018 and followed a 2-stage, randomized choice design for examining improvements in walking performance in people with MS. Specifically, the participants were first randomized into either the assigned or choice arm. The second stage of randomization was then applied only to those in the assigned group, whereby participants were randomly assigned to either the facility-based or telerehab intervention arm. Within the choice group, the participants made a preferred selection of facility (Guidelines for Exercise in People With Multiple Sclerosis-Supervised [GEMS-S]) or telerehab (Guidelines for Exercise in People With Multiple Sclerosis-Telerehabilitation [GEMS-T]).

Both intervention arms received an individualized exercise prescription that consisted of aerobic exercise focused on walking as the modality and strength training exercises targeting the lower body, upper body, and core muscle groups. The participants in the GEMS-S group completed exercise sessions in person under the supervision of an MS exercise behavioral coach based at 1 of the 8 study sites. By contrast, GEMS-T is

delivered remotely via Zoom by exercise behavioral coaches located at the University of Alabama at Birmingham (UAB) Intervention Center. Specifically, the GEMS-T coach oriented the participants to the exercise prescription but did not provide remote supervision during the aerobic and strength exercise training sessions. Instead, the GEMS-T participants had the option of following written or video instructions for the exercises and completing them in their home, at a gym, or on walking trails in their community. In addition, the participants in both groups received one-to-one sessions with behavioral coaches at regular intervals. These sessions focused on the guidance on and oversight of appropriate exercise techniques, discussion of action planning and self-monitoring, and delivery and discussion of newsletters designed to optimize exercise adherence. To ensure the fidelity of intervention delivery across sites, the STEP for MS trial used training and quality checks, including initial and ongoing site training on the exercise training program and social cognitive theory (SCT) principles of behavior change for exercise, weekly meetings with the intervention center project coordinator and all collaborating site behavioral coaches, and audits of one-to-one behavioral sessions across sites. Further details of the intervention protocol and fidelity measurements have been previously reported [19].

Delivery of the STEP for MS intervention began in October 2018; however, the COVID-19 pandemic meant that many of the intended intervention procedures described earlier were no longer feasible for GEMS-S participants as of March 18, 2020, when restrictions were put into place. Specifically, the closure of study sites for clinical trials and studies not related to COVID-19 prevented sites from conducting the GEMS-S in-person exercise training visits. Thus, the STEP for MS trial team worked rapidly to implement adaptations to intervention delivery for the participants in the GEMS-S condition. After an initial 3-week pause in intervention activities for the GEMS-S participants, activities resumed via internet-based and phone-based supervised exercise sessions using web conferencing software (eg, Zoom [Zoom Video Communications, Inc]) instead of face-to-face sessions from early April 2020.

This ancillary qualitative study recruited participants from 2 of the 8 study sites (UAB and Shepherd Center), where lockdown restrictions were implemented for a brief period spanning April 2020, followed by an advisory order only in Alabama through May 2020, but a mandatory stay-at-home order was implemented for people at increased risk in Georgia through May 2020 [20].

Philosophical Assumptions

This research was underpinned by ontological relativism and epistemological constructivism [21,22]. Ontological relativism asserts that reality is a subjective experience, whereas constructivist epistemology is underpinned by the belief that knowledge is constructed through personal interactions with the social and physical environment and that the researcher has an active role in the construction of knowledge generation [21,22]. These philosophical underpinnings informed an interpretivist paradigm, whereby we recognized that the purpose of the research involved identifying various subjective and

multifaceted perceptions of the impact of the pandemic on each participant's exercise behavior.

Recruitment

This qualitative interview study was approved by the Shepherd Center Research Review Committee and conducted as a part of the ongoing STEP for MS comparative effectiveness trial [19]. The qualitative study used purposeful sampling strategies, specifically convenience, criterion-based, and quota-based sampling techniques. The participants of this study were a convenience sample enrolled at either our Shepherd Center or UAB study sites. Criterion-based sampling strategies specifically seek individuals who possess certain characteristics that speak to the research questions. The first and second authors (LCP and WNN) contacted participants who were completing the exercise intervention portion of the STEP for MS trial when COVID-19 restrictions were imposed (March to April 2020) or who had recently concluded the 16 weeks of exercise and who were enrolled at either the Shepherd Center or UAB study location. This sampling method allowed the recruitment of persons with MS who could (1) provide rich data from current personal experiences for addressing the research questions [23] and (2) yield data that were detailed and in-depth enough to inform meaningful and impactful results relevant to the design and implementation of future exercise trials [24]. Quota-based sampling seeks an equal representation of participants [25]. We targeted the recruitment of 5 persons per study location (Shepherd Center and UAB) with equal representation between the study arms (home based [GEMS-T] and facility based [GEMS-S]) for a broad cross-section of feedback on the impact of COVID-19 lockdown restrictions on exercise behavior. The first and second authors (LCP and WNN) contacted 14 participants who met the inclusion criteria stated earlier (ie, those who were currently completing or recently completed the 16-week exercise intervention and were enrolled at either the Shepherd Center or UAB study location). Of these 14 people, 9 (64%) expressed interest. One of the participants from UAB was lost to follow-up or did not attend the interview. We believe that our sample of 8 participants, although small, is acceptable within the context of this pragmatic study and provides sufficient "information power" to answer our research question [26]. Information power refers to the amount of information the sample provides that is relevant for answering the research question. The greater the amount of information contained in the sample, the smaller the number of participants required. Although small, we also believe that our participants provided quality information, another metric for assessing the adequacy of sample size in qualitative research [27].

Data Collection

Data were collected through one-to-one semistructured interviews conducted either on the web (3/8, 38%) or via phone (5/8, 62%) by trained interviewers (LCP and WNN). The interview guide is provided in the Multimedia Appendix 1. We had the camera on for interviews conducted on the web but did not have video for those conducted via phone. There are pros and cons to different interviewing media (Saarijärvi and Bratt [28]), but a mixed format has been used successfully in other

published studies (refer to, eg, Neal et al [29]) and likely does not affect the study findings [28].

The coauthors developed the interview guide through engagement with the literature, guidance from an expert in qualitative research methods, and discussion with the third and fourth authors (RWM and DB) to address the overarching research question, "How has the COVID-19 pandemic impacted your exercise?" The interview guide adopted a chronological approach to explore the levels of participant exercise before the COVID-19 pandemic, during lockdown restrictions, and at the time of the interview (May 2020, when some but not all restrictions had been lifted). After establishing the general pattern of exercise over this period, the interview guide used a strength- and barrier-based approach to explore what helped and hindered exercise during the lockdown. The interviewer (either LCP or WNN) presented questions and prompts in a semistructured format, allowing the participants the freedom to elaborate when discussing experiences that were important to them but affording the interviewer the opportunity to focus on areas of interest. Questions encompassed a range of topics regarding participants' experiences and perceptions related to exercise and coping during the COVID-19 pandemic such as, "What has helped or hindered exercise during the pandemic?"

and "What additional resources would have been helpful during the pandemic?" Then, the participants were asked, "What concerns do you have about remaining in the STEP for MS trial as the pandemic continues?" and "How has COVID-19 changed your thoughts on participating in future exercise studies?" Questions about continuing in the STEP for MS trial and future exercise trials were asked after other questions pertaining to perceptions related to exercise and coping during the pandemic and were open-ended, thereby allowing the participants the freedom to express their views for or against future participation in exercise trials.

Ethics Approval

The participants provided verbal consent for taking part in the interview with audio recording in accordance with the Shepherd Center's institutional review board approval process (protocol number 738; Shepherd Center's Institutional Review Board credentials: FWA00000642 and IORG0001082), and the participant names were removed from the transcripts and replaced with pseudonyms (Textbox 1).

Raw data worth >4 hours were collected, and interviews lasted between 23 and 43 minutes. Clinical and demographic data were collected as part of the STEP for MS trial baseline data collection.

Textbox 1. Participants' group assignments and pseudonyms.

Guidelines for Exercise in People With Multiple Sclerosis-Telerehabilitation

- Kimberly (research site A)
- Sarah (research site A)
- Dana (research site B)
- Leslie (research site B)
- Maureen (research site B)

Guidelines for Exercise in People With Multiple Sclerosis-Supervised

- Anita (research site A)
- Gayle (research site B)
- Wendy (research site B)

Data Analysis

To understand the meaning of the data, we applied reflexive thematic analysis (RTA), a flexible interpretative approach to qualitative data analysis for identifying, analyzing, and interpreting common themes in the data [30]. The data were analyzed using predominantly inductive RTA, whereby codes and themes were generated from the participant testimonies. A degree of deductive analysis was used to ensure that the data-based meanings emphasized in open coding contributed to the production of themes that were meaningful to the research questions. To ensure rigor, data analysis was completed by LCP and WNN through six iterative phases: (1) familiarization with data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining themes, and (6) final analysis. LCP and WNN became immersed in the data by conducting interviews, rereading transcripts, taking notes of initial ideas related to the research question, and creating initial codes (steps

1 and 2). Initial themes were generated by creating a list of codes for each participant, sorting and collating these lists into potential themes, and then placing similar codes in the same group (step 3). To ensure trustworthiness, LCP and WNN met regularly to discuss the meaning of the codes and themes in relation to the research questions. Subthemes were generated when necessary to demonstrate the hierarchy of meanings within a theme. Themes were then refined through discussions between the research team members (including RWM and DB) regarding the appropriateness of each theme in relation to the research questions (step 4). During steps 5 and 6, the themes were defined and named in a way that explained the data content and answered the research question, and the results were collated into a written narrative with data extracts to illustrate each theme, which will be presented in the *Results* section.

Ensuring Rigor

To ensure rigor and trustworthiness throughout the qualitative research process, we adopted a relativist approach, whereby we chose study-specific markers of evaluative quality from Smith and Caddick's ongoing list [31]. We chose the evaluative markers of substantive contribution, worthy topic, and transparency. First, we demonstrated the worthiness of our topic by justifying in the introduction why examining the experiences and perceptions of coping and exercise during the COVID-19 pandemic among people with MS could advance the understanding in this area and have significant implications for practice. Second, we ensured substantive contribution by identifying a gap in knowledge within the field of MS and exercise, which, if answered well, could meaningfully contribute to our understanding and appreciation of exercise in MS. Finally, we sought to be transparent by completing an audit trail, whereby the first and second authors served as "critical friends" throughout the analytical process.

Results

Overview

The mean age of the interview participants was 51.5 (SD 6.5; range 45-60) years; 50% (4/8) of the participants identified as Black and 38% (3/8) as White; and all were female (8/8, 100%). Participants represented a range of MS types and disability status, as reflected in the Patient-Determined Disease Steps and the Expanded Disability Status Scale presented in Table 1. Both groups had similar characteristics in terms of these disease measures. A total of 5 participants were enrolled at the Shepherd Center site, and 3 were enrolled at UAB. Six participants were in the process of completing the exercise intervention at the time of lockdown restrictions, and 2 participants (1 per site) had recently concluded the intervention.

The experiences and perceptions related to exercise during the COVID-19 lockdown restrictions were extensive, complex, and contrasting among the participants. All the participants discussed barriers to exercise during the pandemic, and perceptions differed depending on whether they were in the GEMS-S or GEMS-T study arm. The following sections outline 2 narratives based on these study arms and propose potential reasons for the existence of 2 different narrative paths. Briefly, the GEMS-S participants experienced disruption to exercise during the lockdown restrictions, whereas the GEMS-T participants adapted to the new exercise conditions and continued to exercise seamlessly. Through RTA, LCP and WNN identified a total of seven themes related to the exercise experiences of people with MS during the COVID-19 pandemic (Textbox 2): (1) GEMS-T—disruptions and adaptations to the exercise environment, (2) GEMS-T—applying GEMS strategies to adhere to exercise, (3) GEMS-T—exercise as a coping mechanism, (4) GEMS-S—environmental barriers to exercise, (5) GEMS-S—loss of social support reduced the self-motivation to exercise, (6) GEMS-S and GEMS-T—request for resources to support home-based exercise, and (7) GEMS-S and GEMS-T—COVID-19 pandemic–related concerns.

Table 1. Demographic and clinical characteristics.

Characteristics	GEMS-S[a] (n=3)	GEMS-T[b] (n=5)
Sex (female), n (%)	3 (100)	5 (100)
Age (years)		
40-49, n (%)	1 (33)	3 (60)
50-59, n (%)	2 (67)	1 (20)
60-69, n (%)	0 (0)	1 (20)
Value, mean (SD)	52.7 (6.5)	50.8 (7.2)
Race, n (%)		
African American or Black	3 (100)	1 (20)
White	0 (0)	3 (60)
Chose not to answer	0 (0)	1 (20)
Ethnicity (non-Latino), n (%)	3 (100)	5 (100)
MS[c] type, n (%)		
Relapse-remitting MS	3 (100)	3 (60)
Secondary progressive MS	0 (0)	2 (40)
PDDS[d]		
3—Gait disability, n (%)	1 (33)	0 (0)
4—Early cane, n (%)	2 (67)	1 (20)
5—Late cane, n (%)	0 (0)	2 (40)
6—Bilateral support, n (%)	0 (0)	2 (40)
Value, median (IQR; range)	4 (0.5; 3-4)	5 (0.25; 4-6)
EDSS[e]		
4.5—Relatively severe disability, n (%)	0 (0)	1 (20)
5—Disability affects daily routine, n (%)	1 (33)	0 (0)
6—Assistance required to walk, n (%)	2 (67)	4 (80)
Value, median (IQR; range)	6 (0.5; 5-6)	6 (0; 4.5-6)
Randomization status, n (%)		
Choice	1 (33)	3 (60)
Assigned	2 (67)	2 (40)

[a]GEMS-S: Guidelines for Exercise in People With Multiple Sclerosis-Supervised.

[b]GEMS-S: Guidelines for Exercise in People With Multiple Sclerosis-Telerehabilitation.

[c]MS: multiple sclerosis.

[d]PDDS: Patient-Determined Disease Step.

[e]EDSS: Expanded Disability Status Scale.

Textbox 2. Themes and subthemes along with their definitions.

Theme 1: Guidelines for Exercise in People With Multiple Sclerosis-Telerehabilitation (GEMS-T)—disruptions and adaptations to the exercise environment

- The GEMS-T participants made changes to their environment to facilitate continued exercise during lockdown restrictions.

Theme 2: GEMS-T—applying Guidelines for Exercise in People With Multiple Sclerosis (GEMS) strategies to adhere to exercise

- The GEMS-T participants' use of strategies learned through the exercise intervention facilitated continued exercise during lockdown restrictions, and accountability was gained from participating in the trial.

Theme 3: GEMS-T—exercise as a coping mechanism

- The exercise study provided the GEMS-T participants with a way to cope with boredom and anxiety during the lockdown restrictions.

Theme 4: Guidelines for Exercise in People With Multiple Sclerosis-Supervised (GEMS-S)—environmental barriers to exercise

- The GEMS-S participants identified barriers to exercise in their physical environments.

Theme 5: GEMS-S—loss of social support reduced the self-motivation to exercise

- The GEMS-S participants described how the lack of in-person coaching and peer support during the lockdown restrictions decreased their motivation to exercise. Social support is a latent theme, which facilitates self-motivation, a semantic theme. The GEMS-S participants recommended an increase in social support when transitioning from exercising in the facility to exercising at home.

Theme 6: GEMS-S and GEMS-T—request for resources to support home-based exercise

- Both GEMS-S and GEMS-T participants requested more resources to support home-based exercise.

Theme 7: GEMS-S and GEMS-T—COVID-19 pandemic–related concerns

- These are factors directly related to the COVID-19 pandemic in general that prevented or hindered the participants in both groups from staying physically active.

Theme 7.1: perceived vulnerability determines the level of caution when exercising

- This subtheme reflects participants' general fear about keeping healthy and safe during the pandemic and fears of catching COVID-19 while exercising in public spaces.

Theme 7.2: COVID-19 restrictions deter exercise

- This subtheme reflects participants' discomfort with exercising indoors and dislike of mask wearing while exercising inside and outside.

Theme 1: GEMS-T—Disruptions and Adaptations to the Exercise Environment

Several barriers to the physical environment, such as lack of home aerobic exercise equipment and hilly neighborhood terrain, impacted exercise participation; however, the GEMS-T participants explained how they adapted to the new limitations imposed by the lockdown restrictions and continued their aerobic exercise. For example, Sarah, concerned about catching COVID-19 in outdoor public spaces, changed her walking location from a park to her neighborhood. After learning about the apartment complex's first positive COVID-19 case, she further restricted her exercise to spaces directly around her apartment building.

Similarly, as the garden where Dana previously walked was closed during the lockdown restrictions, she pivoted to using her home exercise gym. Before the lockdown restrictions, Leslie, a teacher, walked on the school exercise track after classes, and, subsequently, she switched to walking on trails by her house:

> [There is] a park a block away. And we're in kind of an isolated area, so it's super safe and easy for us to go out for a walk. We actually have trails around our house. [Leslie]

Finally, Maureen attempted to walk around her neighborhood but found it more exhausting than walking on the treadmill in her subdivision's indoor gym and, therefore, continued using the gym, which she described as clean and empty:

> They have two treadmills, a bike and a stair master, that's it...I'm the only one using it. And then, they left that container of wipes and things to wipe down the equipment that I need...So far, I've never, in all the months since March, I've never seen another person in there when I was in there. [Maureen]

Overall, 80% (4/5) of GEMS-T participants continued exercising during the lockdown restrictions without a break. When classes moved to the web, Leslie found the first week of teaching remotely challenging, with no time for exercise. However, she quickly adapted and resumed exercising:

> After that week, the pandemic didn't make it any harder for me, the pandemic itself. It's just that week was so overwhelming. [Leslie]

XSL•FO

RenderX

Theme 2: GEMS-T—Applying GEMS Strategies to Adhere to Exercise

The GEMS-T participants described using a variety of tools and strategies learned through the STEP for MS trial to adhere to exercise during the pandemic-imposed lockdown restrictions. For example, when Sarah changed her exercise location from a park to what she described as a less inspiring location (her apartment complex), she listened to music for motivation, a coaching suggestion:

> It'll make it seem as if the time is not dragging. [Sarah]

The STEP for MS self-monitoring tools provided both motivation and accountability to the GEMS-T participants during the pandemic. For example, Maureen called the progress log her "accountability partner" and explained how it enabled her to see progress in her step count over the course of the study:

> It [the progress log] kind of lets me know when I started. And I mean, when I started, I was lucky to do 500 steps. Now I'm doing 1700 steps...So it's nice to see the improvement. [Maureen]

Likewise, Dana stated the following:

> It was good for me to keep track of what I was doing and to have the goal of always meeting the next step up. [Dana]

Several participants noticed an improvement in MS symptoms and weight loss as a result of participating in the exercise program. These benefits of exercise became self-rewarding and increased the participants' motivation to continue exercising. Dana said the following:

> It made me more committed...because I can see improvement. [Dana]

Similarly, Maureen lost 20 pounds and noted the following:

> My endurance is better; I can go all day. [Maureen]

The GEMS-T participants considered the commitment they made to the study as key to continued adherence to the exercise program throughout the lockdown:

> I think the accountability of participating in a program and keeping you connected with what you should be doing and what's new, is actually a positive aspect of participating in the trial...It's just a commitment. I made a promise and I'm doing what I said I would do. [Dana]

> It (the trial) kept me accountable...I was like, my data won't be accurate...you'd better do it [exercise]." [Leslie]

Theme 3: GEMS-T—Exercise as a Coping Mechanism

The participants from the GEMS-T group described how participating in the exercise trial provided a positive distraction during the lockdown restrictions and helped them cope with pandemic-related anxiety and depression. For example, Dana gave the following explanation:

> I was just very thankful that I had this program to do at home, and also it made me thankful that I had something to concentrate on as well...It gave me something. [Dana]

Similarly, Maureen noted how she exercised beyond the intervention requirement of 2 times a week to pass the time:

> I've actually been doing it [exercise] four or five times a week...because there's nothing else to do. [Maureen]

Dana also specifically attributed exercise to helping her cope with the anxiety associated with the pandemic:

> So, the anxiety [of the pandemic] is there and yes, I think maybe exercise helps me clear my head...while I'm on the treadmill, I can think through things cohesively. [Dana]

Theme 4: GEMS-S—Environmental Barriers to Exercise

In contrast to the GEMS-T participants, those in the GEMS-S group described multiple barriers to exercise associated with their physical environment, as they transitioned from exercising in the facility under the supervision of a coach to home-based exercise. Although the GEMS-T participants described making adaptations to their physical environment to ensure continued engagement in exercise, several GEMS-S participants considered their outside terrain to be unconducive for aerobic exercise, making walking difficult. Indeed, 2 GEMS-S participants had mostly stopped exercising at the time of the interviews. Anita explained that she had planned to use her gym membership to continue exercising after the study ended and that sometimes she walked inside Walmart for exercise, but neither option was available during the lockdown restrictions:

> But you know, of course since this happened, nobody wants to go into a gym or whatever, no, I don't feel comfortable. [Anita]

Meanwhile, walking outside was challenging because of the hills in Anita's neighborhood:

> The neighborhood I live in is so hilly...If the area was more flat, I would be more apt to just go outside and walk, you know? [Anita]

For Gayle, the transition from walking on a treadmill at the facility to walking outside in her neighborhood was challenging:

> I didn't realize how different it would be walking outside versus walking on the treadmill...It's [the outside terrain] not flat like the treadmill, which is something I didn't really contemplate, or think about, or make allowances for. And I was still trying to walk the same pace. But I got kind of like upset with myself like, "You're not walking as fast." [Gayle]

However, later in the interview, Gayle alluded to a confluence of factors that combined to discourage her from walking outside:

> If I had a treadmill, I would be able to do that. It's just having to go outside. We put on our masks, and we get going. And then, as soon as I get out of my house, we have to go around a curve, and then it goes up a hill. And then the other part of my house is in a cul-de-sac, so I don't have any option except to go up this little hill. And then, when you're going up the

hill, and you start breathing faster, and then you feel like the mask is, you know, you gotta take it out, take your face out of the mask, because you need to breathe better. It's just not...it doesn't feel right. [Gayle]

She continued to talk about the need to take her cane with her to walk outside:

It's more difficult for me to walk up and down the hill because I have to take my cane with me if I'm outside. When I was on the treadmill, I could just walk without even holding on, or if I needed to, I could hold on, but outside I've been slower. I have to take my cane. [Gayle]

For Gayle, these barriers resulted in her dropping the walking portion of the exercise altogether during the lockdown restrictions. Gayle wished that she had been advised on how different walking outside would be compared with the controlled treadmill experience in the gym:

Just let them know...that it may not be the same walking on a treadmill, it may not be the same as walking outside, but make sure that you know that the amount of steps you take really doesn't matter. Just walk. [Gayle]

Although Wendy had stopped exercising at the time of the interviews because of ill-health, she also expressed reservations about walking in her neighborhood because of the terrain and safety concerns. Instead, Wendy would use the treadmill at her home:

I would walk outside, and I also have a treadmill, but because of the stability to walk outside, I don't walk outside as much. I actually kind of stopped, and then our neighborhood had rumors that there were coyotes in the neighborhood. And so, because I was mostly walking by myself, I didn't feel like that was safe. So, I really started to do the treadmill inside more than anything...And my driveway, it's kind of a hill. I could barely move my way up the drive way. So, I said, this is just not a good idea, so that's really when I made the final decision, that I've got to do this inside. [Wendy]

Theme 5: GEMS-S—Loss of Social Support Reduces the Self-motivation to Exercise

Moving from facility to home during the lockdown restrictions disrupted the in-person social connections during exercise that the GEMS-S participants had become accustomed to. Anita talked at length about lacking the motivation that she had in the facility to exercise at home during the lockdown:

And I really just haven't been motivated, but I will put on some music and just do it...It's just in my mind, I've just like, I know I need to do this, but I don't really feel like it. [Anita]

Similarly, Gayle gave the following explanation:

It [lockdown restrictions] took all of my momentum away because I haven't exercised really throughout my life, but I prayed that I would be able to come to

the facility, because I knew that I really needed that. I needed that support. [Gayle]

For both Anita and Gayle, the loss of in-person coaching and peer support that they received at the facility appeared to be connected to a loss of motivation to exercise at home. For example, Anita gave the following explanation:

Cause I mean, that was somewhere I could go the two days out of the week. Me and him [the coach] would laugh and talk...So, even though I was working, I was exercising, but with his method, how he would just be talking to me and we would be talking. [Anita]

Gayle noted the lack of both social support from peers and in-person coaching support as driving her lack of motivation to exercise at home:

At first, I couldn't even do 10 [minutes of walking], I thought I was going to die. But I got up to 30 and I really felt encouraged. And I would see other people at the facility that maybe had...less level of functioning mobility than I had. And so, I was just encouraged like, "You can do this. Look at them, they're doing it." And I really thought I was doing well. And then when I had to do it at home, I just didn't have that. I mean, Irene [the GEMS-S coach] is great. It wasn't her at all. I don't know, I just lost it. [Gayle]

Importantly, here, Gayle noted that her GEMS-S coach was supportive in the web-based environment; therefore, it was not the lack of coaching per se that she missed. Rather, it was the overall environment consisting of peers with disabilities exercising together with in-person coaching. Gayle expounded the following:

In the facility, even though we weren't working out together, it was like we were all on the same team... [Gayle]

I love to see the other people at the center, and if their disability [was] maybe a little bit more pronounced than mine, it's just "look at how she's doing. She's doing so good..." [Gayle]

To have the coaches supporting you [in the facility], and it just felt like I had a purpose, more so than being by myself... [Gayle]

For Gayle, it was not simply receiving peer support that made the difference but also providing it to others:

It was good to hear the encouragement [in facility], or to be able to encourage somebody else. [Gayle]

Theme 6: GEMS-S and GEMS-T—Request for Resources to Support Home-Based Exercise

Unsurprisingly, the GEMS-S participants recommended increased social support and accountability when transitioning from exercising in the facility to exercising at home. Anita recommended "some kind of alarm or some kind of alert or message or something" to hold her accountable to exercise. Other GEMS-S participants enjoyed exercising alongside their peers while in the facility and would have liked a way to remain connected in the web-based environment. For example, Maureen suggested the following:

A visual Zoom program would be more beneficial because you would develop relationships more with people that way I guess. [Maureen]

Both GEMS-S and GEMS-T participants requested more resources to support home-based exercise. These resources include exercise demonstration videos and aerobic exercise equipment such as a treadmill. For example, Anita said the following:

I got my equipment [resistance bands and pedometer], you know, the stuff, but of course the equipment [treadmill] we don't have it here. [Anita]

Anita also requested exercise videos:

If I can find something, I've got a smart TV. Like if there was some kind of YouTube channel or somebody with some little exercises or something. [Anita]

Both Sarah (GEMS-T) and Gayle (GEMS-S) noted the need for a treadmill:

I kind of wish I had a treadmill because I had been thinking about it for a long time. And I'm just like, I feel like even if I do 10 minutes on the treadmill, that'll be equivalent to me walking in a neighborhood or something like that. [Sarah]

The problem is, I just have to buy a treadmill. [Gayle]

Theme 7: COVID-19 Pandemic–Related Concerns

At the time of the interviews, much was still unknown about how COVID-19 was transmitted and how COVID-19 might impact people with MS, and a vaccine remained far away.

Theme 7 covered factors related to the COVID-19 pandemic that hindered participants in both groups from exercising. This theme was divided into 2 subthemes.

Theme 7.1: Perceived Vulnerability Determines the Level of Caution When Exercising

As people with a chronic illness who may experience lowered immunity to disease in general, the participants were cautious in their daily activities, including exercise, to prevent contracting COVID-19. When deciding whether to exercise in a public setting (indoor and outdoor), the participants took precautionary measures based on their perceived vulnerability to COVID-19. For example, Anita said the following:

I'm just kind of leery about it, because you don't know if this is airborne outside. [Anita]

Likewise, Sarah was wary of being around other people outside:

And then when I found out that someone in the community had it, I'm just so afraid. By like with my immune system being compromised, like how it is, I catch a cold in a minute or something, so I'm just like, I'm kind of scared. I took a chance. I just really didn't want to take, so I'm not ready to go quite yet to the park. [Sarah]

Gayle expressed how the uncertainty about COVID-19 transmission led to her wearing a mask while exercising outside and how this also made walking more difficult:

And then they [news anchors] were saying that it can be in the air. And then one show said that the wind carries it. And that's what I was afraid of. We would always go outside with our masks...but then if you're trying to walk, and you have this mask on, you feel like you're smothered a little bit. [Gayle]

Theme 7.2: COVID-19 Restrictions Deter Exercise

Participants disliked wearing masks while exercising both indoors and outdoors but felt unsafe exercising inside gyms (which had just begun to reopen) without wearing masks:

I'm not going to go in there [the gym] without a mask on, so I won't be doing that. [Anita]

...with the face mask and the heat, that was strange, but it impacted where I wouldn't want to go to a park where I would normally go on a walk inside. I wouldn't want to go. [Sarah]

When asked whether Gayle would walk more if the terrain was flat, she responded that the mask was just as much of a barrier to exercising outside:

Yeah. I think if it was something similar to the treadmill, yeah. And if I didn't have to wear the mask, probably because like when you start walking, and start breathing faster, and I don't know, it just feels like you can't really exchange oxygen as well. [Gayle]

Discussion

Principal Findings

This study contributes to the literature by detailing how participants in 2 different arms of an MS exercise trial adhered to the exercise intervention during the COVID-19 lockdown restrictions and immediately after the restrictions were lifted. The participants randomized to the facility-based arm (GEMS-S) of the STEP for MS trial were more likely to describe barriers to continued exercise such as the lack of social support or home aerobic exercise equipment, whereas telerehab participants (GEMS-T) were more likely to highlight positive experiences, including adaptations to their exercise environment and using exercise as a coping mechanism. Our findings indicate important considerations for researchers and providers about how to meet the exercise needs of people with disabilities in the new pandemic reality and for investigators planning future exercise interventions.

A total of 2 different narratives emerged from our findings. During the lockdown time frame, the GEMS-T participants continued apace with the exercise intervention without interruption. By contrast, the GEMS-S participants described how the shift to remote exercise disrupted their progress and motivation to the point of inertia. Although the participants in both groups continued with resistance training to some extent using the provided resistance bands, the walking component of the intervention proved to be more difficult to maintain for the GEMS-S participants. Perhaps because the GEMS-T participants already had several weeks of at-home exercise established by the start of lockdown restrictions, exercise was routinized enough to accommodate the disruption, even when restrictions

necessitated a change in the aerobic exercise location for some participants.

Access to at-home aerobic exercise equipment such as a treadmill or stationary bike appears to be key to facilitating aerobic exercise during lockdown restrictions. In both groups, walking outside was not a viable option during lockdown restrictions for various reasons, such as uneven terrain, heat, mask wearing, and safety concerns. For many participants, the physical terrain of their local neighborhood was not conducive to walking with a mobility disability. The availability of public spaces such as parks or botanical gardens for aerobic exercise also varied among participants, although most reported closing. In this regard, although our study focused on formalized exercise, these findings have accessibility implications for PA more broadly for people with disabilities desiring to undertake leisure and PA in their homes and communities. Future studies could further examine the role of the environment and neighborhood on PA participation during lockdown restrictions.

Our findings provide additional support for the inclusion of SCT in exercise interventions to enhance program uptake and adherence. SCT posits an interplay between personal and environmental factors and identifies self-efficacy, outcome expectations, goal setting, and facilitators or barriers as core determinants of behavior [32,33]. The STEP for MS exercise program is supplemented with an SCT-based behavioral component that incorporates these core SCT determinants into program tools and strategies. The GEMS-T participants referred to several of these tools and strategies as facilitators of exercise during the lockdown restrictions, including the one-to-one coaching sessions for feedback and social accountability, exercise adherence logs and pedometers for accountability and monitoring progress, informational newsletters discussing SCT determinants, and other individualized strategies to enhance exercise adherence and compliance (eg, listening to music). The participants also discussed factors that were self-rewarding, such as decreased fatigue and stress, greater stamina, and weight loss, as facilitators of continued exercise during the COVID-19 lockdown restrictions.

In line with the previous literature examining SCT and PA [34], our findings suggest that in-person social support may be a latent construct that strongly supports exercise behavior in people with MS. Within the SCT framework, social support facilitates self-efficacy [33], which in turn is a key determinant of behavior change [32,35]. In addition to lacking access to a treadmill, the GEMS-S participants frequently attributed the loss of in-person support received from both coaches and peers as a barrier to continuing the exercise program at home. Although the trial was designed as an individual exercise intervention with identical exercise and coaching content in both study arms, our findings are suggestive of experiential differences between these 2 groups of participants, particularly in perceptions of social support. Although both groups of participants desired social support, the impact of not having it differed qualitatively between the groups, with only the GEMS-S participants naming the loss of support as an impediment to exercise. The outcome data from the trial will provide more conclusive evidence on whether in-person or web-based coaching is associated with differences in exercise outcomes

and what role the choice of exercise location plays. Regardless of the impact on the motivation to exercise, several participants requested a way to connect with their peers on the web for social support.

Recommendations for Research and Practice

These findings are important for funding agencies, exercise scientists, kinesiologists, and rehabilitation professionals who are extending the pandemic-driven growth of telerehab programs for people with disabilities and point to several recommendations. First, an assessment of people's home and community environment before exercise initiation may be essential for program adherence and success. Discussion with a behavioral coach about safe locations to perform both aerobic and resistance exercises is a core element of the GEMS-T protocol. For exercise interventions without individualized coaching, providing tips and strategies for overcoming commonly encountered barriers to exercising at home or in the community would be helpful.

Second, rehabilitation, exercise science, and kinesiology providers serving people with disabilities and other immunocompromised populations should address COVID-19-specific concerns about exercising. The science of COVID-19 transmission has advanced since these interviews were completed, and except for the most crowded outdoor situations, exercising outside is a low-risk activity for COVID-19 transmission [36,37]. However, exercise guidelines should be updated to include guidance for vulnerable populations on safely exercising indoors, which, as this study shows, is a preference for many participants.

Finally, telerehab programs may wish to consider creating web-based support communities where participants can interact to increase exercise motivation and accountability and decrease isolation and loneliness.

Limitations

Initially, the GEMS-S participants were informed that they would receive no remote coaching to maintain the integrity of the trial and intervention, and they were encouraged to exercise at home using the provided exercise equipment and study materials. After 3 weeks, the trial co-investigators determined that research participants would be best served by altering the intervention to provide the GEMS-S participants with coaching support remotely to more accurately reflect the original GEMS-S condition. It is impossible to know whether this 3-week gap contributed to the differences in findings between the GEMS-S and GEMS-T groups.

This study used a small convenience sample of 8 participants from the southeast United States and is not representative of the experience of all people in the STEP for MS trial. Therefore, readers should be cautious in extrapolating the findings to all people with MS. The small sample may also obscure other factors that contribute to the differences in experience between the 2 arms of the study, including sociodemographics and geographic and community location. In addition, our sample consisted of only women. Although MS does affect women more than men, gender may influence exercise behaviors during lockdown restrictions.

Additional data may have strengthened our analysis, including data on depression levels, comorbidities, and whether these factors accounted for any exercise differences between the groups. We also did not capture data on the levels of exercise outside the scope of the intervention protocol, although some participants referred to exercising beyond the requirements of the protocol.

The study design randomized participants to 2 groups: either automatic assignment to GEMS-S or GEMS-T or to a group that could choose the study arm. This interview study was unable to detect whether choice had any impact on the experience of the participants during lockdown restrictions. However, the GEMS-S and GEMS-T participants reflected both choice and assigned conditions (Table 1), and the condition did not appear to have had an impact on the exercise experience during lockdown. The STEP for MS trial data analysis will provide insights into the role of choice in exercise outcomes.

Conclusions

Our findings suggest that lockdown restrictions impacted exercise among people with MS enrolled in a large trial depending on the exercise condition, namely facility based or home based. Although we still do not know the outcome of the larger trial, these findings suggest that the telerehab delivery mode was beneficial to people with MS during lockdown restrictions who continued to exercise uninterrupted. Moreover, people in the GEMS-T study arm reported that the exercise intervention benefited them both mentally and physically. We also learned that social support comes in different forms (coaching vs peers), and this should be explored further and perhaps incorporated into future exercise options. As the United States moves to a new pandemic phase in which federal guidelines endorse shorter isolation time frames and less rigorous masking and social distancing [38], people with MS may still fear resuming prepandemic activities and remain isolated. The boom in telerehab platforms for the remote delivery of exercise interventions has the potential to overcome the barriers to traditional, facility-based exercise options if these platforms incorporate best practice recommendations. Considering a future in which COVID-19 is endemic, rehabilitation professionals should incorporate guidelines for people with suppressed immune systems into exercise protocols to address pandemic-related safety concerns.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide.
[DOCX File , 16 KB - rehab_v9i4e42157_app1.docx]

References

1.   WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020. World Health Organization. 2020 Mar 11. URL: https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020 [accessed 2022-10-17]

2.   Haug N, Geyrhofer L, Londei A, Dervic E, Desvars-Larrive A, Loreto V, et al. Ranking the effectiveness of worldwide COVID-19 government interventions. Nat Hum Behav 2020 Dec;4(12):1303-1312. [doi: 10.1038/s41562-020-01009-0] [Medline: 33199859]

3.   Motolese F, Rossi M, Albergo G, Stelitano D, Villanova M, Di Lazzaro V, et al. The psychological impact of COVID-19 pandemic on people with multiple sclerosis. Front Neurol 2020 Oct 30;11:580507 [FREE Full text] [doi: 10.3389/fneur.2020.580507] [Medline: 33193033]

4.   Strober L, Weber E, Lequerica A, Chiaravalloti N. Surviving a global pandemic: the experience of depression, anxiety, and loneliness among individuals with multiple sclerosis. Mult Scler Relat Disord 2022 Feb;58:103497 [FREE Full text] [doi: 10.1016/j.msard.2022.103497] [Medline: 35066271]

5. Colais P, Cascini S, Balducci M, Agabiti N, Davoli M, Fusco D, et al. Impact of the COVID-19 pandemic on access to healthcare services amongst patients with multiple sclerosis in the Lazio region, Italy. Eur J Neurol 2021 Oct;28(10):3403-3410 [FREE Full text] [doi: 10.1111/ene.14879] [Medline: 33896086]

6. Manacorda T, Bandiera P, Terzuoli F, Ponzio M, Brichetto G, Zaratin P, et al. Impact of the COVID-19 pandemic on persons with multiple sclerosis: early findings from a survey on disruptions in care and self-reported outcomes. J Health Serv Res Policy 2021 Jul;26(3):189-197 [FREE Full text] [doi: 10.1177/1355819620975069] [Medline: 33337256]

7. Vogel AC, Schmidt H, Loud S, McBurney R, Mateen FJ. Impact of the COVID-19 pandemic on the health care of >1,000 People living with multiple sclerosis: a cross-sectional study. Mult Scler Relat Disord 2020 Nov;46:102512 [FREE Full text] [doi: 10.1016/j.msard.2020.102512] [Medline: 32977074]

8. Browne P, Chandraratna D, Angood C, Tremlett H, Baker C, Taylor BV, et al. Atlas of Multiple Sclerosis 2013: a growing global problem with widespread inequity. Neurology 2014 Sep 09;83(11):1022-1024 [FREE Full text] [doi: 10.1212/WNL.0000000000000768] [Medline: 25200713]

9. Motl RW, Pilutti LA. The benefits of exercise training in multiple sclerosis. Nat Rev Neurol 2012 Sep;8(9):487-497. [doi: 10.1038/nrneurol.2012.136] [Medline: 22825702]

10. Motl RW, Sandroff BM, Kwakkel G, Dalgas U, Feinstein A, Heesen C, et al. Exercise in patients with multiple sclerosis. Lancet Neurol 2017 Oct;16(10):848-856. [doi: 10.1016/S1474-4422(17)30281-8] [Medline: 28920890]

11. Kinnett-Hopkins D, Adamson B, Rougeau K, Motl RW. People with MS are less physically active than healthy controls but as active as those with other chronic diseases: an updated meta-analysis. Mult Scler Relat Disord 2017 Apr;13:38-43. [doi: 10.1016/j.msard.2017.01.016] [Medline: 28427699]

12. Backus D. Increasing physical activity and participation in people with multiple sclerosis: a review. Arch Phys Med Rehabil 2016 Sep;97(9 Suppl):S210-S217. [doi: 10.1016/j.apmr.2015.09.027] [Medline: 27211007]

13. Adamson BC, Learmonth YC, Kinnett-Hopkins D, Bohri M, Motl RW. Feasibility study design and methods for project GEMS: guidelines for exercise in multiple sclerosis. Contemp Clin Trials 2016 Mar;47:32-39. [doi: 10.1016/j.cct.2015.12.002] [Medline: 26655434]

14. Learmonth YC, Adamson BC, Kinnett-Hopkins D, Bohri M, Motl RW. Results of a feasibility randomised controlled study of the guidelines for exercise in multiple sclerosis project. Contemp Clin Trials 2017 Mar;54:84-97. [doi: 10.1016/j.cct.2016.11.012] [Medline: 27916699]

15. Kalron A, Dolev M, Greenberg-Abrahami M, Menascu S, Frid L, Avrech-Shezifi S, et al. Physical activity behavior in people with multiple sclerosis during the COVID-19 pandemic in Israel: results of an online survey. Mult Scler Relat Disord 2021 Jan;47:102603 [FREE Full text] [doi: 10.1016/j.msard.2020.102603] [Medline: 33246261]

16. Koopmans A, Pelletier C. Physical activity experiences of people with multiple sclerosis during the COVID-19 pandemic. Disabilities 2022 Jan 10;2(1):41-55 [FREE Full text] [doi: 10.3390/disabilities2010004]

17. Marck CH, Hunter A, Heritage B, Gibbs L, Kermode AG, Walker DI, et al. The effect of the Australian bushfires and the COVID-19 pandemic on health behaviours in people with multiple sclerosis. Mult Scler Relat Disord 2021 Aug;53:103042 [FREE Full text] [doi: 10.1016/j.msard.2021.103042] [Medline: 34091177]

18. Moumdjian L, Smedal T, Arntzen EC, van der Linden ML, Learmonth Y, Pedullà L, et al. Impact of the COVID-19 pandemic on physical activity and associated technology use in persons with multiple sclerosis: an international RIMS-SIG Mobility survey study. Arch Phys Med Rehabil 2022 Oct;103(10):2009-2015 [FREE Full text] [doi: 10.1016/j.apmr.2022.06.001] [Medline: 35760106]

19. Motl RW, Backus D, Neal WN, Cutter G, Palmer L, McBurney R, et al. Rationale and design of the STEP for MS Trial: comparative effectiveness of supervised versus telerehabilitation exercise programs for multiple sclerosis. Contemp Clin Trials 2019 Jun;81:110-122. [doi: 10.1016/j.cct.2019.04.013] [Medline: 31022481]

20. Moreland A, Herlihy C, Tynan MA, Sunshine G, McCord RF, Hilton C, CDC Public Health Law Program, CDC COVID-19 Response Team, Mitigation Policy Analysis Unit. Timing of state and territorial COVID-19 stay-at-home orders and changes in population movement - United States, March 1-May 31, 2020. MMWR Morb Mortal Wkly Rep 2020 Sep 04;69(35):1198-1203 [FREE Full text] [doi: 10.15585/mmwr.mm6935a2] [Medline: 32881851]

21. Burr V. Social Constructionism. 3rd edition. London, UK: Routledge; 2015.

22. Papathomas A. Narrative inquiry: from cardinal to marginal . . . and back? In: Smith B, Sparkes AC, editors. Routledge Handbook of Qualitative Research in Sport and Exercise. London, UK: Routledge; 2016.

23. Sparkes AC, Smith B. Qualitative Research Methods in Sport, Exercise and Health: From Process to Product. London, UK: Routledge; 2013.

24. Burke S. Rethinking 'validity' and 'trustworthiness' in qualitative inquiry: how might we judge the quality of qualitative research in sport and exercise sciences? In: Smith B, Sparkes AC, editors. Routledge Handbook of Qualitative Research in Sport and Exercise. London, UK: Routledge; 2016.

25. Robinson OC. Sampling in interview-based qualitative research: a theoretical and practical guide. Qual Res Psychol 2014;11(1):25-41 [FREE Full text] [doi: 10.1080/14780887.2013.801543]

26. Malterud K, Siersma VD, Guassora AD. Sample size in qualitative interview studies: guided by information power. Qual Health Res 2016 Nov;26(13):1753-1760. [doi: 10.1177/1049732315617444] [Medline: 26613970]

XSL•FO

RenderX

27. Sandelowski M. Sample size in qualitative research. Res Nurs Health 1995 Apr;18(2):179-183. [doi: 10.1002/nur.4770180211] [Medline: 7899572]

28. Neal WN, Richardson E, Motl RW. "How come you sent me the Canadian one?" Application and uptake of the Canadian physical activity guidelines for adults with multiple sclerosis in the United States. Adapt Phys Activ Q 2021 Jul 01;38(3):413-434. [doi: 10.1123/apaq.2020-0136] [Medline: 33837163]

29. Saarijärvi M, Bratt EL. When face-to-face interviews are not possible: tips and tricks for video, telephone, online chat, and email interviews in qualitative research. Eur J Cardiovasc Nurs 2021 May 22;20(4):392-396 [FREE Full text] [doi: 10.1093/eurjcn/zvab038] [Medline: 33893797]

30. Braun V, Clarke V. Reflecting on reflexive thematic analysis. Qual Res Sport Exerc Health 2019 Jun 13;11(4):589-597 [FREE Full text] [doi: 10.1080/2159676X.2019.1628806]

31. Smith B, Caddick N. Qualitative methods in sport: a concise overview for guiding social scientific sport research. Asia Pac J Sport Soc Sci 2012 Apr;1(1):60-73 [FREE Full text] [doi: 10.1080/21640599.2012.701373]

32. Anderson ES, Wojcik JR, Winett RA, Williams DM. Social-cognitive determinants of physical activity: the influence of social support, self-efficacy, outcome expectations, and self-regulation among participants in a church-based health promotion study. Health Psychol 2006 Jul;25(4):510-520. [doi: 10.1037/0278-6133.25.4.510] [Medline: 16846326]

33. Bandura A. Social Learning Theory. Englewood Cliffs, NJ, USA: Prentice Hall; 1977.

34. Bandura A. Health promotion by social cognitive means. Health Educ Behav 2004 Apr;31(2):143-164. [doi: 10.1177/1090198104263660] [Medline: 15090118]

35. Bauman AE, Reis RS, Sallis JF, Wells JC, Loos RJ, Martin BW, Lancet Physical Activity Series Working Group. Correlates of physical activity: why are some people physically active and others not? Lancet 2012 Jul 21;380(9838):258-271. [doi: 10.1016/S0140-6736(12)60735-1] [Medline: 22818938]

36. Goulart CD, Silva RN, Oliveira MR, Guizilini S, Rocco IS, Mendez VM, et al. Lifestyle and rehabilitation during the COVID-19 pandemic: guidance for health professionals and support for exercise and rehabilitation programs. Expert Rev Anti Infect Ther 2021 Nov;19(11):1385-1396. [doi: 10.1080/14787210.2021.1917994] [Medline: 33852807]

37. Shurlock J, Muniz-Pardos B, Tucker R, Bachl N, Papadopoulou T, Holloway G, et al. Recommendations for face coverings while exercising during the COVID-19 pandemic. Sports Med Open 2021 Mar 15;7(1):19 [FREE Full text] [doi: 10.1186/s40798-021-00309-7] [Medline: 33721127]

38. CDC Updates and Shortens Recommended Isolation and Quarantine Period for General Population. Centers for Disease Control and Prevention. 2021. URL: https://www.cdc.gov/media/releases/2021/s1227-isolation-quarantine-guidance.html [accessed 2022-10-17]

Abbreviations

GEMS: Guidelines for Exercise in People With Multiple Sclerosis
GEMS-S: Guidelines for Exercise in People With Multiple Sclerosis-Supervised
GEMS-T: Guidelines for Exercise in People With Multiple Sclerosis-Telerehabilitation
MS: multiple sclerosis
PA: physical activity
QOL: quality of life
RTA: reflexive thematic analysis
SCT: social cognitive theory
STEP for MS: Supervised Versus Telerehabilitation Exercise Program for Multiple Sclerosis
telerehab: telerehabilitation
UAB: University of Alabama at Birmingham

Original Paper

A Telerehabilitation Program for Maintaining Functional Capacity in Patients With Chronic Lung Diseases During a Period of COVID-19 Social Isolation: Quasi-Experimental Retrospective Study

Aline Paula Miozzo[1*], PhD; Natiele Camponogara Righi[1*], MSc; Maria Luiza Yumi Shizukuishi[1*], BSc, PT; Hérica Marques Ferreira Aguilar[1*], BSc, PT; Juliessa Florian[2*], PhD; Scheila da Costa Machado[2*], BSc, PT; Jociane Schardong[2*], PhD; Rodrigo Della Méa Plentz[1*], PhD

[1]Physiotherapy Department, Universidade Federal de Ciências da Saúde de Porto Alegre, Porto Alegre, Brazil

[2]Physiotherapy Department, Irmandade Santa Casa de Misericórdia de Porto Alegre, Porto Alegre, Brazil

[*]all authors contributed equally

Corresponding Author:
Rodrigo Della Méa Plentz, PhD
Physiotherapy Department
Universidade Federal de Ciências da Saúde de Porto Alegre
Rua Sarmento Leite, 245
Porto Alegre, 90050-170
Brazil
Phone: 55 51991131651
Email: rodrigop@ufcspa.edu.br

Abstract

Background: Pulmonary diseases represent a great cause of disability and mortality in the world, and given the progression of these pathologies, pulmonary rehabilitation programs have proven to be effective for people with chronic respiratory diseases. During the COVID-19 pandemic, telerehabilitation has become an alternative for patients with such diseases.

Objective: The aim of this study was to compare the outcomes (ie, functional capacity and quality of life) of telerehabilitation to those of usual care among patients who previously participated in face-to-face pulmonary rehabilitation programs.

Methods: We conducted a quasi-experimental retrospective study from April 2020 to August 2021. A total of 32 patients with chronic lung diseases were included and divided into the control and intervention groups. The intervention group performed telerehabilitation synchronously twice per week and was supervised by a physical therapist during breathing, strengthening, and aerobic exercises. Changes in the degree of dyspnea and leg discomfort were assessed based on changes in Borg scale scores. The control group did not perform any activities during the period of social isolation. Functional capacity was assessed with the 6-minute walk test, and quality of life was assessed with the Medical Outcomes Study 36-item Short Form Health Survey.

Results: The telerehabilitation group's mean 6-minute walk distance decreased by 39 m, while that of the control group decreased by 120 m. There was a difference of 81 m between the groups' mean 6-minute walk distances (P=.02). In relation to the quality of life, telerehabilitation was shown to improve the following two domains: social functioning and mental health.

Conclusions: Telerehabilitation programs for patients with chronic lung diseases can ease the deleterious effects of disease progression, be used to maintain functional capacity, and improve aspects of quality of life.

KEYWORDS

XSL•FO
RenderX

Introduction

In 2019, the whole world was impacted by the onset of a new disease—COVID-19. SARS-CoV-2 infection, in the most severe cases, leads to acute respiratory syndrome. Further, it has reached high incidence rates and is associated with mortality, resulting in a pandemic state [1]. The impact of the disease has exceeded expectations with regard to mortality, complications, and hospital costs, leading to significant socioeconomic, political, and psychosocial impacts. Many services that were considered nonessential had their activities stopped, and people were encouraged to seek alternatives to maintain their routines within their own homes or seek other options so that patients with pre-existing diseases could continue to be assisted, thereby avoiding detriments to physical well-being and lung capacity and reducing hospital admissions and mortality rates [2].

Lung diseases, such as the more prevalent chronic obstructive pulmonary disease (COPD) and interstitial lung disease, represent a great worldwide cause of disability and mortality with a growing burden [3-5]. These progressive pathologies can cause dyspnea; fatigue; and reductions in physical activity, exercise tolerance, muscle strength, and health-related quality of life (HRQOL) [6-8]. These may result in immobility, dependency on help from others, and social isolation [4,7].

In this context, given the progression of these pathologies, pulmonary rehabilitation programs (PRPs) are interventions that have proven to be effective for people with chronic respiratory diseases [8-10]. Among the main benefits of PRPs, the improvements in exercise capacity, HRQOL, and survival; the reductions in the intensity of dyspnea, the number of hospitalizations, and the length of hospital stays; and decreased anxiety and depression can be highlighted [11].

Such benefits persist for 8 to 12 weeks among patients with chronic respiratory diseases who participate in face-to-face PRPs [12]. However, over the past 2 years, billions of people have continued to maintain social distancing as a measure for containing the spread of SARS-CoV-2 infection. Social isolation leads to loneliness and chronic boredom, which can have negative effects on the physical and mental well-being of patients with chronic respiratory diseases [2]. Thus, telerehabilitation may offer an alternative for ensuring patients' participation in PRPs [12]. The term *telerehabilitation* has been used to describe the delivery of rehabilitation by using telecommunication technology [13].

Recent studies show that telerehabilitation for patients with chronic lung diseases, when compared to face-to-face PRPs, allows for the maintenance of important outcomes, such as functional capacity, which is assessed with the 6-minute walk test (6MWT) [8,14-17]. Furthermore, it is safe [8,18], with no increase in the rate of adverse events [12], and it has good patient compliance [14]. Telerehabilitation has also been able to reduce disease exacerbations as well as the mean number and duration of hospitalizations [16,19]. However, there are still no studies on conducting telerehabilitation with these patients during the COVID-19 pandemic.

Since 2010, the World Health Organization has encouraged the use of telemedicine to maximize health services while respecting cultural, demographic, and gender differences [20]. In the field of physiotherapy, World Physiotherapy and the International Network of Physical Therapy Regulatory Authorities (INPTRA) have highlighted that the use of modern technologies and practices through digital means creates an excellent opportunity for physiotherapists to engage with broad audiences to improve effects and impacts, resulting in the provision of services, resources, and information in an easier and faster way [21]. However, in Brazil, the law that defends the use of telemedicine was enacted [22] only because of the pandemic, and the Federal Council of Physiotherapy regulated the permission of non–face-to-face services in 2020. The teleconsultation and telemonitoring modalities have thus become recent practices in physiotherapy [23]. Therefore, the aim of this study was to evaluate and compare the effects of telerehabilitation and usual care on the functional capacity and quality of life of patients with chronic lung diseases who were previous participants of face-to-face PRPs, in the context of the social isolation imposed by the COVID-19 pandemic.

Methods

This quasi-experimental retrospective study was carried out at the Pulmonary Rehabilitation Service of the Pavilhão Pereira Filho at Irmandade da Santa Casa de Misericórdia de Porto Alegre (ISCMPA), through the institutional portal and on site, from April 2020 to August 2021.

Ethics Approval

This study was approved by the Ethics Committees in Human Research of ISCMPA and was registered under approval number 04453412.7.0000.5335. All participants signed the informed consent form.

Study Sample

The telerehabilitation program was structured based on the need to retain the content of its face-to-face form as much as possible during social isolation. The sample was for convenience and included patients who were enrolled in and were undergoing pulmonary rehabilitation at the Pulmonary Rehabilitation Service of the Pavilhão Pereira Filho at ISCMPA before the period of social isolation. Patients were recruited from July 2020 to July 2021. The inclusion criteria were patients diagnosed with COPD, interstitial lung disease, bronchiectasis, or pulmonary emphysema; patients of both sexes; patients aged between 18 and 80 years; and patients on optimized drug therapy. The exclusion criteria were patients who were discontinued from the program; patients undergoing lung transplantation; patients who were hospitalized, resulting in the interruption of the home program; and failure to sign the informed consent form. A total of 32 patients were included—14 in the control group and 18 in the telerehabilitation group.

The physical training component of the face-to-face PRP was administered by 2 physical therapists, with sessions conducted 3 times per week. During this physical training, patients performed breathing exercises (respiratory cycle) as a warm-up, followed by arm and leg exercises for muscle strengthening,

XSL•FO

RenderX

which involved an initial load of 30% of the 1-repetition maximum testing load and 1 set of 10 repetitions per exercise. Aerobic exercises were also performed on a treadmill, beginning at 70% of the patients' speed on the 6MWT, with progression. During the PRP, all patients received continuous oxygen therapy in accordance with their medical prescriptions, and they were constantly monitored via pulse oximetry to maintain an oxygen saturation of ≥92%. The modified Borg scale was used for measuring the degree of dyspnea and leg discomfort [24]. This scale is graded from 0 to 10, where 0 indicates no feeling of shortness of breath or discomfort, and 10 indicates the maximum feeling of shortness of breath or discomfort. The Borg scale seems to be an affordable, practical, and valid tool for monitoring and prescribing exercise intensity, independent of sex, age, exercise modality, and physical activity level [25,26]. Assessments of functional capacity and quality of life were collected every 36 sessions [24].

In March 2020, the face-to-face form of the program had to be closed due to the social isolation measures that were implemented to combat the advance of COVID-19. All patients were invited to follow up remotely, and those who accepted the invitation entered the telerehabilitation program.

Telerehabilitation Program

Educational materials containing photos and explanations for performing exercises at home were made available at the beginning of social isolation, and phone calls were also made once per week. Subsequently, the institution developed a connection portal via the institutional website, so that the consultations could take place remotely, and physical therapists, residents, and physical therapy interns began to monitor 26 patients via the internet. The telerehabilitation group held 2 synchronous sessions per week and was monitored by physiotherapists through the institutional portal. These physiotherapists also provided guidance on how to perform the exercises once per day every day. Patients performed breathing exercises (deep inspiration and expiration with a labial fret) during sessions, and resistance exercises for the upper and lower limbs, metabolic exercises, and aerobic exercises (ie, walking, treadmill exercises, or ergometric bicycle exercises) were performed according to patients' availability. Patients were encouraged to buy weights for performing strength exercises, and if this was not possible, the rehabilitation service made the materials available by loaning them to patients. Additionally, pulse oximeters were used to monitor the patients during the exercises. Patients were monitored for heart rate and peripheral oxygen saturation by using a pulse oximeter, and the modified Borg scale was used for measuring the degree of dyspnea and leg discomfort [25,26]. This scale was used due to the familiarity that patients had with its use during the face-to-face PRP. Patients in the control group did not perform any activities during the period of social isolation and therefore did not participate in this phase of the research.

In July 2021, the transition from face-to-face rehabilitation to its hybrid form took place, in which the patients performed a face-to-face session every other week, intercalating with a web-based session. Functional capacity and quality of life

assessments were performed at the times when patients returned to the face-to-face portions of the PRP.

Outcomes

Functional capacity was the primary outcome and was assessed through the 6MWT, in accordance with the recommendations of the American Thoracic Society [27]. The patients made their way through a 30-m corridor (delimited by cones) for 6 minutes, and they were encouraged by the evaluator every minute. Data on heart rate, blood pressure, and effort perception (based on the Borg scale) were obtained before and after the test. In order to evaluate the impact on quality of life and health maintenance, the patients were invited to fill out a questionnaire. The Medical Outcomes Study 36-item Short Form Health Survey (SF-36) [28] was used to evaluate HRQOL. Through this questionnaire, the following eight domains of HRQOL were assessed: physical functioning, physical role, physical pain, general health, vitality, social functioning, emotional role, and mental health [28].

The last assessment in the face-to-face form of the PRP was considered the initial assessment for this study. The final assessment was performed when patients in both groups returned to the face-to-face portion of the PRP. In addition, data, such as the need for continuous oxygen use only during exercise, were collected.

Statistical Analysis

For the data analysis, SPSS software version 23.0 (IBM Corp) was used. Data normality was verified by using the Kolmogorov-Smirnov test. Continuous data were presented as means and SDs, and categorical data were described as frequencies and percentages. Comparisons were performed by using a t test or Mann-Whitney test. The adopted significance level was 5%.

Results

A total of 32 patients were included in the sample—14 in the control group and 18 in the telerehabilitation group. Of note, 63% (20/32) of participants were female, and the control group was older and had higher BMIs when compared to the telerehabilitation group. With regard to lung function, the groups were homogeneous, and the most prevalent pathologies were pulmonary fibrosis, pulmonary emphysema, and COPD. A patient flowchart is shown in Figure 1, and clinical characteristics are presented in Table 1.

In relation to the main outcome, prior to the pandemic, the control group walked more than the telerehabilitation group in the 6MWT (mean 465, SD 84 m vs mean 388, SD 121 m). After about 1.5 years of isolation, the control group walked a mean of 344 (SD 92) m, and the telerehabilitation group walked a mean of 348 (SD 146) m. It can be noted that the control group's mean 6-minute walk distance (6MWD) decreased by 120 m, which represents 4 fewer laps in the 6MWT, and the telerehabilitation group's mean 6MWD decreased by only 39 m, which represents 1 fewer lap in the test. There was a difference of 81 m between the groups' mean 6MWDs (P=.02; Figure 2).

As for HRQOL, of the 8 SF-36 domains, 6 did not show a significant difference in results (physical functioning: P=.95; physical role: P=.13; physical pain: P=.24; general health: P=.92; vitality: P=.34; emotional role: P=.76). However, for important outcomes, such as social functioning and mental health, telerehabilitation showed a beneficial effect (P=.03 and P=.02, respectively; Table 2).

The loss of functional capacity among patients with chronic lung diseases due to the pause in rehabilitation activities imposed by COVID-19 social isolation was also observed through a

qualitative analysis of data regarding the use of continuous oxygen only during exercise. Of the 18 patients in the telerehabilitation group, only 8 used continuous oxygen to perform the exercises, and after the isolation period, all patients needed continuous oxygen for these activities. In the control group, before isolation, no patients used continuous oxygen to perform the exercises, and after the isolation period, 7 patients started to use it. That is, there was about a 50% increase in the need to use continuous oxygen to perform exercises after the period of social isolation in both groups.

Figure 1. Patient flowchart.
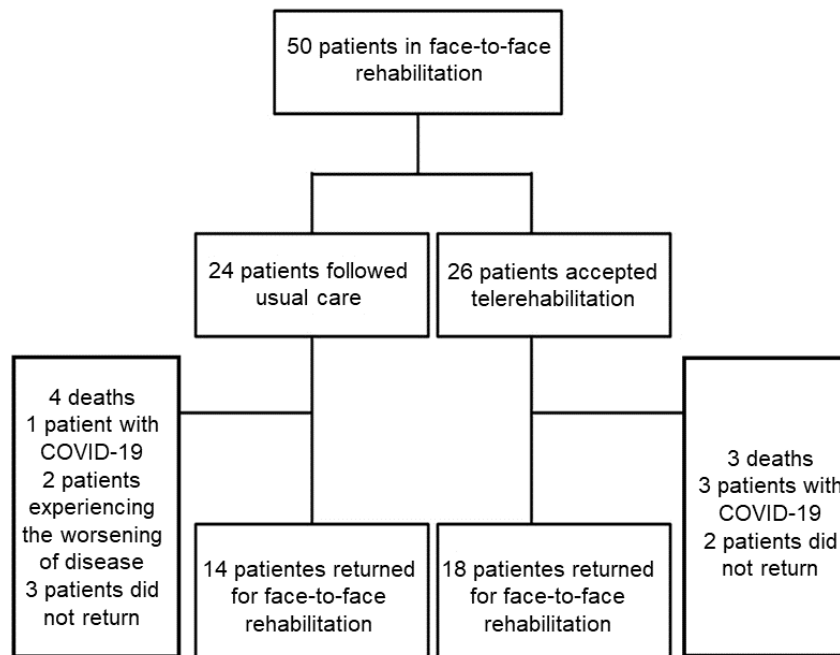
Table 1. Clinical characteristics.

Characteristics	Control group (n=14)	Telerehabilitation group (n=18)	P value[a]
Sex (male), n	4	8	N/A[b]
Age (years), mean (SD)	73.4 (7.4)	54.5 (8.7)	<.001
BMI (kg/m^2), mean (SD)	28 (3.9)	23.9 (3.6)	.004
Pulmonary function (control group: n=12; telerehabilitation group: n=17), mean (SD)			
FEV1[c] (L)	1.2 (0.5)	1.1 (0.7)	.25
FVC[d] (L)	2.1 (0.5)	1.7 (0.7)	.09
FEV1 to FVC ratio	54.9 (16.6)	57.5 (21.1)	.73
Baseline disease, n (%)			
Pulmonary fibrosis	2 (14)	5 (28)	N/A
Bronchiectasis	3 (21)	2 (11)	N/A
Pulmonary emphysema	2 (14)	4 (22)	N/A
Chronic obstructive pulmonary disease	7 (50)	6 (33)	N/A
Pulmonary arterial hypertension	0 (0)	1 (6)	N/A
Comorbidities, n (%)			
Systemic arterial hypertension	6 (43)	5 (28)	N/A
Atrial fibrillation	1 (7)	1 (6)	N/A
Diabetes	3 (21)	2 (11)	N/A
Dyslipidemia	2 (14)	0 (0)	N/A
Osteoporosis	1 (7)	1 (6)	N/A
Depression	1 (7)	1 (6)	N/A
Fibromyalgia	2 (14)	0 (0)	N/A
Hypothyroidism	2 (14)	2 (11)	N/A
Pulmonary arterial hypertension	0 (0)	2 (11)	N/A
Stroke	0 (0)	1 (6)	N/A

[a]Derived from a *t* test or Mann-Whitney test.

[b]N/A: not applicable.

[c]FEV1: forced expired volume in the first second.

[d]FVC: forced vital capacity.

Figure 2. Participants' 6-minute walk test distances. *P=.02.
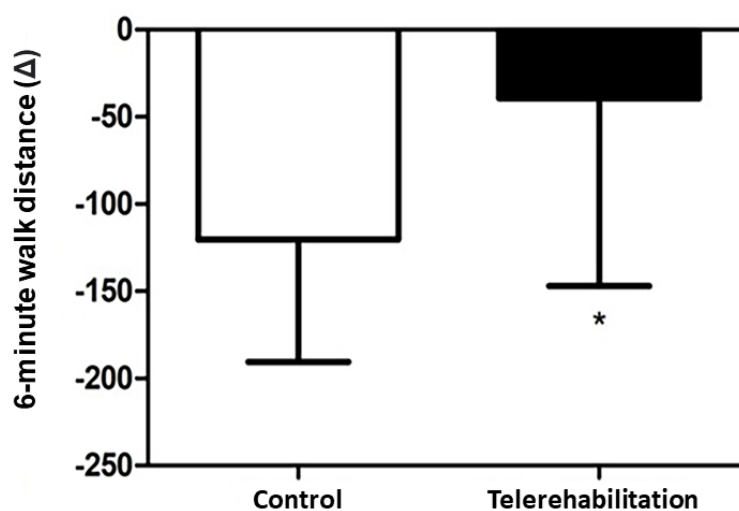
Table 2. Quality of life.

SF-36[a] domains	Control group scores			Telerehabilitation group scores			*P* value[b]
	Before isolation, mean (SD)	After isolation, mean (SD)	Mean Δ	Before isolation, mean (SD)	After isolation, mean (SD)	Mean Δ	
Physical functioning	38 (26)	32 (28)	−6	20 (18)	15 (16)	−5	.95
Physical role	45 (48)	32 (36)	−13	25 (36)	28 (35)	3	.13
Physical pain	53 (17)	50 (20)	−4	46 (12)	49 (13)	3	.24
General health	49 (22)	44 (23)	−5	38 (24)	33 (22)	−5	.92
Vitality	56 (23)	45 (17)	−10	49 (17)	44 (15)	−6	.34
Social functioning	73 (30)	62 (27)	−12	57 (27)	74 (21)	17	.03[c]
Emotional role	62 (43)	55 (43)	−7	63 (46)	63 (46)	0	.76
Mental health	75 (18)	64 (20)	−11	72 (14)	74 (14)	2	.02[c]

[a]SF-36: 36-item Short Form Health Survey.

[b]Derived from a *t* test or Mann-Whitney test.

[c]Significant at the *P*<.05 level.

Discussion

Principal Findings

This study proposed to measure the effects of a telerehabilitation program in patients with chronic lung diseases and compare these effects to those of usual care after PRP interruption due to the social isolation imposed by COVID-19. The main findings of this study were the maintenance of functional capacity through telerehabilitation and the improvement in quality of life domains, such as social functioning and mental health. Furthermore, there was an increase in the need to use continuous oxygen during exercise in 44% (8/18) and 50% (7/14) of patients in the telerehabilitation and control groups, respectively.

As chronic lung diseases advance, exertional breathlessness is triggered by simple activities of daily life and is the strongest determinant of functional capacity and HRQOL [13,14]. The importance of showing positive results in the 6MWT is associated with the fact that, in patients with chronic lung diseases, a lower 6MWD is strongly and independently associated with an increased mortality rate and is a better predictor of death at 6 months than forced vital capacity [29-31]. Our study revealed that telerehabilitation resulted in the maintenance of the 6MWDs obtained in the 6MWT, while the control group's 6MWDs decreased by 4 laps in this test.

Other recent studies that compared telerehabilitation to usual care also found this same maintenance of functional capacity in patients with COPD [16] and in patients with idiopathic pulmonary fibrosis (IPF) [14]. As in our study, Cerdán-de-Las-Heras et al [14] also found a significant reduction in the distances covered in the 6MWT by the control group. When compared to face-to-face rehabilitation, this same maintenance was found in patients with COPD [17,18,32].

In addition to this important benefit, some studies have shown that telerehabilitation can be as effective as face-to-face rehabilitation in reducing the number of exacerbations in patients with chronic lung diseases, as well as reducing the mean duration and number of hospitalizations [16,19]. Telerehabilitation has been shown to be safe and well tolerated among patients with chronic lung diseases, in addition to not being related to an increase in the rate of adverse events [8,12,14,18] and being greatly cost-effective [33].

An important finding of our study is the improvement of the social functioning and mental health components of the SF-36. Corroborating our study, Galdiz et al [15] also found differences in the mental health component when comparing telerehabilitation with face-to-face rehabilitation. Magaluti et al [12] also showed positive results for HRQOL. Cerdán-de-Las-Heras et al [14], on the other hand, did not demonstrate differences in the HRQOL of patients with IPF when comparing telerehabilitation with usual care [14].

It is important to highlight that social isolation leads to loneliness and boredom [2], which result in a reduction in physical activity levels and the worsening of health and general condition [34]. In addition, because of the social isolation imposed by the COVID-19 pandemic, there has been a worsening in life habits, such as increases in the consumption of alcohol and other substances, which directly correlate with mental health factors [35]. Mental health and general well-being have been severely affected by COVID-19 [36]. In March 2020, 25% of the Canadian population reported poor to regular mental health, whereas only 8% reported this degree of mental health in 2018 [37]. Similar results were found in other countries, such as the United Kingdom, Italy, and Spain [38]. In China, half of the adult population experienced symptoms of anxiety and depression [39]. Thus, there is a need for programs that intervene in the quality of life and are related to the mental health and well-being of the population. These programs can be delivered primarily through telecommunication during periods of isolation, such as those that are imposed due to health reasons [40].

Given the abovementioned issues, it is understood that chronic lung diseases result in the progression of a cycle of physical inactivity, low exercise tolerance, increased dyspnea, and the worsening of HRQOL [14]. Additionally, social isolation

increases loneliness and contributes to these adverse effects [2], which can explain the increased need for continuous oxygen use during exercise that was found in our study. With regard to the supply of oxygen in patients with chronic lung diseases, a study showed that providing oxygen through a cylinder for home use for 15 days to patients with IPF showed positive 6MWT results regarding the sensation of shortness of breath and the ability to walk [41]. Further, in a review by Bell et al [42], when exercises were performed with an oxygen supply, the groups showed improvements in the physical functioning, social functioning, mental health, and general health domains of the SF-36.

Telerehabilitation is already well documented in the literature. It is an effective, safe practice; promotes the maintenance and improvement of functional capacity and quality of life; and is cost-effective [8,14-19,33]. This practice is already recommended by several institutions, such as the World Health Organization, World Physiotherapy, and the INPTRA, but each country has its legal issues, depending on the profession [20,21]. For physical therapy, our data are important, given that organizations that carry out programs remotely can reach a greater number of patients with the most diverse comorbidities, even those who have difficulties with accessing such programs due to demographic, cultural, or financial reasons. As such, remote programs are an excellent opportunity for physical therapists to engage with broad audiences to improve effects

and impacts, resulting in the provision of services, resources, and information in an easier and faster way [21].

Our study has several limitations. One of the main limitations is the heterogeneity of the sample. We observed that the control group was older and had higher BMIs than those of the telerehabilitation group. However, we also observed that, in relation to lung function, the groups were similar. The low number of participants and the study design, as it was not possible to conduct a randomized clinical trial due to the urgency of reorganizing the rehabilitation service in view of the advance of the COVID-19 pandemic, are also limitations. It is understood that practices may differ across regions and health care providers; hence, a multicenter, prospective randomized study is needed to understand the role of web-based telerehabilitation in a range of clinical settings. Further research is required to determine optimal exercise training modalities and identify strategies for maximizing the long-term benefits in patients with chronic lung diseases.

Conclusion

This study shows that conducting a telerehabilitation program for patients with chronic lung diseases can ease the deleterious effects of disease progression. Our results indicate that telerehabilitation can be used as a strategy for maintaining functional capacity and improving aspects of quality of life in patients with chronic lung diseases.

Conflicts of Interest

None declared.

References

1. Madjid M, Safavi-Naeini P, Solomon SD, Vardeny O. Potential effects of coronaviruses on the cardiovascular system: A review. JAMA Cardiol 2020 Jul 01;5(7):831-840. [doi: 10.1001/jamacardio.2020.1286] [Medline: 32219363]
2. Banerjee D, Rai M. Social isolation in Covid-19: The impact of loneliness. Int J Soc Psychiatry 2020 Sep;66(6):525-527 [FREE Full text] [doi: 10.1177/0020764020922269] [Medline: 32349580]
3. Khakban A, Sin DD, FitzGerald JM, McManus BM, Ng R, Hollander Z, et al. The projected epidemic of chronic obstructive pulmonary disease hospitalizations over the next 15 years. A population-based perspective. Am J Respir Crit Care Med 2017 Feb 01;195(3):287-291. [doi: 10.1164/rccm.201606-1162PP] [Medline: 27626508]
4. Raghu G, Richeldi L. Current approaches to the management of idiopathic pulmonary fibrosis. Respir Med 2017 Aug;129:24-30 [FREE Full text] [doi: 10.1016/j.rmed.2017.05.017] [Medline: 28732832]
5. Maher TM, Bendstrup E, Dron L, Langley J, Smith G, Khalid JM, et al. Global incidence and prevalence of idiopathic pulmonary fibrosis. Respir Res 2021 Jul 07;22(1):197 [FREE Full text] [doi: 10.1186/s12931-021-01791-z] [Medline: 34233665]
6. Dowman LM, McDonald CF, Hill CJ, Lee AL, Barker K, Boote C, et al. The evidence of benefits of exercise training in interstitial lung disease: a randomised controlled trial. Thorax 2017 Jul;72(7):610-619. [doi: 10.1136/thoraxjnl-2016-208638] [Medline: 28213592]
7. van Manen MJG, Geelhoed JJM, Tak NC, Wijsenbeek MS. Optimizing quality of life in patients with idiopathic pulmonary fibrosis. Ther Adv Respir Dis 2017 Mar;11(3):157-169 [FREE Full text] [doi: 10.1177/1753465816686743] [Medline: 28134007]
8. Cox NS, Dal Corso S, Hansen H, McDonald CF, Hill CJ, Zanaboni P, et al. Telerehabilitation for chronic respiratory disease. Cochrane Database Syst Rev 2021 Jan 29;1(1):CD013040 [FREE Full text] [doi: 10.1002/14651858.CD013040.pub2] [Medline: 33511633]
9. Donaldson GC, Wilkinson TMA, Hurst JR, Perera WR, Wedzicha JA. Exacerbations and time spent outdoors in chronic obstructive pulmonary disease. Am J Respir Crit Care Med 2005 Mar 01;171(5):446-452. [doi: 10.1164/rccm.200408-1054OC] [Medline: 15579723]

10.   Pitta F, Troosters T, Spruit MA, Probst VS, Decramer M, Gosselink R. Characteristics of physical activities in daily life in chronic obstructive pulmonary disease. Am J Respir Crit Care Med 2005 May 01;171(9):972-977. [doi: 10.1164/rccm.200407-855OC] [Medline: 15665324]

11.   Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2019 report. Global Initiative for Chronic Obstructive Lung Disease. 2019. URL: https://goldcopd.org/wp-content/uploads/2018/11/GOLD-2019-v1.7-FINAL-14Nov2018-WMS.pdf [accessed 2022-12-06]

12.   Malaguti C, Dal Corso S, Janjua S, Holland AE. Supervised maintenance programmes following pulmonary rehabilitation compared to usual care for chronic obstructive pulmonary disease. Cochrane Database Syst Rev 2021 Aug 17;8(8):CD013569 [FREE Full text] [doi: 10.1002/14651858.CD013569.pub2] [Medline: 34404111]

13.   Bonnevie T, Smondack P, Elkins M, Gouel B, Medrinal C, Combret Y, et al. Advanced telehealth technology improves home-based exercise therapy for people with stable chronic obstructive pulmonary disease: a systematic review. J Physiother 2021 Jan;67(1):27-40 [FREE Full text] [doi: 10.1016/j.jphys.2020.12.006] [Medline: 33358547]

14.   Cerdán-de-Las-Heras J, Balbino F, Løkke A, Catalán-Matamoros D, Hilberg O, Bendstrup E. Tele-rehabilitation program in idiopathic pulmonary fibrosis-A single-center randomized trial. Int J Environ Res Public Health 2021 Sep 23;18(19):10016 [FREE Full text] [doi: 10.3390/ijerph181910016] [Medline: 34639313]

15.   Galdiz JB, Gómez A, Rodriguez D, Guell R, Cebollero P, Hueto J, et al. Telerehabilitation programme as a maintenance strategy for COPD patients: A 12-month randomized clinical trial. Arch Bronconeumol (Engl Ed) 2021 Mar;57(3):195-204. [doi: 10.1016/j.arbres.2020.03.034] [Medline: 32439253]

16.   Bernocchi P, Vitacca M, La Rovere MT, Volterrani M, Galli T, Baratti D, et al. Home-based telerehabilitation in older patients with chronic obstructive pulmonary disease and heart failure: a randomised controlled trial. Age Ageing 2018 Jan 01;47(1):82-88. [doi: 10.1093/ageing/afx146] [Medline: 28985325]

17.   Hansen H, Bieler T, Beyer N, Kallemose T, Wilcke JT, Østergaard LM, et al. Supervised pulmonary tele-rehabilitation versus pulmonary rehabilitation in severe COPD: a randomised multicentre trial. Thorax 2020 May;75(5):413-421 [FREE Full text] [doi: 10.1136/thoraxjnl-2019-214246] [Medline: 32229541]

18.   Bourne S, DeVos R, North M, Chauhan A, Green B, Brown T, et al. Online versus face-to-face pulmonary rehabilitation for patients with chronic obstructive pulmonary disease: randomised controlled trial. BMJ Open 2017 Jul 17;7(7):e014580 [FREE Full text] [doi: 10.1136/bmjopen-2016-014580] [Medline: 28716786]

19.   Vasilopoulou M, Papaioannou AI, Kaltsakas G, Louvaris Z, Chynkiamis N, Spetsioti S, et al. Home-based maintenance tele-rehabilitation reduces the risk for acute exacerbations of COPD, hospitalisations and emergency department visits. Eur Respir J 2017 May 25;49(5):1602129 [FREE Full text] [doi: 10.1183/13993003.02129-2016] [Medline: 28546268]

20.   WHO Global Observatory for eHealth. Telemedicine: Opportunities and developments in Member States: Report on the second global survey on eHealth. World Health Organization. 2010. URL: https://apps.who.int/iris/bitstream/handle/10665/44497/9789241564144_eng.pdf?sequence=1&isAllowed=y [accessed 2022-12-06]

21.   World Physiotherapy, International Network of Physical Therapy Regulatory Authorities. Report of the World Physiotherapy/INPTRA digital physical therapy practice task force. World Physiotherapy. 2019. URL: https://world.physio/sites/default/files/2021-06/digital-practice-report-2021-FINAL.pdf [accessed 2022-12-06]

22.   Presidência da República, Secretaria-Geral, Subchefia para Assuntos Jurídicos. Lei Nº 13.989, de 15 de Abril de 2020. Presidência da República. 2020. URL: http://www.planalto.gov.br/ccivil_03/_ato2019-2022/2020/lei/L13989.htm [accessed 2022-12-06]

23.   Cepeda RM. Resolução Nº 516, de 20 de Março de 2020 – Teleconsulta, Telemonitoramento e Teleconsultoria. Conselho Federal de Fisioterapia e Terapia Ocupacional. 2020. URL: https://www.coffito.gov.br/nsite/?p=15825 [accessed 2022-12-06]

24.   Florian J, Watte G, Teixeira PJZ, Altmayer S, Schio SM, Sanchez LB, et al. Pulmonary rehabilitation improves survival in patients with idiopathic pulmonary fibrosis undergoing lung transplantation. Sci Rep 2019 Jun 27;9(1):9347 [FREE Full text] [doi: 10.1038/s41598-019-45828-2] [Medline: 31249363]

25.   Ries AL. Minimally clinically important difference for the UCSD Shortness of Breath Questionnaire, Borg Scale, and Visual Analog Scale. COPD 2005 Mar;2(1):105-110. [doi: 10.1081/copd-200050655] [Medline: 17136970]

26.   Scherr J, Wolfarth B, Christle JW, Pressler A, Wagenpfeil S, Halle M. Associations between Borg's rating of perceived exertion and physiological measures of exercise intensity. Eur J Appl Physiol 2013 Jan;113(1):147-155. [doi: 10.1007/s00421-012-2421-x] [Medline: 22615009]

27.   ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. ATS statement: guidelines for the six-minute walk test. Am J Respir Crit Care Med 2002 Jul 01;166(1):111-117. [doi: 10.1164/ajrccm.166.1.at1102] [Medline: 12091180]

28.   Campolina AG, Ciconelli RM. [SF-36 and the development of new assessment tools for quality of life]. Acta Reumatol Port 2008;33(2):127-133 [FREE Full text] [Medline: 18604180]

29.   du Bois RM, Albera C, Bradford WZ, Costabel U, Leff JA, Noble PW, et al. 6-Minute walk distance is an independent predictor of mortality in patients with idiopathic pulmonary fibrosis. Eur Respir J 2014 May;43(5):1421-1429 [FREE Full text] [doi: 10.1183/09031936.00131813] [Medline: 24311766]

30. Lederer DJ, Arcasoy SM, Wilt JS, D'Ovidio F, Sonett JR, Kawut SM. Six-minute-walk distance predicts waiting list survival in idiopathic pulmonary fibrosis. Am J Respir Crit Care Med 2006 Sep 15;174(6):659-664 [FREE Full text] [doi: 10.1164/rccm.200604-520OC] [Medline: 16778159]

31. Wise RA, Brown CD. Minimal clinically important differences in the six-minute walk test and the incremental shuttle walking test. COPD 2005 Mar;2(1):125-129. [doi: 10.1081/copd-200050527] [Medline: 17136972]

32. Godtfredsen N, Frølich A, Bieler T, Beyer N, Kallemose T, Wilcke T, et al. 12-months follow-up of pulmonary tele-rehabilitation versus standard pulmonary rehabilitation: A multicentre randomised clinical trial in patients with severe COPD. Respir Med 2020 Oct;172:106129 [FREE Full text] [doi: 10.1016/j.rmed.2020.106129] [Medline: 32905893]

33. Liu S, Zhao Q, Li W, Zhao X, Li K. The cost-effectiveness of pulmonary rehabilitation for COPD in different settings: A systematic review. Appl Health Econ Health Policy 2021 May;19(3):313-324. [doi: 10.1007/s40258-020-00613-5] [Medline: 33079374]

34. Roschel H, Artioli GG, Gualano B. Risk of increased physical inactivity during COVID-19 outbreak in older people: A call for actions. J Am Geriatr Soc 2020 Jun;68(6):1126-1128. [doi: 10.1111/jgs.16550] [Medline: 32392620]

35. Roberts A, Rogers J, Mason R, Siriwardena AN, Hogue T, Whitley GA, et al. Alcohol and other substance use during the COVID-19 pandemic: A systematic review. Drug Alcohol Depend 2021 Dec 01;229(Pt A):109150 [FREE Full text] [doi: 10.1016/j.drugalcdep.2021.109150] [Medline: 34749198]

36. United Nations. Policy brief: COVID-19 and the need for action on mental health. United Nations Sustainable Development Group. 2020 May 13. URL: https://unsdg.un.org/sites/default/files/2020-05/UN-Policy-Brief-COVID-19-and-mental-health.pdf [accessed 2022-12-06]

37. Canadians' mental health during the COVID-19 pandemic. Statistics Canada. 2020. URL: https://www150.statcan.gc.ca/n1/daily-quotidien/200527/dq200527b-eng.htm [accessed 2022-12-06]

38. Codagnone C, Bogliacino F, Gómez C, Folkvord F, Liva G, Charris R, et al. Restarting "Normal" life after Covid-19 and the lockdown: Evidence from Spain, the United Kingdom, and Italy. Soc Indic Res 2021;158(1):241-265 [FREE Full text] [doi: 10.1007/s11205-021-02697-5] [Medline: 33994649]

39. Xiang YT, Yang Y, Li W, Zhang L, Zhang Q, Cheung T, et al. Timely mental health care for the 2019 novel coronavirus outbreak is urgently needed. Lancet Psychiatry 2020 Mar;7(3):228-229 [FREE Full text] [doi: 10.1016/S2215-0366(20)30046-8] [Medline: 32032543]

40. Bentlage E, Ammar A, How D, Ahmed M, Trabelsi K, Chtourou H, et al. Practical recommendations for maintaining active lifestyle during the COVID-19 pandemic: A systematic literature review. Int J Environ Res Public Health 2020 Aug 28;17(17):6265 [FREE Full text] [doi: 10.3390/ijerph17176265] [Medline: 32872154]

41. Visca D, Mori L, Tsipouri V, Fleming S, Firouzi A, Bonini M, et al. Effect of ambulatory oxygen on quality of life for patients with fibrotic lung disease (AmbOx): a prospective, open-label, mixed-method, crossover randomised controlled trial. Lancet Respir Med 2018 Oct;6(10):759-770 [FREE Full text] [doi: 10.1016/S2213-2600(18)30289-3] [Medline: 30170904]

42. Bell EC, Cox NS, Goh N, Glaspole I, Westall GP, Watson A, et al. Oxygen therapy for interstitial lung disease: a systematic review. Eur Respir Rev 2017 Jan 21;26(143):160080 [FREE Full text] [doi: 10.1183/16000617.0080-2016] [Medline: 28223395]

Abbreviations

6MWD: 6-minute walk distance
6MWT: 6-minute walk test
COPD: chronic obstructive pulmonary disease
HRQOL: health-related quality of life
INPTRA: International Network of Physical Therapy Regulatory Authorities
IPF: idiopathic pulmonary fibrosis
ISCMPA: Irmandade da Santa Casa de Misericórdia de Porto Alegre
PRP: pulmonary rehabilitation program
SF-36: 36-item Short Form Health Survey

Original Paper

Self-Monitoring Physical Activity, Diet, and Weight Among Adults Who Are Legally Blind: Exploratory Investigation

Kamilla Miller[1], MS; Gerald J Jerome[1], PhD

Department of Kinesiology, Towson University, Towson, MD, United States

Corresponding Author:
Gerald J Jerome, PhD
Department of Kinesiology
Towson University
8000 York Road
Towson, MD, 21252
United States
Phone: 1 4107045283
Email: gjerome@towson.edu

Abstract

Background: Obesity is a global pandemic. Lifestyle approaches have been shown effective for weight loss and weight loss maintenance. Central to these evidence-based approaches are increased physical activity, decreased caloric intake, regular self-weighing, and the tracking of these behaviors.

Objective: This exploratory descriptive study surveyed adults who are legally blind to identify strategies related to tracking physical activity, diet, and weight. These health behaviors are essential components to evidence-based weight loss programs. We also identified areas where we can better support adults who are legally blind in their independent efforts to change these behaviors and improve their health.

Methods: Participants (≥18 years of age) who self-identified as being legally blind were recruited using email announcements in low vision advocacy groups. They completed an interviewer-administered survey on the telephone and an in-person visit for standardized assessment of height and weight.

Results: The participants (N=18) had an average age of 31.2 (SD 13.4) years; 50% (9/18) had normal weight (BMI 18.5 to <25); 44% (8/18) were female; 44% (8/18) were Black; and 39% (7/18) were Non-Hispanic White. Most participants (16/18, 89%) used their smartphone to access the internet daily, and 67% (12/18) had at least 150 mins of exercise per week. Although 78% (14/18) of the participants indicated tracking their weight, only 61% (11/18) could indicate how they tracked their weight, and 22% (4/18) indicated they tracked it mentally. Providing individuals with a talking scale was the most consistent recommendation (12/18, 67%) to facilitate independence in managing weight through lifestyle changes. Even though 50% (9/18) of the participants indicated using an app or electronic notes to track some portion of their diet, participants reported challenges with determining portion size and corresponding calorie counts. Most participants (17/18, 94%) reported using apps, electronic notes, smartphones, or wearable devices to track their physical activity. Although strategies such as using wearables and smartphones could provide measurements (eg, step counts) as well as recording data, they also pose financial and technology literacy barriers.

Conclusions: Technology-based solutions were identified for tracking weight, diet, and physical activity for weight management. These strategies have financial and technology literacy barriers. A range of strategies for adopting and tracking health behaviors will be needed to assist individuals with varying skills and life experiences.

KEYWORDS

XSL•FO
RenderX

Introduction

Obesity is a significant public health concern [1,2]. Adults with low vision are 1.5 times more likely to be obese compared to the general population [3,4]. Although there is robust data on the effectiveness of a lifestyle approch to weight management [5], those with vision impairments may have been excluded from weight loss trials due to inaccessible enrollment processes or study materials. The extent to which adults with low vision have been excluded is likely in proportion to their degree of vision impairment and the level of accommodation that is needed. Some individuals with low vision may need basic accommodations, such as larger print or the use of a magnifier. Those with greater vision impairment, who use a screen reader, would need accessible documents and web-based forms. Accessibility has been defined as providing equivalent user experience for those with a disability [6]. In this case, accessible documents refer to documents formatted to provide an equivalent experience when reading or using a screen reader. Providing an accessible enrollment experience would require the development of enrollment processes and study materials to ensure documents and web-based interfaces are accessible. Although studies often indicate their materials were culturally appropriate, it is less clear if the materials were accessible to those with a disability, especially those who are legally blind. In addition, few, if any, weight loss studies have focused on adults with low vision or provided this group with tailored approaches to help them monitor, track, and problem solve challenges related to health behavior change for weight loss [7]. As such, there has been scant attention paid to tailoring strategies to help adults with low vision achieve and maintain a healthy weight.

Lifestyle approaches to weight management include recommendations of increased exercise, caloric restriction, self-weighing, and tracking these health behaviors [8]. Self-monitoring, or being aware of these health behaviors, is important for lifestyle-based weight management. Tracking, or recording data on these behaviors, provides individuals with additional support and opportunities. Tracking these behaviors allows for an objective evaluation of progress, which can provide encouragement. By examining the data provided from tracking, an individual can develop an understanding of the connection between these behaviors and weight change. This can inform problem-solving and assist with increased adoption of and adherence to these health behaviors.

A simple approach to tracking is to keep a record (eg, time spent exercising) on a piece of paper. Individuals who are blind could use braille notes or simple technology such as voice memos. Additional technology-based approaches include using smartphone apps to monitor and track health behaviors. For example, wearables (eg, smart watches) provide frictionless data capture to estimate physical activity, sedentary time, and sleep time. A large number of smartphone apps and technologies are designed to help individuals adopt and adhere to weight loss–related behaviors [9-11]. Unfortunately, weight loss apps do not always provide support across the full complement of evidence-based recommendations [12,13]. Moreover, the accessibility of health apps has been shown to be limited [14].

Despite a proliferation of health-related apps, it is not clear that adults who are legally blind have access to evidence-based support for weight loss.

In this exploratory descriptive study, we survey adults who are legally blind to identify strategies related to tracking physical activity, diet, and weight. We also identify areas where we can better support these adults in their independent efforts to change these behaviors and improve their health.

Methods

Recruitment

We recruited participants through email announcements for individuals who were legally blind and willing to answer questions about their diet and exercise regardless of their interest in weight management. Email announcements were posted on campus and among local low vision advocacy groups. Inclusion criteria included being ≥18 years of age, legally blind, willing to complete the surveys, and able to meet in person for height and weight assessment. Exclusion criteria included being deaf and blind or having a medical condition where caloric restriction or physical activity may be contraindicated, including but not limited to recent cardiac event, chemotherapy, and end stage renal disease. Participants who completed the telephone survey and the in-person visit for height and weight assessment were eligible to receive a US $30 gift card.

Ethics Approval

All procedures were approved by the Towson University Institutional Review Board (1807037548), and the study was conducted in accordance with the Helsinki Declaration. All participants provided informed consent.

Measures

Surveys were interviewer-administered over the telephone. Participants self-identified as legally blind. The telephone survey included items from established questionnaires. Questions to assess demographics, fruit and vegetable consumption, and technology use were from the National Cancer Institute, Health Information National Trends Survey [15]. The Godin Leisure Time Physical Activity Questionnaire was used to assess physical activity levels [16,17]. After these close-ended questionnaire items, participants were asked open-ended questions specific to this study. Study staff provided context for the open-ended questions. They explained the following:

> Studies have shown that tracking a few key behaviors is an important element in safe, effective, long-term weight management.

A definition of tracking was provided, as follows:

> [tracking is] recording a number, for example weight in pounds or minutes of activity in a day, such that you could review that number later.

Participants were then asked a series of three questions regarding past tracking, successes and barriers, and suggestions for assistance. The questions started with "Have you ever tracked your weight, and if so, how did you do it?" Participants were asked to describe any methods or techniques they had used in

the past to track their weight. Next, participants were asked to share any successes or barriers they experienced when tracking their weight. The last question in the sequence was the following:

> *If we were developing a weight management program for adults with low vision and wanted to encourage people to track their weight, what is the most important thing we could do to help?*

The sequence of three questions was repeated two more times, once focused on tracking diet or calories and once focused on tracking physical activity. After completion of the surveys, participants had a single in-person visit, where standardized procedures were used to assess height and weight in light street clothes without shoes.

Analytic Plan

Participant characteristics were summarized using descriptive statistics, including percentages, means, and standard deviations. Minutes of moderate to vigorous physical activity (MVPA) were calculated, and data were reported on the number of participants who met the national guidelines of at least 150 mins per week of MVPA [18]. An inductive coding approach was used to examine the open-ended questions [19]. For each item, an initial review of the responses was used to develop themes. A subsequent review of the items was used to determine the prevalence of the themes among the respondents. Any discrepancy in coding was resolved by discussion among the coders. Results included the prevalence of the themed items presented as a percentage of the total sample size.

Results

Participants

The participants (N=18) had an average age of 31.2 (SD 13.4) years; 44% (8/18) were female; 44% (8/18) were Black; 39% (7/18) were Non-Hispanic White; and 17% (3/18) were classified as "other race/ethnicity" to maintain confidentiality. Based on BMI classifications, 50% (9/18) had normal weight (BMI 18.5 to <25); 22% (4/18) were overweight (BMI 25 to <30); and 28% (5/18) were obese (BMI ≥30). Participants reported the consumption of fruits and vegetables as 1.0 (SD 0.8) and 1.4 (SD 1.0) servings per day, respectively, and 67% (12/18) had at least 150 mins per week of MVPA. Most participants (16/18, 89%) reported accessing the internet daily through a smartphone; the other 2 (11%) participants reported accessing the internet daily at work and occasionally through their smartphone. Most participants (14/18, 78%) reported use of a smartphone or tablet to track progress of a health-related goal.

Tracking, Barriers, and Related Suggestions

More than half of the participants (14/18, 78%) reported tracking their weight; however, only 61% (11/18) could indicate specifically how they tracked it, with 11% (2/18) indicating an electronic note, 22% (4/18) indicating a smartphone or an app, and 22% (4/18) indicating "mentally." One participant indicated their weight was tracked at the doctors. When asked about successes and barriers, the only barrier noted was not having

an accessible scale, as identified by 33% (6/18) of the participants. When asked what would be most helpful to adults with low vision who wanted to track their weight, 67% (12/18) indicated an accessible scale, and 22% (4/18) indicated information and education. Two participants indicated they were not sure of the best way to track their weight to easily review changes across time.

More than half of the participants (14/18, 78%) reported tracking their diet, with 17% (3/18) using some type of electronic note, 33% (6/18) using a smartphone or an app, and 28% (5/18) tracking "mentally." When asked about successes and barriers to tracking calories, 28% (5/18) indicated difficulty with seeing calorie counts, another 17% (3/18) indicated difficulty measuring, and another 22% (4/18) indicated that it was simply hard. Two participants listed meal prepping as a success but did not track calories related to these meals. When asked what would be helpful for adults with low vision who want to track dietary information (eg, calories), 33% (6/18) indicated accessible technology to determine nutritional information, and 56% (10/18) indicated basic information, education, and instruction to learn about nutrition and calories.

Most participants (17/18, 94%) reported tracking their physical activity, with 44% (8/18) using a smartphone or an app, 22% (4/18) using a wearable device, 22% (4/18) tracking "mentally," and 1 (6%) using electronic notes. When asked about successes and barriers to tracking physical activity, those using wearable devices also listed the devices as successes. Among the barriers noted were not having enough time (5/18, 28%), cost (3/18, 17%), lack of a workout partner (3/18, 17%), and not having a place or blind friendly place to work out (3/18, 17%). When asked about how best to help people track their physical activity, 50% (9/18) recommended providing apps or wearables; 33% (6/18) suggested providing more fundamental support, such as information on how to exercise; and 56% (10/18) suggested providing a coach or exercise partner.

Discussion

Principal Findings

Although 78% (14/18) of participants indicated they tracked their weight, less than half used a method where they recorded a number that could be referenced later for personal use. For example, 22% (4/18) reported tracking their weight mentally. The strategy of using an app or electronic notes, which were the most common methods of tracking, has a financial barrier and requires technology literacy. Although the participants reported viable solutions for tracking weight, careful consideration is needed for the wide scale adoption of these options. An additional consideration is the need for a talking scale in order to obtain a weight. Participants indicated tracking of diet or caloric information was possible yet challenging. Participants were tracking aspects of diet using smartphones or apps as well as using electronic notes. However, gaining information about serving size and related calorie information was reported as a barrier. Participants were able to track physical activity through smartphones and apps. This has the advantage of frictionless data capture such as the phone automatically counting steps. However, this technology-based approach has

the same financial and technology literacy barriers as noted previously. Overall, the identified technology-based solutions have limitations for adoption but appear aligned with evidence-based strategies of tracking weight, diet, and physical activity for weight management [8]. It should be noted there is significant heterogeneity among those who are legally blind. Some individuals may have lost their eyesight after establishing certain habits or memory of specific visual references. Others who were blind since birth may not have those visual references but could have a lifetime of skills related to independent travel, using braille, and using screen readers. As such, a range of strategies will be needed to assist individuals with varying skills and life experiences.

Applications in Health Promotion

The most frequent and enthusiastic suggestion from participants was to provide talking scales. Over half of the participants indicated this was an important support component to a weight loss program for adults with low vision. This simple tool can raise daily awareness and empower independence in regular weight monitoring. This appears to be one of the most practical, fundamental, and easily addressed strategies. Providing scales to study participants is common in weight loss trials [20], and providing accessible scales should become standard to ensure all participants have equivalent support in weight loss programs. Over 20% of the participants indicated they mentally tracked weight, exercise, or diet. However, tracking should occur with documentation (eg, using electronic notes or apps) to avoid recall bias and allow for accurate review of data. It also allows data to be shared with a health care provider, wellness coach, or support group.

Although many consider health apps as a scalable approach for weight management, these apps may not provide a comprehensive approach to lifestyle-based weight loss [12,13]. There are additional problems with considering this approach for those who are legally blind. One problem is that some features, such as weight graphs, may not be accessible to those with vision loss [14]. Moreover, there are reported problems using voice control with popular health apps [14]. As noted earlier, the method of tracking should facilitate the examination of trends over time and allow for sharing of data with a wellness coach. Weight graphs are highly effective tools that quickly convey trends across time but do not assist those who are blind. Determining equivalent ways to share weight data is a challenging issue. In fact, developing equivalent data visualization experiences for those with vision impairments is a broad-based concern that extends beyond the current application [21]. Greater attention is needed to develop weight loss apps and programs that provide a full complement of evidence-based features that can be accessed by those with low vision. It is important that those with a disability, in this case individuals who are legally blind, have equivalent experiences with wellness programs compared to those without a disability.

Accessibility of nutrition information appeared to be a significant barrier to tracking diet. In addition, participants wanted help with identifying and preparing healthy foods that are aligned with specific diet goals as well as reading nutrition labels and selecting healthy foods in the supermarket. This is

not directly related to tracking but is a barrier that needs to be addressed when promoting healthy weight among those with vision impairments. Problem-solving efforts for these barriers require additional steps based on an individual's visual acuity and technological savvy. One participant wanted to gain weight and reported challenges reading labels for both nutrition and calories. It is not clear how many individuals with low vision may have the goal of gaining weight, but it deserves further consideration. This could be relevant to older adults who are the fastest growing demographic with respect to low vision [22] and have health concerns related to inadequate nutrition [23].

Some participants reported financial barriers associated with going to the gym, although it was not clear if the burden was associated with transportation or gym membership. Participants also indicated the need for basic information, workout partners, and accessible instruction on different exercise options. This was aligned with previous reports of barriers to physical activity for adults who are blind [24]. One participant indicated they did not always feel that fitness facilities were blind-friendly. The latter deserves further exploration because the Americans with Disabilities Act clearly addresses elements of a facility's physical layout, but it does not address cultural changes to support diversity among gym members [25]. Creating a more inclusive environment may require partnering with fitness facilities in educating fitness staff [26].

Strengths and Limitations

The modest sample size is a limitation of the study but is appropriate for an exploratory study. Some of the participants were technologically savvy, physically active, and conscientious of eating fruits and vegetables. This is both a strength and a limitation. The technologically savvy, health-conscious component of the sample is a strength, as these individuals were able to identify successful strategies, often technology-based, that they used in adopting healthy behaviors. These technologically savvy, health-conscious individuals are also a limitation of the study, as the percentage of these individuals in the current convenience sample are not necessarily representative of adults who are legally blind. Indeed, the percentages reported in this paper should not be considered representative of the population, and they have likely underestimated the amount of technology assistance that might be needed and overestimated the amount of tracking that is occurring. The focus of the paper was not to establish prevalence of activities but rather explore approaches that adults who are legally blind could use to track weight management–related behaviors.

Future Directions

As noted earlier, part of this sample was technologically savvy and active in pursuing healthy lifestyle habits. It was clear from this select group that adults with low vision can be creative, resourceful, and proactive in addressing lifestyle-based health behaviors. Results from this study should inform further efforts to develop tailored, evidence-based weight loss program for those with low vision. This would include ensuring that features in wellness programs and apps are accessible to those with low vision and provide the ability to examine data for trends across time as well as share data with health care providers, wellness

coaches, or rehabilitation specialists. Weight loss programs and smartphone apps should provide adults who are legally blind with an equivalent user experience compared to those who do not have vision impairments.

Data Availability

Participants granted permission for data to be reported in the aggregate by the study team. None of the participants granted permission for data sharing.

Conflicts of Interest

None declared.

References

1. Cawley J, Biener A, Meyerhoefer C, Ding Y, Zvenyach T, Smolarz BG, et al. Direct medical costs of obesity in the United States and the most populous states. J Manag Care Spec Pharm 2021 Mar;27(3):354-366. [doi: 10.18553/jmcp.2021.20410] [Medline: 33470881]
2. Liu B, Du Y, Wu Y, Snetselaar LG, Wallace RB, Bao W. Trends in obesity and adiposity measures by race or ethnicity among adults in the United States 2011-18: population based study. BMJ 2021 Mar 16;372:n365 [FREE Full text] [doi: 10.1136/bmj.n365] [Medline: 33727242]
3. Holbrook EA, Caputo JL, Perry TL, Fuller DK, Morgan DW. Physical activity, body composition, and perceived quality of life of adults with visual impairments. JVIB 2019 Jan 07;103(1):17-29. [doi: 10.1177/0145482x0910300104]
4. Weil E, Wachterman M, McCarthy EP, Davis RB, O'Day B, Iezzoni LI, et al. Obesity among adults with disabling conditions. JAMA 2002 Sep 11;288(10):1265-1268. [doi: 10.1001/jama.288.10.1265] [Medline: 12215134]
5. Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Circulation 2014 Jun 24;129(25 Suppl 2):S102-S138 [FREE Full text] [doi: 10.1161/01.cir.0000437739.71477.ee] [Medline: 24222017]
6. Accessibility fundamentals: accessibility, usability, and inclusion. Initiative WAI. URL: https://www.w3.org/WAI/fundamentals/accessibility-usability-inclusion [accessed 2022-12-05]
7. Capella-McDonnall M. The need for health promotion for adults who are visually impaired. JVIB 2019 Jan 07;101(3):133-145. [doi: 10.1177/0145482x0710100302]
8. Wadden TA, Tronieri JS, Butryn ML. Lifestyle modification approaches for the treatment of obesity in adults. Am Psychol 2020;75(2):235-251 [FREE Full text] [doi: 10.1037/amp0000517] [Medline: 32052997]
9. Bardus M, van Beurden SB, Smith JR, Abraham C. A review and content analysis of engagement, functionality, aesthetics, information quality, and change techniques in the most popular commercial apps for weight management. Int J Behav Nutr Phys Act 2016;13(1):35 [FREE Full text] [doi: 10.1186/s12966-016-0359-9] [Medline: 26964880]
10. Flores MG, Granado-Font E, Ferré-Grau C, Montaña-Carreras X. Mobile phone apps to promote weight loss and increase physical activity: a systematic review and meta-analysis. J Med Internet Res 2015;17(11):e253 [FREE Full text] [doi: 10.2196/jmir.4836] [Medline: 26554314]
11. Islam MM, Poly TN, Walther BA, Jack Li Y. Use of mobile phone app interventions to promote weight loss: meta-analysis. JMIR Mhealth Uhealth 2020 Jul 22;8(7):e17039 [FREE Full text] [doi: 10.2196/17039] [Medline: 32706724]
12. Chen J, Cade JE, Allman-Farinelli M. The most popular smartphone apps for weight loss: a quality assessment. JMIR Mhealth Uhealth 2015;3(4):e104 [FREE Full text] [doi: 10.2196/mhealth.4334] [Medline: 26678569]
13. Pagoto S, Schneider K, Jojic M, DeBiasse M, Mann D. Evidence-based strategies in weight-loss mobile apps. Am J Prev Med 2013 Nov;45(5):576-582. [doi: 10.1016/j.amepre.2013.04.025] [Medline: 24139770]
14. Radcliffe E, Lippincott B, Anderson R, Jones M. A pilot evaluation of mhealth app accessibility for three top-rated weight management apps by people with disabilities. Int J Environ Res Public Health 2021 Apr 01;18(7):3669 [FREE Full text] [doi: 10.3390/ijerph18073669] [Medline: 33915917]
15. Survey Instruments. National Cancer Institute Health Information National Trends Survey. 2018. URL: https://hints.cancer.gov/instrument.aspx [accessed 2022-12-05]
16. Amireault S, Godin G, Lacombe J, Sabiston CM. Validation of the Godin-Shephard Leisure-Time Physical Activity Questionnaire classification coding system using accelerometer assessment among breast cancer survivors. J Cancer Surviv 2015 Sep;9(3):532-540. [doi: 10.1007/s11764-015-0430-6] [Medline: 25666749]

17. Godin G, Shephard RJ. A simple method to assess exercise behavior in the community. Can J Appl Sport Sci 1985 Sep;10(3):141-146. [Medline: 4053261]

18. Piercy KL, Troiano RP, Ballard RM, Carlson SA, Fulton JE, Galuska DA, et al. The physical activity guidelines for Americans. JAMA 2018 Nov 20;320(19):2020-2028. [doi: 10.1001/jama.2018.14854] [Medline: 30418471]

19. Thomas DR. A general inductive approach for analyzing qualitative evaluation data. AJE 2016 Jun 30;27(2):237-246. [doi: 10.1177/1098214005283748]

20. Steinberg DM, Tate DF, Bennett GG, Ennett S, Samuel-Hodge C, Ward DS. The efficacy of a daily self-weighing weight loss intervention using smart scales and e-mail. Obesity (Silver Spring) 2013 Sep;21(9):1789-1797 [FREE Full text] [doi: 10.1002/oby.20396] [Medline: 23512320]

21. Marriott K, Lee B, Butler M, Cutrell E, Ellis K, Goncu C, et al. Inclusive data visualization for people with disabilities. Interactions 2021 May;28(3):47-51. [doi: 10.1145/3457875]

22. Chan T, Friedman DS, Bradley C, Massof R. Estimates of incidence and prevalence of visual impairment, low vision, and blindness in the United States. JAMA Ophthalmol 2018 Jan 01;136(1):12-19 [FREE Full text] [doi: 10.1001/jamaophthalmol.2017.4655] [Medline: 29098289]

23. Marshall TA, Stumbo PJ, Warren JJ, Xie XJ. Inadequate nutrient intakes are common and are associated with low diet variety in rural, community-dwelling elderly. J Nutr 2001 Aug;131(8):2192-2196. [doi: 10.1093/jn/131.8.2192] [Medline: 11481416]

24. Lee M, Zhu W, Ackley-Holbrook E, Brower DG, McMurray B. Calibration and validation of the Physical Activity Barrier Scale for persons who are blind or visually impaired. Disabil Health J 2014 Jul;7(3):309-317. [doi: 10.1016/j.dhjo.2014.02.004] [Medline: 24947572]

25. Americans With Disabilities Act of 1990, as Amended. URL: https://www.ada.gov/law-and-regs/ada/ [accessed 2022-11-28]

26. Rimmer JH, Riley B, Wang E, Rauworth A. Accessibility of health clubs for people with mobility disabilities and visual impairments. Am J Public Health 2005 Nov;95(11):2022-2028. [doi: 10.2105/AJPH.2004.051870] [Medline: 16254234]

Abbreviations

MVPA: moderate to vigorous physical activity

XSL•FO
RenderX

XSL•FO

RenderX