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Original Paper

The Value of a Virtual Assistant to Improve Engagement in Computerized Cognitive Training at Home: Exploratory Study

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Abstract

Background: Impaired cognitive function is observed in many pathologies, including neurodegenerative diseases such as Alzheimer disease. At present, the pharmaceutical treatments available to counter cognitive decline have only modest effects, with significant side effects. A nonpharmacological treatment that has received considerable attention is computerized cognitive training (CCT), which aims to maintain or improve cognitive functioning through repeated practice in standardized exercises. CCT allows for more regular and thorough training of cognitive functions directly at home, which represents a significant opportunity to prevent and fight cognitive decline. However, the presence of assistance during training seems to be an important parameter to improve patients' motivation and adherence to treatment. To compensate for the absence of a therapist during at-home CCT, a relevant option could be to include a virtual assistant to accompany patients throughout their training.

Objective: The objective of this exploratory study was to evaluate the interest of including a virtual assistant to accompany patients during CCT. We investigated the relationship between various individual factors (eg, age, psycho-affective functioning, personality, personal motivations, and cognitive skills) and the appreciation and usefulness of a virtual assistant during CCT. This study is part of the THERADIA (Thérapies Digitales Augmentées par l'Intelligence Artificielle) project, which aims to develop an empathetic virtual assistant.

Methods: A total of 104 participants were recruited, including 52 (50%) young adults (mean age 21.2, range 18 to 27, SD 2.9 years) and 52 (50%) older adults (mean age 67.9, range 60 to 79, SD 5.1 years). All participants were invited to the laboratory to answer several questionnaires and perform 1 CCT session, which consisted of 4 cognitive exercises supervised by a virtual assistant animated by a human pilot via the Wizard of Oz method. The participants evaluated the virtual assistant and CCT at the end of the session.

Results: Analyses were performed using the Bayesian framework. The results suggest that the virtual assistant was appreciated and perceived as useful during CCT in both age groups. However, older adults rated the assistant and CCT more positively overall than young adults. Certain characteristics of users, especially their current affective state (ie, arousal, intrinsic relevance, goal conduciveness, and anxiety state), appeared to be related to their evaluation of the session.

Conclusions: This study provides, for the first time, insight into how young and older adults perceive a virtual assistant during CCT. The results suggest that such an assistant could have a beneficial influence on users' motivation, provided that it can handle

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different situations, particularly their emotional state. The next step of our project will be to evaluate our device with patients experiencing mild cognitive impairment and to test its effectiveness in long-term cognitive training.

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KEYWORDS

cognitive training; cognitive decline; cognitive disorders; mild cognitive impairment; Alzheimer disease; digital therapies; virtual health assistant; conversational agent; artificial intelligence; social interaction; THERADIA

Introduction

Background

Impaired cognitive function is observed in many pathologies, including neurodegenerative diseases, neurodevelopmental disorders, and certain psychiatric disorders (eg, depression and schizophrenia). The most prevalent cause of cognitive decline is dementia, for which aging is the main risk factor. According to the World Health Organization [1], 55 million people are currently affected by dementia worldwide, and this number could increase to 139 million by 2050. Dementia is a chronic and progressive syndrome characterized by an impairment of cognitive functions such as memory, reasoning, language, and executive functions. At advanced stages, it severely affects autonomy and quality of life, making it a major public health concern. Alzheimer disease is the most common cause of dementia (60% to 70% of the cases), but there are other potential causes (eg, vascular, Lewy bodies, and Parkinson disease) [2].

At present, there is no effective pharmacological treatment for the symptoms of Alzheimer disease and dementia. Cholinesterase inhibitors and memantine offer only modest and short-term cognitive benefits, with substantial side effects [3-6]. Because of the controversial effectiveness of the existing pharmacological treatments, there has been a strong research interest in developing nonpharmacological treatments that are safe, noninvasive, and with few side effects. The main objective of these treatments is to preserve the quality of life and autonomy of patients for as long as possible. They encompass a wide range of techniques, such as cognitive intervention (including cognitive stimulation, cognitive training, and cognitive rehabilitation), motor rehabilitation, psychotherapy, occupational therapy, and assistive technologies [7].

A nonpharmacological treatment that has received considerable attention is computerized cognitive training (CCT), which aims to maintain or improve cognitive functioning through repeated practice in standardized exercises [8]. CCT targets one or more cognitive domains (eg, memory and attention) and adapts exercise difficulty to individual performance. These therapies have many advantages: they are safe and relatively inexpensive and allow patients to train their cognitive functions on a more regular basis by conducting sessions at home, eliminating the need to travel to the therapist's office or hospital. Regarding effectiveness, meta-analyses of randomized controlled trials reported significant but moderate effects of CCT in healthy older adults [9], in patients with Parkinson disease [10,11] and mild cognitive impairment (MCI) [8,12]. MCI refers to the transitional state between normal aging and dementia, which is characterized by a greater cognitive decline than what is considered normal for a given individual (based on age and education), but not significant enough to affect autonomy in daily life [13]. Individuals with MCI have a high probability of progressing to dementia, but this is not systematic [2,13]. Once dementia is diagnosed, CCT appears to become ineffective in countering cognitive decline [8].

There is currently no consensus on the best time to start cognitive training to prevent cognitive impairment in older individuals. The available data suggest an improvement in cognitive functioning in healthy older adults who receive cognitive training, whereas the results are more mixed in those already experiencing cognitive impairment [9,14-17]. In addition, there is still insufficient evidence to support a preventive effect of cognitive training on the onset of cognitive disorders or dementia in the long term [14,16]. It is however reasonable to hypothesize that the earlier cognitive training begins, the more beneficial the effects on cognitive functioning could be, in line with the cognitive reserve theory [18,19]. Further research is needed to test whether CCT is a promising tool for the prevention of cognitive decline in healthy older adults and an effective treatment for patients with MCI.

In general, the effectiveness of cognitive training in preserving or improving cognitive function is still debated in the literature [14,20,21]. Methodological issues (eg, unclear randomization methods and inadequate sample sizes) have often been put forward as an explanation for the moderate effects of CCT and the lack of a strong consensus across studies [7,15,21,22]. Nevertheless, other important factors related to the format of training programs and to individual differences are likely to impact CCT effectiveness. A meta-analysis in particular showed that unsupervised at-home CCT is less beneficial for cognitive function than group-based CCT [9]. The main difference is that group-based CCT involves social interactions and the presence of a therapist who ensures adherence, treatment fidelity, compliance, and computer assistance. The therapist and social dimension are absent when patients perform CCT at home, which may decrease the motivation to complete or succeed in the exercises. Motivation plays a key role in CCT success, as well as other individual factors such as preexisting ability and the need for cognition (ie, how much one enjoys cognitively challenging tasks) [23].

CCT allows for more regular and thorough training of cognitive functions directly at home, which represents a significant opportunity to fight cognitive decline. However, the design of CCT needs to be reconsidered to address parameters that may reduce therapy effectiveness. Various individual factors can represent limitations for performing CCT at home, such as personal motivations and familiarity with computers, as well as psychological factors such as anxiety level, mood, or personality. From the abovementioned evidence, the presence

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of assistance during training seems to be an important parameter to improve patients' motivation, adherence to treatment, and thus benefits on cognition. To compensate for the absence of a therapist during at-home CCT, a relevant option could be to include a virtual assistant to accompany patients throughout their training.

The addition of a virtual assistant in CCT seems to be particularly relevant for older adults with or without cognitive impairment, who are the main targets of cognitive training. To our knowledge, there are currently no published studies assessing the benefits of a virtual assistant to accompany individuals during CCT. However, outside cognitive training, some studies suggest that older adults do appreciate assistive technologies such as virtual home assistants (eg, Amazon Echo Alexa and Google Home) [24-26], conversational agents [27-29], and social robots [30] to help them with daily activities. Older adults find virtual home assistants useful for setting reminders, searching for information in real time, and entertainment [24-26,29]. They appreciate the interaction with the assistant and its companionship [26]. As for applications dedicated to care and health, the few studies available suggest a good perception by older adults of the support provided by virtual companions [27,31]. Older adults seem to prefer embodied to nonembodied virtual assistants, particularly assistants with humanoid rather than zoomorphic or machine-like features [32-34], female rather than male assistants [34,35], and assistants that are not too realistic [33]. However, it was observed that movement realism had a more positive impact on user satisfaction and interaction quality than the appearance of the assistant (eg, graphics and texture quality) [36]. A recent literature review suggested that patients with dementia enjoy interacting with embodied conversational agents, although data on this topic are still scarce [37]. Regarding social robots, there is some evidence that robot-assisted cognitive training can improve memory and executive function in older adults [38]. Social robots also have a positive influence on well-being [30]. However, such robots are currently too expensive to be implemented at home, so patients must travel to centers to benefit from their assistance during training. A virtual assistant may represent a less expensive and easier solution to implement in the patient's home.

In addition to assisting patients in their cognitive training exercises, a virtual assistant could be capable of less formal social interactions (eg, small talk) and provide cognitive stimulation. Cognitive stimulation is a type of cognitive intervention that consists of various activities aimed at enhancing an individual's overall cognitive and social functioning [7]. It has been shown to improve general cognitive functioning in patients with mild-to-moderate dementia [7]. The combination of cognitive training, cognitive stimulation, and social interactions provided by a virtual assistant could thus be beneficial for patients' motivation and long-term adherence to CCT. Moreover, some data suggest that individuals might build stronger therapeutic alliances with a conversational agent than with a human caregiver in certain contexts (eg, major depression) [39]. Many older adults with cognitive disorders are embarrassed by their condition and may be more willing to interact with a virtual, anonymous device for help or advice than with humans [40].

Finally, certain design parameters are particularly important to consider when developing an effective virtual assistant to accompany older adults, with or without cognitive impairment, during CCT at home. In addition to the appearance and animation quality discussed earlier, talking virtual assistants rather than silent ones appear to improve the engagement of older adults with low computer literacy [35], which patients with cognitive disorders are likely to be. More generally, the simultaneous presence of visual and auditory modalities when interacting with the assistant could improve the acceptance and user experience of older adults [41]. The virtual assistant must be able to provide adequate emotional support during the session, encouraging and rewarding participants for their efforts, to increase adherence [40]. In this respect, the development of an emotional artificial intelligence that would enable the assistant to detect and automatically adapt to the user's affective states would be particularly useful [42]. To provide a safe environment for patients with cognitive disorders, it is also necessary that the assistant's speech and its interactions with the user are scripted in such a way as to provide a stable and rather predictable framework [40].

Objectives

In the light of these observations, we started the THERADIA (Thérapies Digitales Augmentées par l'Intelligence Artificielle) project in 2020 [42]. This 5-year project aims to develop an empathetic virtual assistant that can accompany users during at-home CCT. The first version of our CCT software will be targeted at older adults with or without cognitive disorders, with the aim of maintaining, or even improving, cognitive functioning. To successfully complete this project, it was first necessary to better understand the factors that may contribute to the effectiveness of such a device. As discussed earlier, users' characteristics play an important role in the adherence to CCT programs. Therefore, the objective of this study was to investigate the relationship between various individual factors (eg, age, psycho-affective functioning, personality, personal motivations, and cognitive skills) and the appreciation and usefulness of a virtual assistant during CCT. To do so, young and older adults were invited to the laboratory to answer several questionnaires and perform 1 CCT session hosted by a virtual assistant, animated by a human pilot via the "Wizard of Oz" method. This exploratory study thus presents 1 stage of the development of the future virtual assistant that will be proposed by the THERADIA consortium.

Methods

Participants

Although older adults are the first target for our future cognitive training software with virtual assistance, young adults can also experience cognitive disorders in certain situations (eg, after a stroke or in certain psychiatric conditions). As computer skills may vary with age, older adults may not have the same abilities or needs as young adults when performing CCT at home. Therefore, we included both young and older adults in our study to explore age-related differences in the evaluation of our device,

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with the goal of potentially adapting it to a younger population in the future.

To determine the sample size, we relied on the available literature whose objectives were closest to our own, that is, to investigate the appreciation and preferences of older adults regarding virtual assistants in general [24,26-29,31-36]. Most of these studies used qualitative research methods (focus groups or interviews) involving small experimental groups of 5 to 24 older adults [24,26,28,29,32,34,36]. Studies using quantitative research methods included 20 to 46 older adults per experimental group, with 46 participants being more common [27,31,33,35]. On the basis of studies using quantitative research methods, more similar to our study design and analysis plan, we decided to slightly increase the number of participants usually included to 52 per age group to improve power.

Therefore, a total of 104 healthy participants were recruited between April 2021 and September 2022, including 52 (50%) young and 52 (50%) older adults. The key characteristics of the participants are summarized in Table 1. Inclusion criteria were to be aged between 18 and 30 years for young adults and >60 years for older adults. All participants were French speakers; had normal or corrected-to-normal vision and hearing; and were free from known psychiatric conditions, neurological disorders, and neurodegenerative diseases. They also had to confirm that they were not undergoing any treatment (eg, medication, therapy, or inclusion in another study) likely to affect memory or movement. Older participants presenting altered cognitive functions (a score <25 at the Mini-Mental State Examination [MMSE] [43]) were excluded from the analysis.

Table 1. Description of participants by age group (N=104).

Group	Young adults (n=52)	Older adults (n=52)
Sex, n (%)		
Female	35 (67)	40 (77)
Male	17 (33)	12 (23)
Age (y), mean (SD; range)	21.17 (2.90; 18-27)	67.92 (5.14; 60-79)
Highest diploma obtained, n (%)		
CAP[a,b]	1 (2)	6 (12)
Baccalaureate[c]	33 (63)	8 (15)
Bachelor's degree	15 (29)	16 (31)
Master's degree	3 (6)	19 (37)
PhD[d]	0 (0)	3 (6)
Occupation, n (%)		
Student	43 (83)	0 (0)
Retired	0 (0)	47 (90)
Employee	4 (8)	3 (6)
Executive or manager	2 (4)	1 (2)
Worker or laborer	1 (2)	0 (0)
Company director	0 (0)	1 (2)
Unemployed	2 (4)	0 (0)

[a]CAP: Certificat d'Aptitude Professionnelle.

[b]Equivalent to the NVQ (National Vocational Qualification) in the United Kingdom.

[c]Equivalent to A-levels in the United Kingdom and high-school diploma in the United States.

[d]PhD: Doctor of Philosophy.

The young adults were recruited on the campus of the Université Lumière Lyon 2 via mail announcements as well as diffusion on social networks such as Facebook (Meta platforms, Inc). For the older adults, 2 advertisements were published in regional newspapers: Le Progrès and Le Dauphiné Libéré. A campaign to recruit older adults was also carried out by advertising to people enrolled in a teaching program open to individuals of all ages ("University of All Ages") attached to the Université Lumière Lyon 2.

Ethical Considerations

This study was approved by the Ethics Committee of the Université Grenoble Alpes (CERGA-Avis-2021-1). All participants provided written informed consent before starting the experiment. At the end of the experiment, each participant received a €20 (US $21) gift card as a reward.

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Evaluation of Individual Characteristics

Overview

Several characteristics of the young and older participants were assessed along four dimensions: (1) psycho-affective functioning, (2) personality, (3) personal motivations, and (4) personal habits. We also assessed the cognitive functions of the older adults to ensure that they were not experiencing cognitive decline and to test the relationship between cognitive functioning and the evaluation of the virtual assistant. These dimensions of interest were selected to provide a global view of the participants' psychological and cognitive functioning, including stable parameters (eg, personality traits, motivational factors, and habits) and more fluctuating parameters (eg, current emotional state and state anxiety). Each dimension was studied using specific questionnaires in paper form, which are summarized in Table 2 and described in detail subsequently.

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Table 2. Summary of the questionnaires used to assess various psychological and cognitive characteristics of the participants by dimension and subdimensions investigated.

Dimension, subdimensions, and questionnaires	Scores calculated
Psycho-affective functioning	
Global affective experience	
Modified PANAS[a] [44]	• Positive affect score • Negative affect score
Current affective state	
Modified SAM[b] [45]	• Intrinsic relevance • Controllability • Arousal • Novelty • Goal conduciveness
BMIS[c] [46]	• Pleasant-unpleasant • Arousal-calm
Anxiety	
STAI-Y[d] (French version) [47]	• State anxiety • Trait anxiety
Personality	
Extraversion, agreeableness, conscientiousness, emotional stability, and openness	
TIPI[e] [48]	• Extraversion • Agreeableness • Conscientiousness • Emotional stability • Openness
Personal motivations	
Intrinsic motivation, extrinsic motivation, and amotivation	
GMS[f]-28 [49]	• Knowledge • Accomplishment • Stimulation • Introjected motivation • Identified motivation • External motivation • Amotivation
Personal habits and cognitive abilities	
Cognitive abilities and habits	
Cognitive abilities and habits (homemade questionnaire)	• Familiarity with computers • Familiarity with cognitive exercises • Familiarity with cognitive training • Memory difficulty • Attentional difficulty • Playing a musical instrument • Playing board games • Playing games such as chess or crossword puzzles • Sports and exercise • Meditation and relaxation
Cognitive functioning (older adults only)	
Global cognitive function	
MMSE[g] [43]	• Total score

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Dimension, subdimensions, and questionnaires	Scores calculated
Executive functions	
TMT[h] [50]	• Execution time (in seconds) • Number of errors
FAB[i] [51]	• Total score
Memory	
5WT[j] [52]	• Total score

[a]PANAS: Positive and Negative Affect Schedule.
[b]SAM: Self-Assessment Manikin.
[c]BMIS: Brief Mood Introspection Scale.
[d]STAI-Y: State-Trait Anxiety Inventory.
[e]TIPI: Ten-Item Personality Inventory.
[f]GMS: Global Motivation Scale.
[g]MMSE: Mini-Mental State Examination.
[h]TMT: Trail Making Test.
[i]FAB: Frontal Assessment Battery.
[j]5WT: 5 Words Test.

Psycho-Affective Functioning

We studied the psycho-affective functioning of the participants according to 3 aspects: general affective functioning in everyday life, affective state at the time of the session (emotions and mood), and anxiety level.

On the basis of the Positive and Negative Affect Schedule [44], we constructed a 39-item scale to measure the participants' general affective experience. The items were words describing positive and negative affects, and the participants were asked to indicate how frequently they experienced each one of these affects during the last 6 months using a 7-point scale ranging from 1 ("never") to 7 ("several times a day"). A positive affect score and a negative affect score were calculated separately.

A modified Self-Assessment Manikin [45] was used to assess the current affective state of the participants at the time of the session. They were instructed to rate their affective state toward the present situation with a 9-point scale along 5 dimensions: intrinsic relevance, controllability, arousal, novelty, and goal conduciveness. Intrinsic relevance refers to the current level of pleasure felt and was rated from 1 ("unpleasant") to 9 ("pleasant"). Controllability reflects the feeling of control over the situation, ranging from 1 ("uncontrollable") to 9 ("controlled"). Arousal refers to the physiological and psychological state of being awake and alert and was rated from 1 ("sleep") to 9 ("excitation"). As some authors have pointed out that 3 dimensions are not sufficient to capture the current affective state of individuals [53], we included 2 supplementary dimensions that are considered essential in emotional episodes according to appraisal theories of emotion [54], namely, novelty and goal conduciveness. Novelty refers to the feeling of novelty of the current situation and was rated on a scale from 1 ("predictable") to 9 ("surprising"). Goal conduciveness refers to the consistency of the situation with current achievement concerns and was rated on a scale from 1 ("obstructive") to 9 ("conducive").

The second scale used to assess the current affective state of participants was the Brief Mood Introspection Scale [46] including 16 mood adjectives. Participants were asked to rate the extent to which each adjective described their current mood on a 4-point scale ranging from XX ("definitely do not feel") to VV ("definitely feel"). A total of 2 mood scores were calculated on the following scales: pleasant-unpleasant (valence dimension) and arousal-calm (arousal dimension). For each scale, the higher the score, the more the current state of the participant tended toward the first cited component (such as "pleasant" for the pleasant-unpleasant scale).

The French version of the State-Trait Anxiety Inventory [47] was used to evaluate participants' anxiety. This questionnaire is divided into 2 subscales, one measuring the current state of anxiety (S-Anxiety) and the other measuring the anxiety trait in general (T-Anxiety). The S-Anxiety scale consists of 20 items describing current statements (eg, "I feel safe" and "I feel blue") that participants were asked to rate from 1 ("not at all") to 4 ("very much so") to indicate how they feel "right now." The T-Anxiety scale contains 20 items of statements that participants feel in general. Participants were asked to rate from 1 ("almost never") to 4 ("almost always") the extent to which each of the statements corresponded to them. Therefore, the total score from both scales varies from 20 to 80. The higher the score, the higher the level of anxiety.

Personality

The Ten-Item Personality Inventory [48] was used to measure the personality traits of the participants: extraversion, agreeableness, conscientiousness, emotional stability, and openness to experience. Participants were asked to rate how well a pair of personality traits matched them by choosing on a 7-point scale from 1 ("disagree strongly") to 7 ("agree strongly"). An average of the 2 items by dimension was calculated. The higher the score, the more the participant tended toward the dimension trait.

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Personal Motivations

The Global Motivation Scale-28 [49] was used to assess the personal motivations of our participants. It includes 28 items, each of which describes a possible reason that drives individuals to act in their lives (eg, "In general, I do things because I like making interesting discoveries"). The participants were asked to indicate the extent to which each of the statements corresponded to the reasons why they do different things in general on a 7-point scale ranging from 1 ("does not correspond accordingly") to 7 ("corresponds completely"). A total of 7 scores were calculated that reflect different motivations: intrinsic motivation (toward knowledge, accomplishment, and stimulation), extrinsic motivation (identified, introjected, and external regulation), and amotivation. The higher the score, the more the source of motivation influenced the participant's behavior.

Personal Habits and Cognitive Abilities

To measure personal habits and cognitive abilities, we created a 10-item questionnaire divided into 3 parts. In the first part, participants rated their familiarity with computers, cognitive exercises, and cognitive training from 1 ("very weak") to 5 ("very strong"). In the second part, participants rated their attentional and memory difficulty from 1 ("a lot of difficulties") to 5 ("very few difficulties"). In the last part, participants rated how often they practice different activities from 1 ("never") to 5 ("very often"): playing musical instruments, playing board games, playing chess, solving crossword puzzles, playing sports, and meditation.

Cognitive Functioning (Older Adults Only)

We used 4 questionnaires to assess cognitive functions in older adults: the MMSE [43], Trail Making Test (TMT) [50], Frontal Assessment Battery (FAB) [51], and 5 Words Test [52]. All these tests are widely used to detect cognitive decline associated with dementia syndromes.

The MMSE was administered to investigate global cognitive functioning. It consists of 30 items measuring different cognitive abilities in a few minutes (eg, attention, memory, language, and calculation) and provides a total score out of 30 that gives a global view of cognitive functioning (the higher the score, the better the cognitive abilities). A score of 23 out of 30 is the generally accepted cutoff indicating the presence of cognitive impairment.

The TMT and FAB were used to assess executive function. Successful completion of the TMT requires several cognitive skills, such as visual scanning and mental flexibility. The TMT is divided into 2 parts. In Part A, measuring the speed of processing, the participants had to connect numbers in ascending order (from 1 to 25) as quickly as possible and without error, and in Part B, measuring mental flexibility, the participants had to connect numbers and letters in alternating and increasing order (ie, 1, A, 2, B, and so on). Slower execution time and a higher number of errors, compared to the norms of the tested population, indicate a decline in executive functions.

The FAB was used to assess frontal lobe function and screen for dysexecutive disorders through 6 subtests that examine different cognitive functions: abstract reasoning, mental flexibility, motor programming, interference sensitivity, inhibitory control, and environmental autonomy. A total score <16 out of 18 indicates the possibility of an executive function disorder.

Finally, we used the 5 Words Test to examine episodic memory. This test consists of evaluating the memorization of a short list of words in 4 steps: a learning phase, an immediate free and cued recall, an interfering task, and then a delayed free and cued recall. A total score should normally equal 10.

Evaluation of the Virtual Assistant

A specific questionnaire, administered in paper form, was created for the evaluation of the virtual assistant. It contained 10 items investigating the participants' opinion on the virtual assistant and its impact on cognitive training across main dimensions: (1) overall appreciation of the assistant, (2) impact of the assistance on the comprehension of the exercises, (3) impact on motivation, and (4) personality of the assistant. Although the assistant was animated by a human pilot, an evaluation of the assistant's personality was included to explore some design features that users might be sensitive to and that might influence their motivation to interact with the assistant and complete the cognitive exercises (ie, sense of humor and familiarity). The participants responded to each item using visual analog scales ranging from 0 to 10 cm, which were then rated in millimeters to calculate 7 scores exploring the dimensions of interest (Table 3). Of the 7 scores, 3 (appreciation, comprehension, and engagement) were calculated as the mean of 2 items.

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Table 3. Synthesis of the items used and the scores calculated to evaluate the virtual assistant by dimension.

Dimensions examined, scores calculated, and items	Response (visual analog scales)
Overall appreciation of the virtual assistant	
"**Appreciation**"	
In general, did you find that the virtual assistant accompanied you well during the cognitive training session?	From "not at all" to "absolutely"
If you had to do several cognitive training sessions per week at home, would you like to be accompanied by a virtual assistant like this one?	From "not at all" to "absolutely"
Impact of virtual assistance on comprehension	
"**Comprehension**"	
Did you always understand what you were supposed to do in the exercises?	From "not at all" to "absolutely"
Were the instructions and tips given by the virtual assistant useful for you to do your exercises?	From "not at all" to "absolutely"
Impact of virtual assistance on motivation	
"**Engagement**"	
How would you rate your level of engagement in the exercises that you have done?	From "very weak" to "very strong"
Did you feel able to perform the exercises?	From "never" to "Always"
"**Desire to give up**"	
Did you ever feel like giving up the session?	From "never" to "all the time"
"**Fatigue level**"	
After this session, how would you rate your level of fatigue?	From "not at all tired" to "extremely tired"
Personality of the virtual assistant	
"**Familiarity**"	
Regarding the behavior of the virtual assistant, would you prefer it to be more or less familiar?	From "less familiar" to "more familiar"
"**Sense of humor**"	
Regarding the virtual assistant's sense of humor, would you like it to be more or less humorous?	From "less humor" to "more humor"

CCT and Wizard of Oz Method

The participants performed the CCT on a Dell (Dell Inc) computer with a diagonal monitor width of 24 inches. The CCT consisted of 4 exercises that were selected from the HappyNeuronPro cognitive training program designed by Humans Matter (Lyon, France), a company providing services for health and paramedical professionals such as speech therapists and neuropsychologists. The selected exercises engaged different cognitive functions such as memory, language, attention, and planification.

During the CCT session, the participant was guided by a virtual assistant and could interact with her. The CCT was conducted via the software developed for this purpose by the Atos company (Echirolles, France), which allowed alternating appearances of the virtual assistant and the exercises. In reality, the virtual assistant was animated by a human pilot via the so-called Wizard of Oz method, that is, the pilot was in another room, and the participant was not informed of her existence (refer to Figure 1 for pictures of the Wizard of Oz device). All sessions were led by the same pilot.

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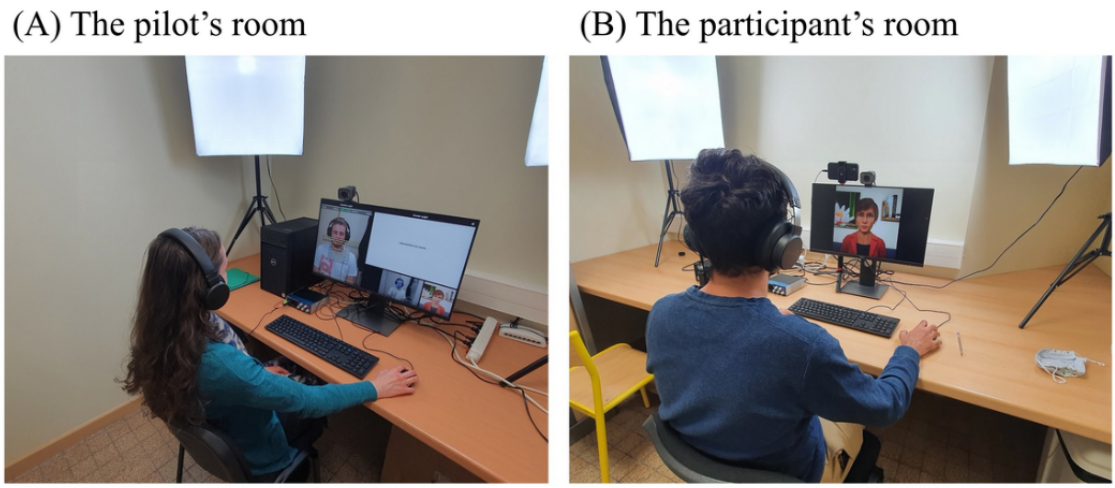
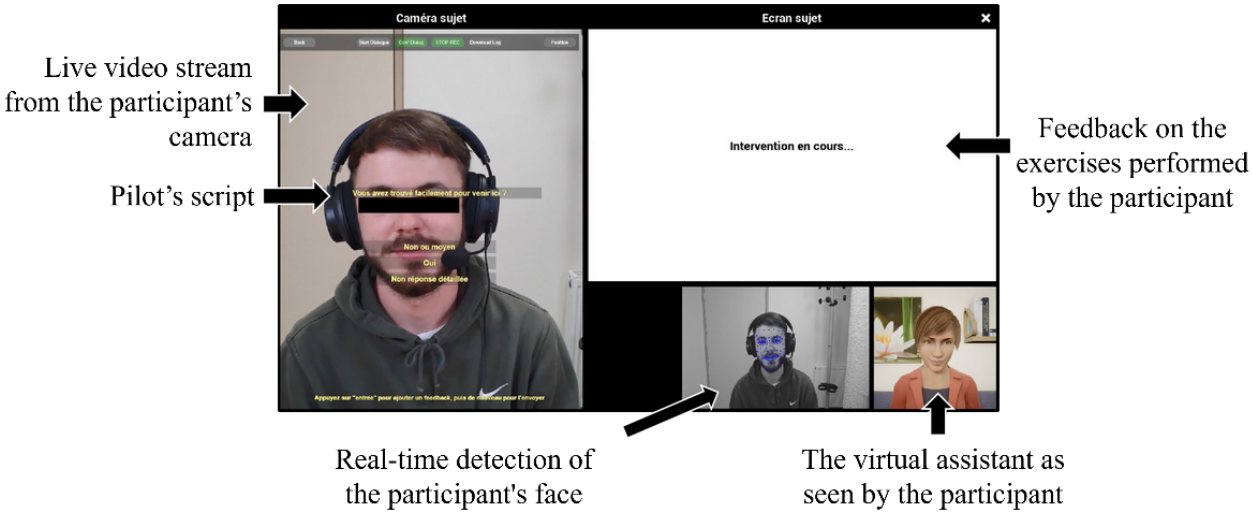
Figure 1. Wizard of Oz device.



The pilot sat in front of a Dell computer identical to that of the participant. With a high-quality camera, we used the facial motion capture solution proposed by the Dynamixyz company (Rennes, France) to drive, in real time, the head and face movements of a 3D avatar from those of the human pilot via video analysis. A humanlike appearance was chosen for the avatar, in line with the literature suggesting that older adults prefer to interact with humanoid virtual assistants [32-34] especially with feminine features [34,35]. The avatar represented a woman in her thirties, with fair skin and short brown hair, wearing a red jacket. The avatar was displayed from the front, with the head, shoulders, and upper arms visible. She appeared on a 3D background simulating the office of a health professional, similar to those of neuropsychologists or speech therapists who usually perform cognitive remediation. The image of the avatar was transmitted in real time on the participant's screen via the software developed by Atos. Conversely, a webcam also transmitted the participant's face in real time to the pilot's screen so that the pilot could follow the participant's gaze and movements during the discussions to make them more natural. The videos of the pilot and participant were recorded for later use in the development of the empathic virtual assistant proposed by the THERADIA consortium [42]. The pilot and participant communicated via headsets with integrated microphones, and no audio processing was performed to alter the pilot's voice.

The speech of the virtual assistant was scripted and appeared on the screen of the pilot, who could thus read it and scroll it (refer to Figure 2 for a detailed view of the pilot screen). The main framework of the assistant's speech was therefore identical from one participant to another; however, if necessary, the device allowed the pilot to intervene freely at any time during the session to help participants with questions or difficulties. In case of technical problems that could not be solved by the virtual assistant, the pilot informed the experimenter who could intervene.

Figure 2. The pilot's screen during a discussion between the virtual assistant and a participant (Atos software interface).



The assistant's speech was scripted to structure the session and provide the best support for the participant throughout the exercises. It was developed in line with the literature and the recommendations of experts working with older adults experiencing cognitive impairment, particularly with regard to the need for a reassuring, predictable environment and emotional support [40]. The assistant's main roles are listed in Textbox 1.

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Textbox 1. The main roles of the assistant.

Roles

- Welcome the participant
- Explain the purpose of the session and exercises
- Explain how to complete the exercises
- Help participants with technical difficulties (eg, explain how to launch or perform an exercise and re-explain if necessary)
- Provide feedback on exercise performance
- Provide advice on how to improve performance
- Provide regular emotional support (eg, encourage participants, inquire about their emotional state, and suggest breaks if necessary)
- Provide information on cognitive functions and cognitive training in general
- Create a bond with the participant to create a comfortable environment and increase motivation (eg, make small talk and ask more personal questions)
- Handle any situation that may arise during a computerized cognitive training session (eg, need for a break, loss of motivation, or distraction)

Thus, this study has thus enabled us to test this script to perfect it and integrate it into the dialogue manager with an event-controlled finite state automaton that will be used for the final CCT software.

Procedure

The participants were invited to the Université Lumière Lyon 2 (Bron, France) to perform a single session of CCT accompanied by a virtual assistant. The complete experiment lasted between 2 and 4 hours, depending on the participants. The average duration of the CCT session, including interactions with the virtual assistant, was around 1 hour and 15 minutes. After completing the consent form, the participants answered all the questionnaires assessing individual characteristics with the assistance of the experimenter. A break was suggested at the end of this first part, and participants were informed that they could take a break whenever they needed. Next, participants were seated in front of the computer and provided with headphones to perform the CCT with the virtual assistant. For this second part of the experiment, the experimenter left the room and let the participants attend the session alone.

The virtual assistant welcomed the participants and tried to get to know them, asking for some official information (name and age) and making some conversation about more personal topics, such as their job and hobbies. This first discussion was scripted in such a way as to make the participants feel comfortable and get them used to interacting with the assistant. The assistant then explained the interest of CCT in training cognitive functions and presented the course of the session, regularly asking questions to the participants.

Before each exercise, the virtual assistant gave the instructions and explained in an interactive way which cognitive functions were going to be trained. Then, the assistant disappeared for the duration of the exercise but could reappear to intervene if the participant had difficulty completing the exercise. After each exercise, the virtual assistant asked the participants how it went and gave them feedback on their performance, sometimes tips for improvement, and encouragement for the next exercise. Each exercise was performed twice, with the level of difficulty adjusted the second time based on the performance the first time. After the last exercise, the virtual assistant asked the participants how it went, whether they enjoyed the session, and which exercises they liked best and why. The assistant then thanked the participants before ending the CCT.

In the last part of the experiment, the participants answered the questionnaire evaluating the virtual assistant and the session with the help of the experimenter. Finally, they were informed about the Wizard of Oz device and were invited to meet the human pilot.

Data Analysis

Data were analyzed using R (version 1.4; The R Foundation). The package *BayesFactor* (version 0.9.12-4.4) [55] was used to extract Bayes factors. Priors were set to default with an ultrawide scale [56]. The 95% credible interval (CI), representing the 95% highest density interval, was computed from posterior distribution using the package *bayestestR* (version 0.9.0) [57].

Analyses were performed using the Bayesian framework because it is more informative than the frequentist framework [58,59]. Indeed, rather than providing binary rejection information as the *P* value does, the Bayes factor (BF_{10}) provides a level of evidence in favor of the alternative hypothesis against the null hypothesis. According to Kass and Raftery [60], BF_{10} can be interpreted as follows: $BF_{10} \geq 3$ highlights moderate evidence, $BF_{10} \geq 10$ highlights strong evidence, and $BF_{10} \geq 100$ highlights decisive evidence.

We first tested whether the evaluation of the virtual assistant differed with age by comparing age groups with 1-tailed Bayesian *t* tests on each of the 7 scores of the assistant evaluation (ie, appreciation, comprehension, engagement, desire to give up, fatigue level, familiarity, and sense of humor). Then, for each age group separately, we performed Bayesian correlation analyses to investigate the relationship between the virtual assistant's evaluation and individual characteristics (ie, psycho-affective functioning, personality, personal motivation, habits, and cognitive functioning). The groups were analyzed separately to highlight the specific profile of each population. Bayesian Pearson correlation coefficients and the corresponding

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BF_{10} were computed between the scores obtained on the questionnaires measuring participants' characteristics and the 7 scores evaluating the virtual assistant. Descriptive data on participants' responses to all questionnaires were also computed.

Results

Evaluation of the Virtual Assistant and Group Comparison

The mean ratings given by young and older participants to the virtual assistant are presented by dimension in Table 4. Results from Bayesian *t* tests suggested that young adults and older adults rated the assistant differently on all measures. Strong evidence was provided for the presence of a difference between age groups in the appreciation of the assistant (Cohen *d*=–0.32, 95% CI –0.70 to 0.05, BF_{10}=23.00), comprehension of the exercises (Cohen *d*=–0.31, 95% CI –0.68 to 0.06, BF_{10}>18.82), and desire to give up training (Cohen *d*=0.25, 95% CI –0.12 to 0.62, BF_{10}=10.18). There was moderate evidence of an age-related difference in engagement (Cohen *d*=–0.19, 95% CI –0.55 to –0.18, BF_{10}=5.70), as well as in ratings of familiarity (Cohen *d*=0.20, 95% CI –0.17 to 0.56, BF_{10}=5.79) and sense of humor (Cohen *d*=0.17, 95% CI –0.19 to 0.54, BF_{10}=4.69) of the assistant. Finally, decisive evidence was provided for the presence of a difference between groups in the level of fatigue reported at the end of the training (Cohen *d*=0.69, 95% CI 0.30-1.09, BF_{10}>1000).

Table 4. Rating results for the virtual assistant evaluation questionnaire by dimension and age group.

Dimension	Older adults, mean (SD; range)	Young adults, mean (SD; range)	All, mean (SD)
Appreciation	7.88 (1.46; 3.57-9.80)	7.35 (1.43; 3-9.57)	7.62 (1.46)
Engagement	7.89 (1.25; 3.70-9.80)	7.62 (1.23; 4-9.9)	7.75 (1.24)
Comprehension	8.13 (1.37; 3.70-10)	7.67 (1.30; 4.25-9.80)	7.90 (1.35)
Desire to give up	1.17 (1.64; 0.20-8.30)	1.56 (1.75; 0.10-7.10)	1.36 (1.70)
Fatigue level	3.45 (2.45; 0.20-8.30)	5.19 (2.31; 0.40-9.30)	4.30 (2.53)
Familiarity	5.75 (1.25; 3.70-9.30)	6.02 (1.44; 3.50-8.50)	5.89 (1.35)
Sense of humor	6.71 (1.74; 3.90-9.80)	7.00 (1.59; 3.30-9.80)	6.85 (1.67)

Correlational Analyses Between Individual Characteristics and Virtual Assistant Evaluation

Psycho-Affective Functioning

In young adults, analyses revealed moderate evidence for negative associations between the desire to give up and the following: arousal (*r*=–0.35, 95% CI –0.56 to –0.1, BF_{10}=10.36), intrinsic relevance (*r*=–0.30, 95% CI –0.53 to –0.09, BF_{10}=4.43), and goal conduciveness (*r*=–0.32, 95% CI –0.57 to –0.12, BF_{10}=7.65). We also observed moderate evidence for the presence of a positive association between goal conduciveness and the overall appreciation of the virtual assistant (*r*=0.32, 95% CI 0.07-0.53, BF_{10}=8.35). No evidence was provided for other correlations.

In older adults, moderate evidence was observed for a negative association between fatigue level and intrinsic relevance (*r*=–0.28, 95% CI –0.50 to 0, BF_{10}=3.20) and for a positive association between fatigue level and state anxiety (*r*=0.28, 95% CI 0.04-0.53, BF_{10}=3.84). No evidence was provided for other correlations. Participants' scores on questionnaires assessing psycho-affective functioning are presented in Table 5.

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Table 5. Rating results for the psycho-affective measures by questionnaire and age group.

Questionnaire and score	Young adults, mean (SD; range)	Older adults, mean (SD; range)
Modified PANAS[a]		
Positive affect score	4.63 (0.92; 2.61-6.50)	4.58 (0.87; 2.28-6.17)
Negative affect score	3.08 (0.82; 1.71-5.05)	2.11 (0.61; 1.14-3.90)
Modified SAM[b]		
Arousal	5.46 (1.81; 1-9)	7.98 (1.23; 5-9)
Intrinsic relevance	6.94 (1.16; 5-9)	8.00 (1.10; 5-9)
Goal conduciveness	7.02 (1.20; 3-9)	7.81 (1.27; 5-9)
Controllability	5.87 (1.77; 2-9)	6.73 (1.21; 3-9)
Novelty	6.90 (2.52; 1-9)	7.27 (2.22; 1-9)
BMIS[c]		
Pleasant-unpleasant	3.13 (0.36; 2.3-7.5)	3.55 (0.25; 2.94-4)
Arousal-calm	2.22 (0.33; 1.25-3)	2.41 (0.31; 1.58-3.08)
STAI-Y[d]		
State anxiety	1.52 (0.40; 1-3.15)	1.30 (0.24; 1-2.1)
Trait anxiety	2.15 (0.53; 1.3-3.4)	1.75 (0.41; 1.05-2.75)

[a]PANAS: Positive and Negative Affect Schedule.
[b]SAM: Self-Assessment Manikin.
[c]BMIS: Brief Mood Introspection Scale.
[d]STAI-Y: State-Trait Anxiety Inventory.

Personality

The Bayes factor showed no evidence in favor of the presence of correlations between personality scores and the assistant's evaluation in either young or older adults (refer to Table 6 for Ten-Item Personality Inventory scores).

Table 6. Ten-Item Personality Inventory (TIPI) scores by age group.

TIPI scores	Young adults, mean (SD; range)	Older adults, mean (SD; range)
Extraversion	4.13 (1.41; 1.5-7)	3.94 (1.21; 1-7)
Agreeableness	5.17 (0.96; 3.5-7)	5.38 (0.83; 3.5-7)
Conscientiousness	5.17 (1.19; 1.5-7)	5.85 (0.95; 3.5-7)
Emotional stability	3.85 (1.34; 2-6.5)	4.94 (1.14; 2-7)
Openness to experience	5.25 (1.06; 2-7)	5.18 (0.98; 2.5-7)

Personal Motivations

In young adults, the Bayes factor showed no evidence of correlations between personal motivation scores and the assistant's evaluation. In older adults, results revealed moderate evidence of a negative correlation between intrinsic motivation toward knowledge and fatigue level (r=–0.26, 95% CI –0.52 to –0.06, BF_{10}=3.02; refer to Table 7 for a description of Global Motivation Scale-28 scores).

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Table 7. Global Motivation Scale (GMS)-28 scores by age group.

GMS-28 scores	Young adults, mean (SD; range)	Older adults, mean (SD; range)
Motivation toward knowledge	5.46 (1.21; 1.75-7)	6.00 (0.78; 4.25-7)
Motivation toward accomplishment	5.08 (1.44; 1.25-7)	4.82 (1.28; 2.25-7)
Motivation toward stimulation	5.20 (0.94; 2.75-7)	5.42 (0.99; 2.75-7)
Introjected motivation	4.25 (1.23; 1.75-6.75)	3.31 (1.25; 1-5.75)
Identified motivation	5.17 (1.05; 2.25-7)	4.13 (1.94; 5-6.75)
External motivation	3.94 (1.38; 1.25-6.75)	2.81 (1.54; 3.65-5.25)
Amotivation	2.76 (1.11; 1-5.75)	2.62 (1.19; 1-6)

Personal Habits

In young adults, analyses provided moderate evidence for a negative correlation between fatigue level and sport activity habit (r=–0.27, 95% CI –0.49 to –0.03, BF_{10}=3.28). No other correlations were observed.

In older adults, moderate evidence was observed for a positive relationship between exercise engagement and familiarity with cognitive training exercises (r=0.27, 95% CI 0.01-0.53, BF_{10}=3.33), as well as between the desire to give up and the habit of playing board games (r=0.28, 95% CI 0.04-0.50, BF_{10}=3.67). No other correlations were observed. Descriptive statistics of participants' responses to the questionnaire on personal habits and cognitive abilities are provided in Table 8.

Table 8. Rating results for the personal habits and cognitive abilities questionnaire by item and age group.

Personal habits and cognitive abilities	Young adults, mean (SD; range)	Older adults, mean (SD; range)
Familiarity with...		
Computers	3.75 (0.74; 2-5)	3.42 (0.67; 2-5)
Cognitive exercises	2.53 (0.88; 1-4)	2.98 (1.04; 1-5)
Cognitive training	1.94 (0.75; 1-4)	2.48 (1.04; 1-4)
Cognitive abilities		
Memory difficulty	3.56 (0.67; 2-5)	3.65 (0.62; 3-5)
Attentional difficulty	3.52 (0.92; 2-5)	3.88 (0.83; 2-5)
Frequency of activities		
Playing a musical instrument	1.98 (1.13; 1-5)	1.35 (0.86; 1-5)
Playing board games	3.23 (1.02; 1-5)	3.15 (0.98; 1-5)
Playing games such as chess or crossword puzzles	2.17 (1.00; 1-5)	3.06 (1.32; 1-5)
Sports and exercise	3.54 (1.13; 1-5)	4.19 (0.66; 2-5)
Meditation and relaxation	2.04 (1.10; 1-5)	2.31 (1.26; 1-5)

Cognitive Functioning (Older Adults Only)

Moderate evidence was observed for a positive correlation between overall cognitive functioning (as measured by MMSE total score) and exercise engagement (r=0.31, 95% CI 0.09-0.55, BF_{10}=6.28). No evidence was provided for other correlations. Descriptive statistics of older adults' performance on the questionnaires measuring cognitive functioning are presented in Table 9.

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Table 9. Older adults' scores on questionnaires measuring cognitive functioning.

Questionnaire and score	Values, mean (SD; range)
MMSE[a]	
Total score	28.96 (1.24; 25-30)
TMT[b]	
Execution time	82.62 (32.22; 47.5-208)
Number of errors	0.30 (0.69; 0-4)
FAB[c]	
Total score	17.10 (1.42; 13-18)
5WT[d]	
Total score	9.90 (0.45; 7-10)

[a]MMSE: Mini-Mental State Examination.

[b]TMT: Trail Making Test.

[c]FAB: Frontal Assessment Battery.

[d]5WT: 5 Words Test.

Discussion

Principal Findings

In this study, we explored the interest of adding a virtual assistant during CCT, with the objective of improving patients' adherence to cognitive training programs performed autonomously at home. To this end, we recruited young and older adults to complete and evaluate a CCT session conducted by a virtual assistant and explored the relationship between their evaluation and various individual factors (ie, age, psycho-affective functioning, personality, personal motivations, and cognitive skills). Overall, the results suggested that a virtual assistant would be appreciated and useful during CCT in both age groups. Certain characteristics of users, especially their current affective state, would be related to their evaluation of the session.

The high appreciation scores showed that both young and older adults felt well accompanied by the virtual assistant during CCT. The virtual assistant appeared to have had a beneficial impact on exercise comprehension and motivation, as suggested by the strong engagement and very low desire to give up reported by both groups. The level of fatigue declared at the end of the session was fairly mild and can be partly explained by the novelty of the device and the experimental context. As for the assistant's personality, both groups would have preferred it to be more familiar and humorous; therefore, these parameters should be considered when developing such an assistant. A recent review of the literature showed that other parameters regarding conversational style should also be considered [61]. For example, virtual health assistants exhibiting nonverbal relational behaviors and self-disclosure were associated with a better user experience. In addition, these same authors stressed the importance of a realistic rendering of the assistant's appearance, evoking a medical context. However, there may be cultural differences in design preferences for virtual assistants. One study showed, for example, a preference for strong realism among older participants from the Netherlands, while Swiss participants preferred a cartoon-like appearance [34]. One solution could be to offer avatar customization options in this kind of software. Further research on the optimal design of virtual assistants is nevertheless necessary.

Moreover, Bayesian analyses brought evidence for differences between age groups on all dimensions assessed. Older adults appreciated the virtual assistant slightly more than young adults and reported higher engagement and better comprehension of the exercises. They reported less desire to give up and less fatigue at the end of training than their younger counterparts. The main explanation for these differences is certainly that this version of the device was specifically conceived for older adults with or without cognitive impairments, considering their preferences and needs, which may differ from those of young adults [32-35,40,41]. Young adults may also have felt less concerned by cognitive training; adaptations will be necessary to propose the device to a younger public experiencing cognitive disorders. For example, analyses showed that familiarity and sense of humor were more important for young than for older adults, suggesting that the assistant's personality should be adapted according to the target audience. In addition, there is some evidence that young adults may prefer to interact with less realistic, nonhuman virtual assistants (eg, zoomorphic or machine-like assistants), unlike older adults [32].

Because older adults' responses tended to amplify the beneficial aspects of the virtual assistant during CCT and minimize the negative effects, such as the desire to give up or fatigue, it is also possible that a social desirability bias was at work in older adults. This bias refers to people's tendency to present themselves in an overly positive manner in self-reports [62], and it has been shown to increase with age, especially when it comes to reports of well-being, depressive symptoms, and mood [62,63]. The differences observed between age groups were nevertheless quite small on all dimensions measured, except for fatigue, where older adults reported a much lower level of fatigue than young adults. Because fatigue may be a more direct reflection of health and self-image than the other measures,

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which may both be negatively impacted by aging, it seems possible that the social desirability bias would be particularly visible in this dimension.

Bayesian correlations allowed us to identify interesting associations between some individual characteristics and the evaluation of the virtual assistant. Psycho-affective functioning, especially affective state at the time of the session, appeared to play an important role in both age groups. In young adults, the results showed that 3 parameters of current affective state would be moderately associated with the desire to give up the session: goal conduciveness, arousal, and intrinsic relevance. As goal conduciveness (ie, the consistency of the situation with current concerns) increased, the desire to give up decreased and the appreciation of the virtual assistant increased, suggesting that goal conduciveness would be particularly associated with young adults' motivation during CCT. In addition, the higher the arousal (ie, state of alertness) and intrinsic relevance (ie, level of pleasure) at the time of the session, the lesser the desire young adults had to give up the session.

The results obtained in older adults also highlighted the importance of current affective state (ie, intrinsic relevance and anxiety state) during CCT but in relation to the level of fatigue reported at the end of the session. Indeed, older adults' fatigue increased with anxiety state and decreased as intrinsic relevance increased. To minimize fatigue during CCT, help from the virtual assistant to manage anxiety could therefore be beneficial. In both age groups, no evidence was provided for correlations between the assistant's evaluation and global affective experience in everyday life (modified Positive and Negative Affect Schedule), anxiety trait (State-Trait Anxiety Inventory), and some other measures of current affective state (Brief Mood Introspection Scale scores, controllability, and novelty). We did not observe any relationships between psycho-affective functioning and participants' engagement in and comprehension of the exercises.

Nevertheless, our data overall suggest that different dimensions of emotional state, such as arousal, goal conduciveness, intrinsic relevance, and anxiety, are likely to modulate participants' appreciation of the CCT and their motivation (ie, desire to give up and fatigue), which could eventually impact adherence to the training program. The ability to detect and react to emotional states would therefore be a particularly useful feature for a virtual assistant in CCT, which would contribute to maintaining or even improving motivation [42]. This proposition is consistent with the available literature, suggesting that virtual health assistants who demonstrate empathy are associated with a more positive user experience [61] and may increase adherence by giving the impression of being understood [40]. When developing an empathetic virtual assistant, for example, the detection of anxiety in the user's facial expression or voice could lead the assistant to question them about the cause of their anxiety, to reassure them, to propose a break, or to adapt the difficulty level of the exercises.

Our analyses did not provide evidence for correlations between users' personality traits (based on the Big Five personality traits) and the evaluation of the assistant in any age group. Moreover, no relationship was observed in young adults between their personal motivations and the assistant's evaluation, whereas older adults presented a decrease in the level of fatigue as intrinsic motivation toward knowledge increased. We also observed some correlations with personal habits (eg, sports activity, familiarity with cognitive training exercises, or playing board games) in both age groups. In young adults, high sports activity was associated with low fatigue at the end of CCT. In older adults, we observed that (1) the more they were used to cognitive training exercises, the more engaged they felt during CCT, and (2) the more they were used to playing board games, the more they desired to give up the session. Further investigations are necessary to clarify these results.

Interestingly, we did not observe any correlation between computer familiarity and session evaluation. However, the CCT in our study was led by a human pilot who was able to provide optimal support by reacting appropriately to any situation. For home-based CCT, without human assistance, one can expect that computer familiarity will be a determining factor in handling the CCT software. A virtual assistant would be a key element in ensuring the success of cognitive training by directly answering users' questions and helping them solve their difficulties, especially among those who are not familiar with computers. However, as older adults have expressed their need for personalized help in acquiring knowledge of new technologies [64], minimal training in using the CCT software will remain necessary and can be provided by health professionals.

Analyses also revealed that exercise engagement positively correlated with overall cognitive functioning (assessed by MMSE total score) in older adults. This result means that older adults with low cognitive functioning would be likely to be less engaged in completing the exercises. This is a delicate point because CCT with or without an assistant is aimed particularly at people with, or at risk of, cognitive disorders. Furthermore, cognitive training is typically prescribed at an average of 1 to 2 sessions per week over a minimum of 8 weeks to several months to have a beneficial effect [14,15,65,66], so the repetitiveness of the sessions is likely to cause a drop in motivation. In line with the propositions made earlier, extreme attention should then be paid to the management of motivation and reassurance of patients when developing a virtual assistant to accompany CCT. In this regard, this exploratory study has 2 major limitations. First, we have not yet collected the opinions of patients with MCI on CCT with a virtual assistant. It is indeed possible that patients with cognitive disorders may evaluate the virtual assistant differently from healthy people. Nevertheless, we did anticipate possible discrepancies by considering the particularities of patients with cognitive impairment when developing the virtual assistant. The assistant's script was notably conceived in line with the recommendations of experts working with older adults with cognitive disorders [40]. The second limitation of our study is that it provides no information on the effectiveness of our device in the training of cognitive functions, compared to CCT without a virtual assistant. On the basis of the data collected in this first study, including the videos of the human pilot and participants, we are currently developing the first version of our future autonomous virtual assistant [42]. The videos of the human pilot will be used to develop the facial

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expressions and voice of the virtual assistant, and the participants' videos will be used to train our artificial intelligence to autonomously detect users' facial expressions, particularly those expressing emotions and fatigue, so that the virtual assistant can react appropriately. The next step in our work will be to test this autonomous agent with patients with MCI in a longitudinal approach to evaluate the benefits of cognitive training accompanied by a virtual assistant in the long term.

In this context, the last topic that we wanted to address concerns the technology that will underpin our virtual assistant and virtual assistants in general. In this study, interactions between the assistant and user were scripted: this enabled us to test a series of adapted dialogues, with the aim of using them later to develop a dialogue manager with an event-controlled finite state automaton. While we were conducting this study and writing this paper, large language models such as ChatGPT were undergoing significant development. However, dialogue managers with a finite number of possible interactions have certain advantages, especially for patients with cognitive disorders. First, such a device allows us to master and certify all verbal content, thus providing a stable and rather predictable environment for those patients who may have comprehension difficulties. Although popular generative models such as ChatGPT have not been technically disclosed, it is known that human knowledge is used by reinforcement learning to avoid systems providing misleading information, particularly on at-risk topics such as health or religion. However, these limitations are not clearly defined and vary according to model updates, so the risk of leading the user to inappropriate actions or behaviors due to misinterpretation of the model is far from negligible. People with cognitive disorders need a safe environment in which to interact with a virtual assistant, which requires total control over the possible responses given by the technology. Second, we avoid confidentiality and ethical issues by not basing our virtual assistant on this technology. Indeed, the European Union Artificial Intelligence Act [67] will specifically ban artificial intelligence systems with unacceptable risks that include cognitive behavioral manipulation of specific vulnerable individuals or groups. Finally, we have more control over processing issues such as response time using cost-effective and lightweight processing with no graphics processing units. However, we do use large language models to enhance the capacity of the virtual assistant to detect the user's intention and emotion. The dialogue editor also uses the ChatGPT application programming interface to facilitate the work of scriptwriters, notably by generating paraphrases to avoid too repetitive interventions. All scripts are examined and revised by human scriptwriters.

Conclusions

The recent COVID-19 pandemic has emphasized the urgency of developing digital health technologies, as they are a useful tool for remote monitoring and can help ensure continuity of patient follow-up [68]. In our aging population, the number of individuals with cognitive impairment, MCI, and dementia is expanding, and CCT is a key solution for patients to continue their training at home. Because the lack of social interactions may contribute to the lower effectiveness of home-based CCT [9], the addition of a virtual assistant in CCT would allow for a more stimulating accompaniment with social interactions that would compensate for the absence of a therapist and reduce the feelings of loneliness often reported by older adults [69]. This study has shown that such a virtual assistant would be appreciated by young and older adults and could have a beneficial influence on users' motivation, provided that it can handle different situations and, in particular, take into account their emotional state. Following this exploratory study, the next step will be to evaluate our solution with patients with MCI and test its effectiveness in long-term cognitive training.

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Conflicts of Interest

None declared.

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Abbreviations

BF10: Bayes factor

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CCT: computerized cognitive training
CI: credible interval
FAB: Frontal Assessment Battery
MCI: mild cognitive impairment
MMSE: Mini-Mental State Examination
THERADIA: Thérapies Digitales Augmentées par l'Intelligence Artificielle
TMT: Trail Making Test

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Clinical Utility and Usability of the Digital Box and Block Test: Mixed Methods Study

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Abstract

Background: The Box and Block Test (BBT) is a clinical tool used to measure hand dexterity, which is often used for tracking disease progression or the effectiveness of therapy, particularly benefiting older adults and those with neurological conditions. Digitizing the measurement of hand function may enhance the quality of data collection. We have developed and validated a prototype that digitizes this test, known as the digital BBT (dBBT), which automatically measures time and determines and displays the test result.

Objective: This study aimed to investigate the clinical utility and usability of the newly developed dBBT and to collect suggestions for future improvements.

Methods: A total of 4 occupational therapists participated in our study. To evaluate the clinical utility, we compared the dBBT to the BBT across dimensions such as acceptance, portability, energy and effort, time, and costs. We observed therapists using the dBBT as a dexterity measurement tool and conducted a quantitative usability questionnaire using the System Usability Scale (SUS), along with a focus group. Evaluative, structured, and qualitative content analysis was used for the qualitative data, whereas quantitative analysis was applied to questionnaire data. The qualitative and quantitative data were merged and analyzed using a convergent mixed methods approach.

Results: Overall, the results of the evaluative content analysis suggested that the dBBT had a better clinical utility than the original BBT, with ratings of all collected participant statements for the dBBT being 45% (45/99) equal to, 48% (48/99) better than, and 6% (6/99) lesser than the BBT. Particularly in the subcategories “acceptance,” “time required for evaluation,” and “purchase costs,” the dBBT was rated as being better than the original BBT. The dBBT achieved a mean SUS score of 83 (95% CI 76-96). Additionally, several suggested changes to the system were identified.

Conclusions: The study demonstrated an overall positive evaluation of the clinical utility and usability of the dBBT. Valuable insights were gathered for future system iterations. These pioneering results highlight the potential of digitizing hand dexterity assessments.

Trial Registration: Open Science Framework qv2d9; https://osf.io/qv2d9

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KEYWORDS

assessment; clinical utility; digital Box and Block Test; dBBT; hand dexterity; dexterity; usability

Introduction

Hand function is crucial for performing all activities of daily living [1]. Accidents, injuries, or diseases can lead to limitations in hand function, which need to be assessed in the health care setting. Hand assessment involves a systematic evaluation to quantify and assess the quality of a person’s hand function [2].

The Box and Block Test (BBT) is a widely used assessment for measuring hand dexterity, a crucial aspect of hand function [3]. The original BBT comprises a wooden box with a raised partition at the center (see Figure 1A). The objective is to transfer as many blocks as possible from 1 side of the partition to the other within a 60-second time frame [4]. This assessment, in its unaltered format, has been used for decades, predominantly in clinical settings, to quantify gross manual dexterity [5].

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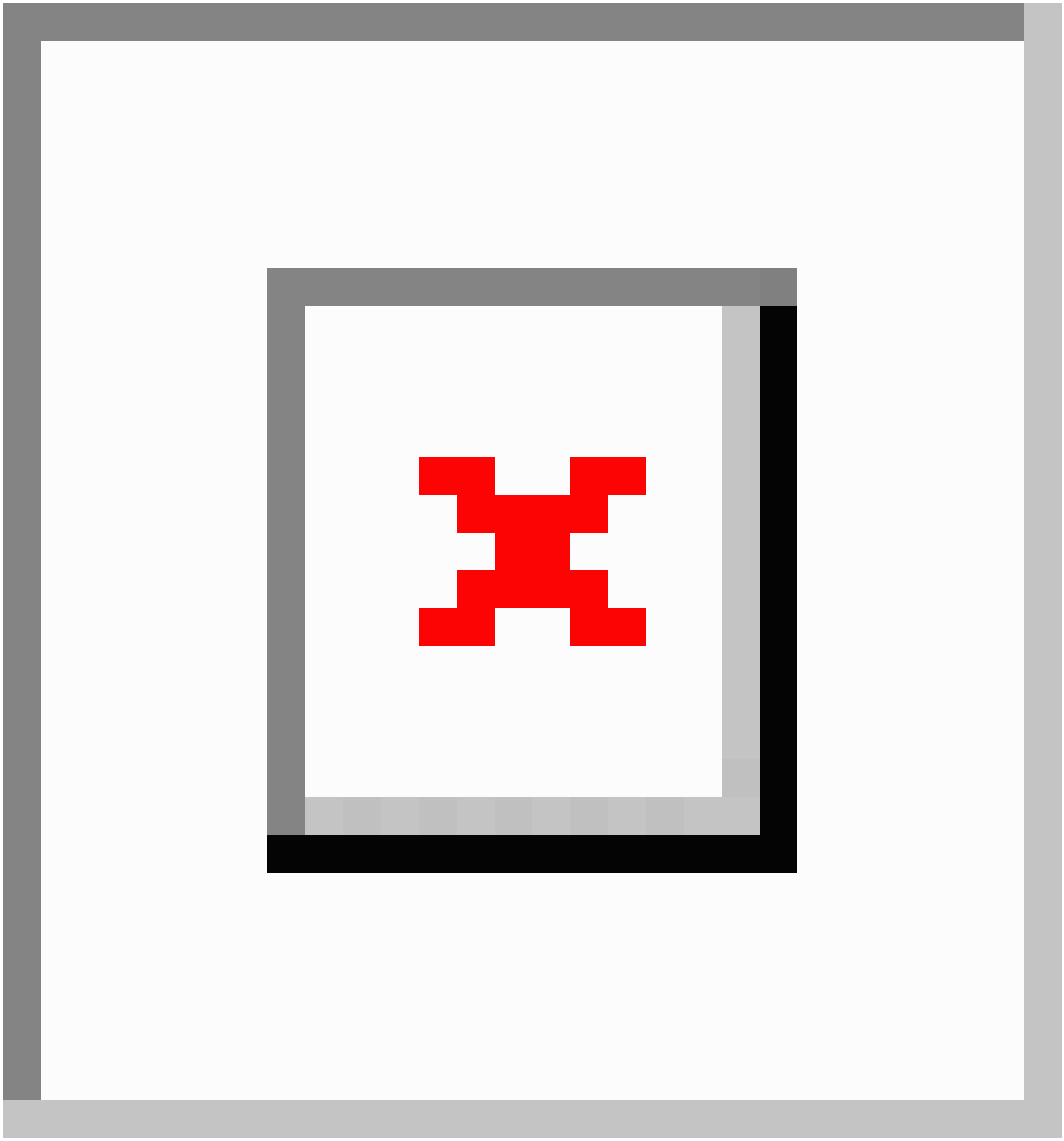
Figure 1. (**A**) The original Box and Block Test and (**B**) the digital Box and Block Test.



In recent times, several projects have focused on digitizing the BBT to improve the quality of collected data through automated measurement processes [6] or to enable cost-effective home use [7]. Technologies such as depth cameras [8], sensor wristbands [9], and infrared sensors [10] have been used to monitor hand and block movements, providing detailed data on hand dexterity, including kinematic movement profiles [11]. Virtual adaptations of the BBT use leap motion sensors [12], Microsoft Kinect sensors [11,12], or virtual reality headset [3,13-16], eliminating the need for physical BBT materials and offering cost-effective alternatives that are suitable for home use. Additionally, interactive haptic devices provide tactile and force feedback in a virtual environment, aiding in motor function recovery [7].

However, although the advancements offer various advantages, they also present several drawbacks:

- Additional costs: Implementing these advancements can be costly due to the need for extra technologies such as computers, cameras, sensors, and specialized software.
- Additional knowledge: Using technical devices requires extra knowledge, both in operating the systems and managing the increased amount of collected data.
- Increased preparation time: Testers and patients need training before using these methods to ensure the correct handling of the necessary equipment.
- Impact on clinical utility: These new developments sacrifice the simplicity and speed of test performance offered by the original BBT measurement method, potentially affecting

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their usefulness in clinical settings. However, little attention has been paid to this aspect in previous studies [11].

We have therefore developed the digital BBT (dBBT) with the aim of preserving its clinical utility [17]. This digital adaptation maintains the structural and form aspects of the original BBT while incorporating automated functions for time measurement, cube counting (see Figure 1B), and failure detection. The psychometric properties, including validity, test-retest reliability, and interrater reliability, of the dBBT have been previously examined in a separate study [17]. In addition to validity and reliability, clinical relevance is determined by clinical utility and usability. Hence, this study is focused on assessing the clinical utility and usability of the newly developed dBBT.

When introducing new technology or systems in health care, demonstrating clinical utility is essential. Although widely used, the term "clinical utility" lacks a formal definition [18]. It is used in evaluating clinical effectiveness [19], as well as in economic assessments of costs, benefits, and effectiveness [20]. First et al [21] define it as the degree to which a system aids in various clinical functions. However, this definition overlooks practical, nonclinical concerns.

Simply being valid and reliable does not guarantee clinical usefulness. For instance, therapists may avoid using a test if it is time-consuming or overly complex [22]. Therefore, a comprehensive definition of clinical utility should encompass aspects such as therapist time and ease of use, as outlined by Fawcett [23]. Fawcett's key dimensions of clinical utility include acceptance, portability, energy and effort, time, and cost.

A usability test is a method of evaluating how user-friendly or intuitive a product is. It involves representative users performing a specific task with the product. Usability tests can be used to identify usability problems, collect data, and determine satisfaction with a product. The System Usability Scale (SUS) is a widely used scale to quantify the usability of many software and hardware products [24]. The SUS was thus selected for this study.

The objective of this study was to evaluate the clinical utility and usability of the dBBT among occupational therapists, who are prospective users. Additionally, the study sought to identify potential areas for future system enhancements.

Methods

Participants

The BBT protocol requires a therapist to perform the hand function measurements [5]. Therefore, occupational therapists were selected as the target group for this evaluation. Recruitment took place at the University of Applied Sciences Campus Vienna, with initial outreach conducted by lecturers of the occupational therapy program. Interested individuals were then contacted and provided with study details via email. Inclusion criteria encompassed individuals who (1) were member of the occupational therapy professional group, (2) have practical experience with the original BBT, (3) were at least 18 years old, and (4) have practical experience in the field of occupational therapy and with the BBT.

A total of 4 occupational therapists were recruited. For focus groups, an optimal group size of 4 to 6 participants is recommended [25,26], whereas a minimum of 3 suffices for usability studies [27]. Therefore, a group size of 4 participants was considered adequate for this study.

Ethical Considerations

The study protocol was conducted in accordance with the Declaration of Helsinki and was approved by the ethics committee (EK Nr 97/2022) of the University of Applied Sciences Campus Vienna. All participants provided written informed consent prior to participation.

Study Design

The Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist [28] was used for planning, conducting, and reporting this study. This study has been registered on the Open Science Framework [29]. We adopted a mixed methods approach, blending quantitative and qualitative data collection and analysis within a single study [30]. Combining quantitative and qualitative methods typically offers a fuller perspective on the research problem [31]. This study used a convergent mixed methods design, as depicted in Figure 2.

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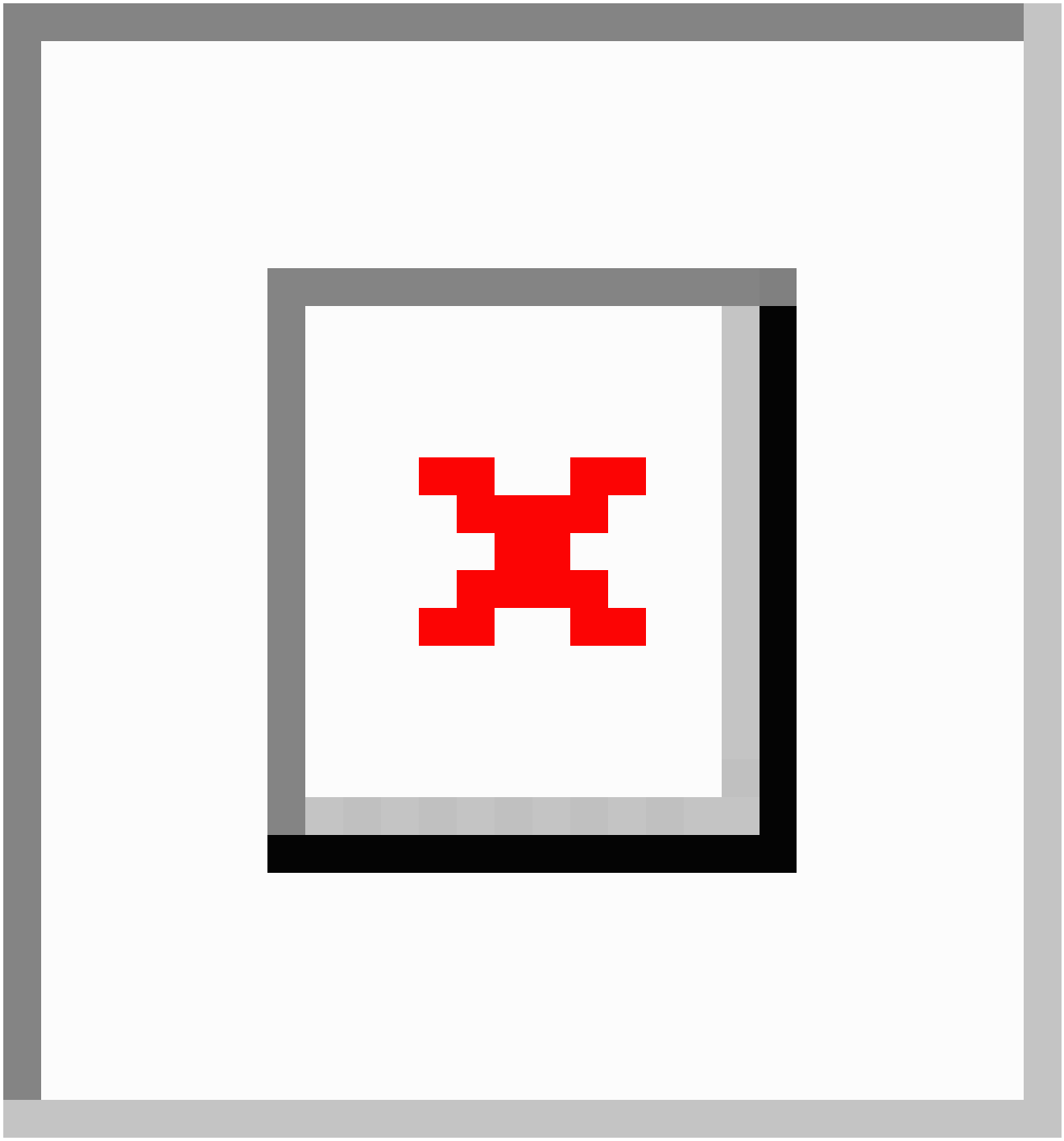
Figure 2. Overview of the mixed methods study design. SUS: System Usability Scale.



All data collection was overseen by a single researcher (EP), who has been specializing in medical informatics since 2016. The researcher has collaborated with the occupational therapy department on various projects, including the development and ongoing enhancement of the dBBT. Importantly, participants in this study had no prior personal acquaintance with the researcher before recruitment.

The study took place in a laboratory situated at the University of Applied Sciences Campus Vienna, chosen to control for potential confounding variables and enhance result validity. The selection of the study setting was carefully deliberated and considered during implementation.

Data Collection and Analysis

Overview

All data collection and analysis were conducted by a single researcher, with input from a second researcher during the initial coding phase of the data. Data processing and analysis were carried out using MAXQDA 2022 (VERBI GmbH).

For qualitative data, including those from observations and focus groups, an evaluative qualitative content analysis was used [32,33]. This method assessed, classified, and evaluated content, akin to a content-structuring qualitative content analysis. However, in an evaluative content analysis, additional categories are generated to allow researchers to rate the material on the selected dimensions [33-35]. In this research, these assessment

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dimensions were defined as being less than, equal to, or better than the original BBT measurement instrument. The predefined coding categories in the content analysis process were grounded in 5 key dimensions of clinical utility. Subcategories and guiding questions were subsequently developed for each dimension, serving as the foundation for the observation studies and focus group (see Table 1).

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Table . The dimensions and subcategories of clinical utility (adapted from Fawcett [23]).

Dimensions and subcategories		Description and guiding questions
Acceptance		
	Therapists	• Is the test administrator (therapist) motivated to work with it? • Does he or she enjoy using the measurement instrument?
	Stakeholders	• Is the test accepted by clinic management, lay observers, or relatives of clients?
	Clients	• Is the test acceptable to clients? Does the test cause stress or test anxiety? • Does the client recognize the relevance of the test?
	Professionality	• Does the test look professional?
	Face validity	• Does the system appear valid? On the surface, does it measure what it is supposed to measure?
Portability		
	Clarity of required components	• Is it easy to handle in terms of the number of components required?
	Transportability	• Can the assessment be transferred from 1 location to another with little effort?
Energy and effort		
	Physical exertion	• How high is the physical load for the test administrator when performing the test? • For example, does the client need to be physically supported?
	Ease of test execution	• How easy is it to perform the test? Are there a large number of tasks or extensive material that must be used?
	Ease of learning	• How easy is it to learn how to perform the test?
Time		
	For learning test execution	• How much time is required to learn how to administer and instruct clients on the test?
	For evaluation	• How much time is required for the interpretation of the test results?
	For preparation	• How much time is required to prepare the test in order to perform the measurement on a client?
	For execution	• The most obvious time factor of a measurement procedure [23] • How much time is required to perform the test?
Cost		
	Ongoing costs	• What ongoing costs are incurred for test implementation? (software, test sheets, etc)

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Dimensions and subcategories		Description and guiding questions
	Required training	• Are fee-based training courses required for the use of the test?
	Required qualifications	• Are there any special qualifications required for test administration or the interpretation of the test results? • Must the scoring be performed by specially qualified persons?
	Purchase costs	• Which costs are calculated for the acquisition of the test, if necessary for manual and test sheets?

System Use Observations

The aim of these observations was to evaluate the clinical utility of the dBBT. Observations in general can provide important real-time data on behavior [36]. The object of observation was the use of the dBBT to measure hand dexterity by a therapist, with another participant as the person to be tested. Each occupational therapist completed the hand dexterity assessment with the dBBT as a test administrator once, whereas another participant took the role of the tested person. The exact procedure was as follows: following the standardized procedure as defined for the original BBT [4], the test administrator read the test instructions to the person to be tested and performed the hand dexterity measurement once on the writing hand of the tested person. The whole exercise session was observed by the researcher, using the previously developed observation guide.

As the observation sequence lasts only a few minutes (including the start-up of the dBBT by the therapist, instruction of the participant by the therapist, practice run following the test protocol, and the actual dexterity test), there was limited time for extensive note-taking. Therefore, the researcher opted for a quantitative assessment of the observations. The following aspects of the five dimensions of clinical utility were assessed, which were directly observable and comparable to the original BBT using a three-part scale of less than, equal to, or better than: (1) time for preparation by the therapist, (2) time for patient instruction by the therapist, and (3) time for the person to be tested to understand the test task. Further assessment points covered possible application problems: (4) problems during preparation (which ones, severity, and consequences), (5) problems during implementation (which ones, severity, and consequences), and (6) open questions from the therapist (see Multimedia Appendix 1).

Each session was video recorded using a Dell Latitude 5480 Laptop, and data were collected using the aforementioned observation protocol.

The data were transcribed verbatim, anonymized, and coded using predefined categories (see Table 1), and additional categories were developed based on the data (for potential improvements to the dBBT). Subsequently, the data were analyzed using verbal-interpretative methods based on the categories, and key statements were presented accordingly. All these steps were carried out by the same person, the researcher (EP).

Usability Questionnaire

The usability of dBBT was then assessed quantitatively with the SUS (see Multimedia Appendix 2). The participants (N=4) completed the SUS directly after using the dBBT.

The SUS is one of the most frequently used questionnaires for evaluating the usability of eHealth applications [37]. Even with a very small sample, the SUS provides valid results about whether an application has problems in the area of usability [38].

The process for computing a SUS score was following: (1) subtract 1 from the Likert ratings for odd-numbered items, (2) subtract the Likert ratings from 5 for even-numbered items (each item score will range from 0 to 4), and (3) sum the numbers and multiply the total by 2.5 [24]. This resulted in SUS scores ranging from 0 to 100. The following SUS score ratings were used in this study: scores ≥52 represented “OK” usability, ≥73 represented “good” usability, and ≥85 represented “excellent” usability [39].

The mean SUS score from 3500 surveys within 273 studies was 72 [39]. It is recommended to the report mean, SD, median, CI, and *P* value (Shapiro-Wilk) in addition to the SUS score [24].

Focus Group Interview

Following the completion of the usability questionnaire, a focus group session was conducted with all 4 occupational therapists. The aim was to evaluate the clinical utility of the dBBT compared to the original version and to gather suggestions for potential system improvements.

The focus group followed a predefined guideline (see Multimedia Appendix 3), developed in accordance with qualitative research standards [40] and reviewed by a second researcher. This guideline was structured around the dimensions of clinical utility (see Table 1), with the assessment criteria for the evaluative content analysis (less than, equal to, or better than the BBT) also included.

An audio recording was made during the focus group session. This audio file, an observation protocol created by the researcher following the focus group, and notes from the guideline were used for data analysis. For analysis, an evaluative qualitative content approach was chosen [33]. An initial coding frame was

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derived from the focus group guideline and refined as more data were analyzed. This involved identifying patterns, assigning codes, and establishing themes and subthemes from the coded data [41]. Ultimately, the data were interpreted verbally according to categories and presented alongside relevant statements.

Merging Qualitative and Quantitative Data

We used a convergent mixed methods design, integrating the findings from both qualitative and quantitative data [42]. Following separate collection and analysis of quantitative and qualitative information, the 2 data sets were combined.

The purpose of merging the results was twofold: (1) to enhance the validation of clinical utility and usability and (2) to identify potential optimization strategies.

The following data were included in the merging process:

- Qualitative results from the focus group and observations
- Quantitative results from the observations (observation protocols, see Multimedia Appendix 1) and usability questionnaires (see Multimedia Appendix 2)

Subsequently, recommendations for future improvements were extracted from the compiled data and presented.

Results

Overview

The studies were conducted in April 2023. The focus group lasted approximately 1.5 hours, the observational studies lasted a total of 10 minutes for the dexterity measurements, and the SUS required 5 minutes per person. All 4 occupational therapists involved in the study were between 21 and 30 years old, and all participants were female.

This section is divided into three subsections: (1) results for clinical utility, (2) results for usability, and (3) recommendations for potential future changes for the dBBT. In the subsection on clinical utility, statements regarding each of the 5 aspects of clinical utility are highlighted, representing the obtained results. Quotes are labeled with their corresponding line numbers in the audio transcript. The assessment of usability follows immediately afterward. Finally, the section concludes with recommendations, presenting a concise list of potential optimization measures identified for the dBBT based on the validation results.

Clinical Utility

Acceptance

The acceptance of the newly developed prototype dBBT differed from the original BBT in several ways. First, simplicity was enhanced by eliminating the need for manual counting (with the original BBT, the therapist has to count the transported blocks by hand to obtain a final test result; on average, 80-100 blocks have to be counted by hand, which makes the evaluation more time-consuming than the BBT itself) and by automating time measurement instead of using a stopwatch: “for me the automatic time measurement easier than dealing with a stopwatch - because I just never use a stopwatch otherwise” (p.25).

Second, the trustworthiness of the results provided by the dBBT was emphasized, ensuring that the results are credible to clients: “and above all, that the result [note: for clients] is credible - if a ‘device’ measure that” (p.125).

Another important finding was the clinical and professional appearance of the dBBT, which was documented in several statements, such as “[the dBBT] transports a higher level of professionalism to the external environment” (p.128).

The evaluative analysis showed that the dBBT achieved higher acceptance compared to the BBT. As shown in Table 2, a total of 89% (33/37) of statements by the occupational therapists showed a higher acceptance of the dBBT than the original BBT. Particularly, all occupational therapists judged the “professionalism” (defined as whether the test looks professional [13]) of the dBBT as higher than that of the original BBT.

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Table . The clinical utility of the digital Box and Block Test (dBBT) as expressed by occupational therapists. "Less than," "equal to," and "better than" indicate their evaluated statements for the dBBT (ie, the dBBT performs less than, equal to, or better than the original Box and Block Test).

Dimensions and subcategories		Statements on the dBBT with rating[a]			
		Total, n[b]	Less than, n (%)[c]	Equal to, n (%)[c]	Better than, n (%)[c]
Acceptance					
	By administrator	10	1 (10)	0 (0)	9 (90)
	By stakeholder	6	0 (0)	1 (17)	5 (83)
	By patients	8	1 (12)	1 (12)	6 (75)
	Professionality	8	0 (0)	0 (0)	8 (100)
	Face validity	5	0 (0)	0 (0)	5 (100)
	Total	37	2 (5)	2 (5)	33 (90)
Portability					
	Clarity of components	1	0 (0)	1 (100)	0 (0)
	Transportability	8	3 (38)	5 (62)	0 (0)
	Total	9	3 (33)	6 (67)	0 (0)
Energy and effort					
	Physical exertion	2	0 (0)	2 (100)	0 (0)
	Ease of execution	2	0 (0)	2 (100)	0 (0)
	Ease of learning	3	1 (33)	2 (67)	0 (0)
	Total	7	1 (14)	6 (86)	0 (0)
Time					
	Learning test execution	3	0 (0)	3 (100)	0 (0)
	For evaluation	4	0 (0)	0 (0)	4 (100)
	For preparation	6	0 (0)	6 (100)	0 (0)
	For execution	11	0 (0)	11 (100)	0 (0)
	Total	24	0 (0)	20 (83)	4 (17)
Cost					
	Ongoing costs	8	0 (0)	2 (25)	6 (75)
	Required training	8	0 (0)	7 (88)	1 (12)
	Required qualifications	2	0 (0)	2 (100)	0 (0)
	Purchase costs	4	0 (0)	0 (0)	4 (100)
	Total	22	0 (0)	11 (50)	11 (50)
Total		99	6 (6)	45 (45)	48 (48)

[a]Due to rounding, percentages may not sum to 100%.

[b]Overall number of statements for the respective item, both in the observation analysis or focus group.

[c]Percentages are calculated with the values in the "Total, n" column as the denominators.

Portability

The clarity of the components was rated as equal to the BBT, but the transportability of the dBBT was rated as lesser than that of the BBT. This is because the original BBT can be folded to half its size, whereas the dBBT does not offer this feature: "possibly it is bulkier the dBBT" (p.92).

Regarding the clarity of required components ("Is it easy to handle in terms of the number of components required?"), the dBBT was rated as equal to the BBT: "so there is no difference to the BBT - except that you don't have to assemble the dBBT - then the dBBT is even rather clearer." (p.116).

The dBBT is slightly heavier than the BBT. However, the therapists came to the conclusion that the higher weight of the dBBT is irrelevant because "normally the BBT will not be transported either - it will be in the therapy room" (p.112).

According to the evaluative analysis results for portability, 67% (6/9) of statements reported that the portability of the dBBT was equal to that of the BBT. The remaining statements (3/9,

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33%) suggested that the dBBT had less transportability than the BBT (Table 2).

Energy and Effort

In most of the statements in the energy and effort category and its subcategories (physical exertion, ease of test execution, and ease of learning), no difference was found between the dBBT and BBT: "so certainly none of the three aspects [note: of energy and effort] shows somehow more effort or energy than with the BBT" (p.108) and "I would see it the same way" (p.109).

The energy required to perform the measurement with the dBBT and to learn how to perform dexterity measurement with the dBBT was also rated as equal to that for the BBT: "the physical effort for the test administrator is the same as for a measurement with the BBT" (p.105) and "the effort required for implementation is the same, learning is just as easy as with the BBT" (p.110).

In the evaluative analysis results for energy and effort in Table 2, a total of 86% (6/7) of the statements reported equal energy and effort in using the dBBT in comparison to the BBT.

Time

In the subcategory of time for evaluation, the dBBT was rated as better than the BBT by all participants. The therapists appreciated the simplification resulting from the omission of counting the blocks, especially when evaluating multiple patients consecutively: "then I would also prefer the digital BBT - because it would be tedious to count and check it all the time" (p.52) and "slightly less time for the evaluation of the test with the dBBT than with the BBT" (p.96).

In the subcategories for learning test execution, preparation, and implementation, the dBBT was rated as equal to the BBT (Table 2): "I only see a little less time for the evaluation - everything else is the same" (p.86) and "the time to learn how to perform the test cannot be different" (p.98).

The preparation and execution of the hand function measurement with the dBBT were evaluated as equal to the BBT: "you have to plug in the dBBT and try it out, I guess – but at the BBT I have to check whether the stopwatch is working" (p. 89-90) and "The preparation is also no different than with the BBT - put it there…" (p.88).

In the evaluative analysis results for time in Table 2, a total of 83% (20/24) of statements in the time category rated the dBBT as equal to the BBT, whereas 17% (4/24) rated the dBBT as better than the BBT.

Cost

The BBT is available for purchase at prices ranging from US $240 to US $450. The new dBBT was estimated to cost a fraction of this amount. The manufacturing costs are estimated to be less than US $65. This information was given to the test participants before the discussion of costs.

The ongoing costs for dBBT were estimated to be relatively lower (if one classified the power consumption as negligible): "less are the running costs with the dBBT - because I don't need a battery for the stopwatch" (p.78).

Regarding necessary training, all therapists were receptive to the fact that the technical device requires minimal additional effort due to its straightforward operation. However, it was noted that an introduction to the functions of the dBBT was required initially: "I think it balances out - since you don't have to count with the dBBT. that's not necessary. but the three buttons and plugging the device in [to the power supply] are the 'more' - but once you know it, you can do it anyway" (p.17) and "you have to be told at least once what, for example, the black button is for and so on" (p.19).

At the same time, however, familiarity with using a stopwatch, which was required for the original BBT, had decreased: "the stopwatch I need to use in the original, I also need to practice" (p.22). Therefore, the expense of required training was rated as equal to the BBT.

The required qualification for executing a dexterity measurement with the dBBT was rated as equal to the BBT: "the qualification for the admin is the same, as the standardized test protocol is just as possible with the dBBT as with the BBT" (p.5).

In total, 50% (11/22) of statements in the cost category rated the dBBT as equal to the the original BBT and 50% (11/22) rated it as better than the BBT. The purchase cost of the dBBT was considered better than the BBT, whereas in all other subcategories, the dBBT was considered equal to the BBT.

Summary

The evaluative qualitative content analysis used selected dimensions (less than, equal to, and better than) to assess the clinical utility of the dBBT compared to the original BBT measurement instrument. In summary, 45% (45/99) of all statements reported an equivalent assessment of the dBBT. Furthermore, 48% (48/99) of all statements rated the clinical utility of the dBBT as better than that of the dBBT, whereas only 6% (6/99) of the statements rated the dBBT as less than the BBT (refer to Table 2).

Therefore, in this study, the dBBT consistently appeared to have at least comparable, and often superior, results in terms of clinical utility compared to the BBT.

Usability

Usability was evaluated using the standardized SUS. The SUS was administered immediately following the observation study. Consequently, participants engaged in a standardized hand dexterity assessment (in a laboratory setting) before evaluating the dBBT using the SUS. Table 3 presents the survey results obtained after the observations.

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Table . System Usability Scale (SUS) score for the digital Box and Block Test from 4 therapists.

Metric	SUS score
Mean (SD)	83 (10)
Median (range)	87.5 (72.5-95)
95% CI	76-96

Recommendations

Several themes regarding potential future changes for the dBBT emerged from observations and the focus group discussion. A total of 3 points for potential improvements had been identified, supported by collected data and defined recommendations.

Theme 1: Shape of the Blocks

The most commonly suggested improvement for the system pertained to the shape of the blocks. Participants expressed that making the edges less sharp would enhance the ease of handling the blocks: "The cubes are more difficult to grip [the edges are sharper than on the BBT]…" (p.10) and "...Edges are sharper or very sharp in the dBBT, which means that they are arranged more closely in the box and it is harder to grip them" (p.13).

- Recommendation 1: Adaption of edge shapes of the dBBT, by making the edges rounder

Theme 2: Additional Acoustic Signal for Test Ending

The second point focused on signaling the end of the test period. Currently, the dBBT uses 2 LEDs, placed on the partition, that change from green to red when the 60-second test period concludes. However, the participants preferred an audible signal, as it would provide a clearer notification for both the person being tested and the therapist: "…the stopwatch beeps so nicely [note: on the original BBT] - then the patient knows that the measurement period is over" (p.80) and "…that would also be good if this prototype can do that…" (p.81).

Additionally, it was observed in 3 (75%) out of 4 instances, the visual signal for the test ending was not perceived by either the test administrator or the person being tested.

- Recommendation 2: The implementation of an acoustic signal that marks the end of the test period

Theme 3: Continuous Display During Test Run

The third point became evident from observations alone. During the test, 2 (50%) out of the 4 occupational therapists were distracted by the display, which constantly showed the elapsed time and the number of blocks currently being counted. The standardized test procedure requires occupational therapists to ensure that the person being tested (1) crosses the partition with their fingers and (2) transports only one block at a time. However, constantly checking the changing display diverted the therapists' attention from this task. None of the participants in the focus group mentioned this issue. It is possible that this observed behavior is a result of using a new device, and whether this problem persists with continued use of the dBBT cannot be conclusively answered by this study alone.

- Recommendation 3: Deactivate the continuous display during the test procedure; activate the display only at the start and end of the test

No other subthemes regarding future changes were found.

Discussion

This study is the first thorough assessment of the clinical effectiveness and user-friendliness of the dBBT, revealing user opinions and possible advantages of such systems. Apart from insights into its clinical utility and usability, the findings present valuable perspectives from end users that can shape the future development of digital assessments.

Clinical Utility

Clinical utility plays a pivotal role in selecting and using a measurement technique. The original BBT is well regarded for its characteristics: quick administration, simplicity, clinic-friendliness, and portability [4,5,43,44]. However, using a wooden measuring tool with a stopwatch is outdated now. Switching to digital methods for measuring hand dexterity can enhance data collection quality [6] and increase acceptance among both patients and therapists. However, these advantages matter only in the health care sector if digitalization does not make measuring hand dexterity more complicated.

To evaluate the clinical utility of the dBBT, we divided it into different aspects based on existing literature. These aspects encompassed acceptance, portability, energy and effort, time, and cost, totaling 17 subcategories [23]. We assessed these aspects in comparison to the original BBT, using a 3-point scale (less than, equal to, and better than).

The dBBT surpassed the original BBT in terms of acceptance (across all 5 subcategories) and in the subcategories of evaluation time and purchase costs. Compared to the BBT, the dBBT garnered higher acceptance from users and patients. The improved rating in evaluation time is attributed to the fact that the test administrator no longer needs to manually tally the approximately 80-100 transported blocks after completing the test. The results are automatically recorded and displayed, saving the time required for measurement. The assessment of the notably lower purchase cost of the dBBT is grounded in a comparison between the costly BBT, as outlined in the *Results* section, and the estimated manufacturing expenses of the dBBT.

In summary, the comparison of the clinical utility of the BBT and dBBT revealed superior results for the dBBT in terms of acceptance, time, and costs. The results were comparable in the dimensions of energy and effort, whereas the BBT demonstrated better results in transportability.

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Usability

The usability of the dBBT was evaluated using the SUS, a standardized and validated tool even with small random samples [38]. All participants provided data immediately after using the dBBT, which was then quantitatively analyzed. The mean SUS score for the dBBT was 83 (SD 10). This result exceeded the mean SUS score of 72 from 237 studies for hardware [39]. Since a SUS score of 85 or higher is considered excellent, the outcomes are highly favorable [39].

Future Work

The systematic evaluation of the dBBT has generated valuable insights for future system iterations. Subsequent efforts will be directed toward incorporating these enhancements into the system. Moreover, future endeavors will concentrate on gauging users' perceptions of the system within authentic clinical settings and through prolonged use over time. This approach will enable the objective assessment of the system's influence on users in clinical environments and facilitate a comparison with the perceived impact identified in this study.

Comparison With Prior Work

In the early stages of digital innovation, understanding usability from an end user's perspective is critical. Active and early involvement of users in the design process helps identify unforeseen user experience issues, enhancing user engagement, a crucial factor in overall user acceptance [38]. Assessing clinical utility is essential for a comprehensive evaluation of assessments [23].

Several publications discuss advancements in various versions of the BBT, integrating additional technologies such as sensors, cameras, or virtual reality [3,8,10,11,13,15,16]. However, there remains a lack of validation regarding the clinical utility of digitized measurement instruments [11].

One study examined the perceived user-friendliness and acceptance of a virtual BBT using a satisfaction questionnaire, yielding highly positive results for the examined development [13]. Another study, using the Intrinsic Motivation Inventory, reported greater motivation with the virtual BBT compared to the traditional BBT [7]. However, Cho et al [11] noted reduced accessibility with a further virtual iteration of the BBT due to the additional technical equipment required. To our knowledge, no studies have explored the clinical advantages of newly developed digital versions of the BBT using the dimensions proposed by Fawcett [23].

Everard et al [3,14] reported comparable usability results, with SUS scores of 78 and 83 among healthy participants using a virtual BBT. At the time of this study, no additional results on the usability of digitized BBTs were available.

Clinical Implications

During development, researchers should not only consider the functionality of a new system but also its practicality. Without the cooperation and acceptance of users, the functionality of a new system may prove ineffective [6].

Overall, the data suggested that the dBBT prototype maintained the fundamental advantage of the BBT (simplicity and quick execution) despite its digitization.

The measurement of hand dexterity with the dBBT adheres to the standardized test protocol of the BBT. Given that the BBT and its testing procedure are widely used and well-known among clinicians, the adoption of the dBBT as a measurement tool is straightforward. There is no need to develop new descriptions for test procedures and patient instructions, as these are readily available for the BBT and are equally applicable to the dBBT.

With its automated measurement of time and results, the dBBT holds significant potential for resource savings in research. The automated measurement can minimize variability among different testers, thereby enhancing data quality. Moreover, the high acceptance among all participants can yield additional benefits for clinical practice.

The advantages of the dBBT can enhance the assessment of hand dexterity in health care. The dBBT has the potential to become a complementary tool for clinical practice.

Limitations

Several contextual factors should be considered when interpreting our findings. All results in this study reflected participants' first experiences with the system. Although this approach is suitable for identifying perceived clinical utility and usability issues, it is possible that perceptions may evolve over time. Further studies are warranted to explore the long-term clinical utility and usability of the dBBT.

Additionally, this study was conducted in a controlled laboratory environment. Evaluating the system in real clinical settings may uncover additional usability and functionality issues, as well as opportunities for further improvements.

Due to the early stage of development, the involvement of patients was rejected for ethical reasons. This combined with the small sample size and homogeneity of participants may limit the generalizability of results, particularly when considering diverse demographics or populations with varying levels of interest in technology.

Data collection, transcription, and analysis were performed by a single researcher, with the first coding of the data supported by feedback from a second researcher. Although there was high consistency in merging the quantitative and qualitative results, it is important to acknowledge the potential influence of a single researcher.

Furthermore, this paper primarily focused on assessing the clinical utility and usability of the dBBT. Extensive details on the psychometric properties of the dBBT are available in a recent publication by the authors [17].

Conclusions

In conclusion, this study serves as a pioneering exploration into the clinical utility and usability of the dBBT, offering valuable insights into user perspectives and the potential advantages of digital assessment systems.

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This research sheds light on the promising prospects of the dBBT in terms of clinical utility and usability, acting as a bridge between traditional assessments and digital innovations. As we further refine and broaden our understanding of this digital tool, the dBBT holds significant potential for enhancing hand dexterity assessments in clinical practice, benefiting both patients and health care providers.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Observation guideline.
[DOCX File, 14 KB - rehab_v11i1e54939_app1.docx]

Multimedia Appendix 2
System Usability Scale.
[DOCX File, 58 KB - rehab_v11i1e54939_app2.docx]

Multimedia Appendix 3
Focus group guideline.
[DOCX File, 25 KB - rehab_v11i1e54939_app3.docx]

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Abbreviations

BBT: Box and Block Test
COREQ: Consolidated Criteria for Reporting Qualitative Research
dBBT: digital Box and Block Test
SUS: System Usability Scale

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Original Paper

Exploring the Major Barriers to Physical Activity in Persons With Multiple Sclerosis: Observational Longitudinal Study

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Abstract

Background: Physical activity (PA) represents a low-cost and readily available means of mitigating multiple sclerosis (MS) symptoms and alleviating the disease course. Nevertheless, persons with MS engage in lower levels of PA than the general population.

Objective: This study aims to enhance the understanding of the barriers to PA engagement in persons with MS and to evaluate the applicability of the Barriers to Health Promoting Activities for Disabled Persons (BHADP) scale for assessing barriers to PA in persons with MS, by comparing the BHADP score with self-reported outcomes of fatigue, depression, self-efficacy, and health-related quality of life, as well as sensor-measured PA.

Methods: Study participants (n=45; median age 46, IQR 40-51 years; median Expanded Disability Status Scale score 4.5, IQR 3.5-6) were recruited among persons with MS attending inpatient neurorehabilitation. They wore a Fitbit Inspire HR (Fitbit Inc) throughout their stay at the rehabilitation clinic (phase 1; 2-4 wk) and for the 4 following weeks at home (phase 2; 4 wk). Sensor-based step counts and cumulative minutes in moderate to vigorous PA were computed for the last 7 days at the clinic and at home. On the basis of PA during the last 7 end-of-study days, we grouped the study participants as active (≥10,000 steps/d) and less active (<10,000 steps/d) to explore PA barriers compared with PA level. PA barriers were repeatedly assessed through the BHADP scale. We described the relevance of the 18 barriers of the BHADP scale assessed at the end of the study and quantified their correlations with the Spearman correlation test. We evaluated the associations of the BHADP score with end-of-study reported outcomes of fatigue, depression, self-efficacy, and health-related quality of life with multivariable regression models. We performed separate regression analyses to examine the association of the BHADP score with different sensor-measured outcomes of PA.

Results: The less active group reported higher scores for the BHADP items *Feeling what I do doesn't help*, *No one to help me*, and *Lack of support from family/friends*. The BHADP items *Not interested* in PA and *Impairment* were positively correlated. The BHADP score was positively associated with measures of fatigue and depression and negatively associated with self-efficacy and health-related quality of life. The BHADP score showed an inverse relationship with the level of PA measured but not when dichotomized according to the recommended PA level thresholds.

Conclusions: The BHADP scale is a valid and well-adapted tool for persons with MS because it reflects common MS symptoms such as fatigue and depression, as well as self-efficacy and health-related quality of life. Moreover, decreases in PA levels are often related to increases in specific barriers in the lives of persons with MS and should hence be addressed jointly in health care management.

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KEYWORDS

physical activity; barriers to physical activity; Barriers to Health Promoting Activities for Disabled Persons scale; BHADP scale; multiple sclerosis; Fitbit; wearable

Introduction

Background

For decades, physical activity (PA) was believed to exacerbate multiple sclerosis (MS) symptoms such as fatigue [1]. It was only in the late 1990s that positive effects of PA for persons with MS were recognized [2]. In the context of MS, PA can ameliorate physical and cognitive functions of persons with MS, improve their health-related quality of life, and mitigate fatigue symptoms [3]. PA is recommended as symptomatic treatment in persons with MS, and emerging data even suggest disease-modifying or preventive effects of PA on MS [4,5]. Notwithstanding these findings, persons with MS are, on average, less active than the general population [6].

Recent World Health Organization guidelines recommend that adults with disabilities (aged ≥18 years) engage in 150 to 300 minutes of moderate PA or 75 to 150 minutes of vigorous PA per week [7]. For additional benefits, adults with disabilities should undertake muscle-strengthening activities at least 2 days per week and multicomponent PA focusing on functional balance and strength training at least 3 days per week. The World Health Organization does not provide an equivalent recommendation for the number of steps per day. Nevertheless, a threshold of 10,000 daily steps is commonly associated with an active lifestyle [8-10].

Activity sensors and Fitbit devices in particular have seen increasing adoption in MS research over the past years [11]; for example, such devices have been used to reduce sedentary behavior in persons with MS [12] or for remote monitoring of MS disability [13]. Despite the lower accuracy of Fitbit sensors at lower activity intensity [14] and slower walking speed [15-18], particularly relevant in the case of persons with MS, earlier studies have demonstrated the validity of Fitbit sensors in measuring step count [19-21]. These sensors enable individualized, passive, and inconspicuous monitoring of various metrics, including PA intensity and step counts, over an extended period of time [22,23].

In view of the numerous positive effects of PA on the health of persons with MS, it is crucial to understand facilitators as well as barriers to regular PA in general to achieve the recommended World Health Organization PA thresholds. However, understanding PA barriers can be challenging because they may be highly individual and multidimensional [24]. As for the latter, a narrative review identified at least five dimensions of PA barriers in persons with MS: (1) MS-related impairment and disability; (2) personal attitudes; (3) fatigue as a highly prevalent symptom; (4) the perceived benefits of exercise; and (5) logistical factors, including finances, support, and accessibility [25].

The multitude of possible influencing factors for PA levels makes studies on barriers to PA methodologically challenging. Among existing assessment frameworks for PA barriers, the Barriers to Health Promoting Activities for Disabled Persons (BHADP) scale plays a prominent role in studies concerning persons with MS [26]. However, research is lacking on whether the BHADP scale is a valid measure to understand PA barriers and their effects in real-world settings and to inform effective interventions to increase PA levels; for example, it remains unclear how the severity of PA barriers is perceived by active (≥10,000 steps/d) and less active (<10,000 steps/d) persons with MS, which social (eg, peer support) or health factors (eg, prevalent MS symptoms) may mitigate or exacerbate perceived barriers, and to what extent PA barriers decrease real-world PA.

Objectives

Therefore, this analysis aimed to (1) compare PA barriers—as summarized by the BHADP scale—between physically active and less active persons with MS, (2) examine how other health factors such as fatigue or depression are independently associated with the BHADP score, and (3) explore the association of the BHADP score with sensor-measured outcomes of PA. Combined, these analyses contribute to the understanding of measurement characteristics and the validity of the BHADP scale in persons with MS.

Methods

Data Source

The data used in this study originated from the *Barrieren für körperliche Aktivität bei Multiple Sklerosis-Betroffenen* (BarKA-MS; Barriers to Physical Activity in People With Multiple Sclerosis) study, a 2-phased observational longitudinal cohort study repeatedly assessing barriers to PA and continuously measuring PA levels of persons with MS with a consumer-grade fitness tracker [27]. In the first phase (2-4 wk), persons with MS who were recruited at a rehabilitation clinic—Kliniken Valens, Switzerland—attended an inpatient rehabilitation program. The second phase corresponded to the first 4 weeks after the participants returned home. This analysis focuses on the primary objective of our trial preregistration.

Ethical Considerations

The BarKA-MS study was approved by the ethics committee of the canton of Zurich (BASEC 2020-02350). All study participants provided written informed consent. Upon completion of the study, they were permitted to retain the consumer-grade fitness tracker used to measure PA during the study. No additional incentives were provided. The data was analyzed in a de-identified format.

Eligibility and Recruitment

The BarKA-MS study aimed to recruit 45 participants. This target sample size was determined on the basis of similar studies [19], recent recommendations from the literature [28], and feasibility considerations. The feasibility considerations encompassed factors such as the number of potentially eligible persons with MS attending neurorehabilitation. All persons with

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MS attending an inpatient rehabilitation program at Kliniken Valens were considered eligible for inclusion in the study. The following eligibility criteria were considered for recruitment into the BarKA-MS study: (1) be aged ≥18 years; (2) present a confirmed diagnosis of MS (relapsing or progressive form); (3) have an Expanded Disability Status Scale (EDSS) score of 2.0 to 6.5 (ie, with reduced walking ability but still able to walk independently with or without an assistive device) and not use a wheelchair at home; (4) be able to complete the weekly questionnaires in German; (5) own a mobile device with Bluetooth functionality, such as a mobile phone or a tablet, required for the Fitbit synchronization; and (6) willingness to participate. Persons with MS who were unable to either (1) complete the baseline questionnaires or activate the Fitbit device or (2) adhere to the study procedures safely were deemed ineligible for participation. In addition, study participants who withdrew their informed consent were excluded from the study. Data collection was finalized in mid-November 2021. More details about the recruitment are provided elsewhere [29].

Inpatient Rehabilitation Program

Throughout the inpatient rehabilitation program, study participants followed a personalized therapy plan, concentrating on individualized goals. Physiotherapy, which included balance and endurance training, was an important component of the rehabilitation program, with persons with MS attending 5 to 6 sessions per week, each lasting 30 to 60 minutes. In addition, study participants engaged in strength training 3 times per week, with each session lasting 30 to 45 minutes, and occupational therapy sessions 2 to 3 times per week for 30 minutes each, focusing on everyday life activities as well as arm and hand training. Furthermore, depending on the specific needs of the participants, other therapies were prescribed, including treadmills, water therapy, hippotherapy, and therapies that included virtual reality apps.

At the conclusion of inpatient rehabilitation, study participants were provided with an individualized training plan comprising 3 to 4 exercises to be performed at home. They were instructed on the proper execution of these exercises and received the instructions either in printed form or through an app, which included videos and photos based on the patient's preferences. Caregivers offered encouragement in a relatively unstructured manner, encouraging participants to engage in these exercises at home and maintain PA.

Variables

Measures

The BarKA-MS study participants were instructed to wear a Fitbit Inspire HR (Google LLC) during waking hours on their nondominant wrist throughout the study. The validity of the Fitbit Inspire HR–collected data in the context of our study was demonstrated previously [21]. Median step count and cumulative minutes in moderate to vigorous PA (MVPA) over the last 7 measurement days at the rehabilitation clinic and the last 7 measurement days at the end of the study (ie, 4 weeks after rehabilitation discharge) were used in the analyses (refer to Multimedia Appendix 1 [29-36] for more details about the Fitbit data processing). The sensor data were continuously collected using Fitabase (Small Steps Labs LLC), a secure commercial data aggregation platform for wearable devices.

Throughout the study, participants were invited to complete web-based questionnaires using the Research Management Information System survey platform [37]. At study enrollment, demographic (ie, sex, age, nationality, marital status, education, and employment status), and health (ie, MS type, MS duration, time since last relapse, and comorbidities) information were collected with the support of the recruiting on-site study coordinator. Additional measures such as BMI and EDSS score were assessed at study enrollment and at the end of the inpatient rehabilitation stay by medical professionals. Study participants also completed web-based patient-reported instruments, including the 12-item Multiple Sclerosis Walking Scale (range 0-100 [lowest walking ability]; refers to the last 2 weeks) [38], Fatigue Scale for Motor and Cognitive Functions (FSMC; range 20-100 [highest fatigue]; refers to everyday life) [39], General Self-Efficacy Scale (GSE; range 10-40 [highest self-efficacy]; refers to everyday life) [40], the 8-item Patient Health Questionnaire depression scale (PHQ-8; range 0-24 [severe depression]; refers to the last 2 weeks) [41], EQ-5D-5L (weighted using the French values set; range 0-100 [best quality of life]; refers to *today*) [42,43], and a visual analog scale to assess pain ("How bad was your pain when it was at its worst during the last 7 days?"; range 0-10 [worst pain]). The 12-item Multiple Sclerosis Walking Scale and the FSMC were developed for persons with MS and are well validated for this population [38,39]. By contrast, the GSE, PHQ-8, and EQ-5D-5L were not developed for persons with MS in the first place but were subsequently validated among this population group as well [40-44]. These patient-reported outcomes were recorded at enrollment, at the end of the inpatient rehabilitation stay, and at the end of the study. The main variable of interest was the BHADP score to measure barriers to PA. The BHADP scale, which was originally designed to evaluate the frequency of barriers to health promoting activities among individuals who are disabled, was additionally used for assessing the barriers to PA in persons with MS [26]. The BHADP scale comprises 18 items, scored from 1 to 4, leading to a total score of 18 to 72 points, with higher scores indicating greater PA barriers [26,45,46]. As the BHADP scale is only available in English, we translated it into German. A back translation into English confirmed the high consistency of both versions. The BHADP score was assessed at 3 time points of the BarKA-MS study: at study enrollment, at the end of the inpatient rehabilitation (2-4 weeks after enrollment, our analysis baseline), and at the end of the study (4 weeks after discharge). In addition, study participants were invited to answer the following free-text questions about PA engagement on a weekly basis. The first question pertained to the barriers to PA: "What kept you from being physically active this week?" The second question pertained to PA facilitators: "What made it easier for you to be physically active this week?" (refer to Multimedia Appendix 1 for more details). Further details on the BarKA-MS study, including measures that were not used for this analysis, are reported elsewhere [29].

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Statistical Analysis

As part of study aim 1 (ie, the comparison of barriers to PA between active and less active persons with MS), descriptive statistics were used to characterize active and less active study participants. To this end, we considered participants *active* if the median daily step count over the last 7 valid wear days in home settings exceeded 10,000 steps; otherwise, the participants were assigned to the *less active* group [8]. For the group comparison, continuous variables were described as medians and IQRs and categorical variables as frequency counts and percentages. Furthermore, we described and compared the 18 barriers of the BHADP scale between the 2 activity groups by using unpaired 2-tailed *t* tests with Welch corrections for unequal variance.

For study aim 2 (ie, the examination of the association of health factors with the BHADP score), we examined the correlations among the 18 barriers of the BHADP scale assessed at the end of the study. In addition, we explored the construct validity, that is, the associations of the BHADP score with external criteria, which, in this case, are end-of-study reported outcomes of fatigue, depression, self-efficacy, and health-related quality of life. These analyses were based on Spearman correlations and unstandardized multivariable regression models. The multivariable regression models included the baseline variables age, sex, MS duration in years, and continuous forms of EDSS and BMI. The regression analyses were conducted on the imputed data set (refer to Multimedia Appendix 1 for more details).

In the context of study aim 3 (ie, the investigation of the association of the BHADP score with PA level), we conducted linear and logistic multivariable regression analyses to examine the association of the BHADP score assessed at the end of the study (explanatory variable) with sensor-based PA level (outcomes) measured over the last 7 end-of-study days. As sensor-based PA outcomes, we investigated median step counts and median cumulative minutes in MVPA in a continuous manner, as well as dichotomized median step counts (<10,000 or ≥10,000 steps/d) and dichotomized median cumulative minutes in MVPA (<150 or ≥150 min MVPA/wk). Basic multivariable regression models were controlled for the same baseline sociodemographic and health characteristics as in the regression analysis for aim 2. Further extensions of basic regression models were additionally controlled for either the PA level or the BHADP score measured at the end of rehabilitation, or both, to account for individualized starting levels at analysis baseline. As this is a mainly exploratory study, we did not correct for multiple testing. The regression analyses were conducted on the imputed data set. The results tables were presented using the *gtsummary* package (version 1.6.1) in R.

All analyses were conducted in R (version 4.2.1; R Foundation for Statistical Computing) [47], using the RStudio environment (version 2022.7.1.554; Posit Software, PBC) [48].

Results

Baseline Characteristics

Between January and September 2021, a total of 47 persons with MS were recruited during inpatient rehabilitation at Kliniken Valens to participate in the BarKA-MS study. Of the 47 participants, 2 (4%) withdrew from the study owing to reasons unrelated to either the study or their disease level [29]; thus, 45 (96%) participants completed the study. The characteristics of all study participants and participant subgroups based on their daily step count (<10,000 or ≥10,000 steps/d) are presented in Table 1. Of the 45 participants, 33 (73%) made up the less active subgroup, whereas 12 (27%) made up the active subgroup. Similar descriptive statistics were obtained in the sensitive analysis based on a threshold of 7000 steps per day (Table S1 in Multimedia Appendix 1).

During the last week of rehabilitation (analysis baseline), the 45 study participants performed, in median, 8656 (IQR 6103-10547) steps per day and 231 (IQR 86-478) minutes of MVPA per week. During the last week of the study at home (ie, 4 weeks after rehabilitation discharge), the participants accomplished, in median, 27% (2327/8656) fewer steps per day (ie, 6329/8656, 73% steps) and 51% (118/231) fewer minutes of MVPA per week (ie, 113/231, 49% min) than during the last week of rehabilitation (full distributions are shown in Figures S1-S4 in Multimedia Appendix 1).

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Table 1. Study participants' characteristics.

Characteristics	Study participants (n=45)	Less active study participants (<10,000 steps/d; n=33)	Active study participants (≥10,000 steps/d; n=12)
Baseline demographics			
Sex , n (%)			
Female	29 (64)	21 (64)	8 (67)
Male	16 (36)	12 (36)	4 (33)
Age (y), median (IQR)	46 (40-51)	48 (43-53)	44 (40-46)
Nationality[a], n (%)			
Swiss	34 (76)	25 (76)	9 (75)
German	6 (13)	5 (15)	1 (8)
Italian	2 (4)	1 (3)	1 (8)
Other	3 (7)	2 (6)	1 (8)
Marital status, n (%)			
Single	12 (27)	10 (30)	2 (17)
Married	23 (51)	17 (52)	6 (50)
Separated	1 (2)	1 (3)	N/A[b]
Divorced	7 (16)	4 (12)	3 (25)
Widowed	2 (4)	1 (3)	1 (8)
Education, n (%)			
Mandatory school not completed (or up to and including grade 7)	2 (4)	2 (6)	N/A
Apprenticeship or secondary education completed (ie, *matura* schools or intermediate diploma schools)	25 (56)	18 (55)	7 (58)
Higher professional education, universities of applied sciences, or university completed	18 (40)	13 (39)	5 (42)
Employment status, n (%)			
Working full time	5 (11)	4 (12)	1 (8)
Working >50% but <100%	5 (11)	4 (12)	1 (8)
Working ≤50%	17 (38)	12 (36)	5 (42)
Not working	18 (40)	13 (39)	5 (42)
Baseline health information			
Multiple sclerosis type, n (%)			
Relapsing-remitting multiple sclerosis	18 (40)	11 (33)	7 (58)
Primary-progressive multiple sclerosis	8 (18)	5 (15)	3 (25)
Secondary-progressive multiple sclerosis	19 (42)	17 (52)	2 (17)
Multiple sclerosis duration (y), median (IQR)	11 (5-21)	14 (5-23)	10 (3-12)
Expanded Disability Status Scale score, median (IQR)	4.5 (3.5-6)	5 (3.5-6)	3.75 (2.9-4)
Expanded Disability Status Scale score, n (%)			
0-3.5	15 (33)	9 (27)	6 (50)
4-5.5	18 (40)	13 (39)	5 (42)
≥6	12 (27)	11 (33)	1 (8)
Time since last relapse (y)			
Value, median (IQR)	3 (1-5)	3 (1-6)	2 (1.5-4)
Missing information, n (%)	8 (18)	7 (16)	1 (2)

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Characteristics	Study participants (n=45)	Less active study participants (<10,000 steps/d; n=33)	Active study participants (≥10,000 steps/d; n=12)
BMI (kg/m^2), median (IQR)	24 (21-28)	23 (21-26)	27 (21-30.8)
BMI (kg/m^2), n (%)			
<18.5 (underweight)	5 (11)	4 (12)	1 (8)
18.5-24.9 (healthy weight)	22 (49)	18 (55)	4 (33)
25.0-29.9 (overweight)	10 (22)	7 (21)	3 (25)
≥30.0 (obesity)	8 (18)	4 (12)	4 (33)
Comorbidities[a], n (%)			
None	18 (40)	13 (39)	5 (42)
Hypertension	5 (11)	5 (15)	0 (0)
Depression	5 (11)	5 (15)	0 (0)
Skin diseases (eg, acne)	4 (9)	3 (9)	1 (8)
Orthopedic diseases (eg, joint or back pain)	4 (9)	4 (12)	0 (0)
Type 2 diabetes	3 (7)	2 (6)	1 (8)
Migraine	2 (4)	N/A	2 (17)
Hypothyroidism	2 (4)	1 (3)	1 (8)
Other[c]	9 (20)	7 (21)	2 (17)
Change in the amount of sport practiced after the multiple sclerosis diagnosis, n (%)			
Less	27 (60)	21 (64)	6 (50)
Same amount	2 (4)	1 (3)	1 (8)
More	15 (33)	10 (30)	5 (42)
Missing information	1 (2)	1 (3)	N/A
Time spent at the rehabilitation clinic (d), median (IQR)	22 (18-26)	22 (18-26)	22 (19-24)
Barriers to Health Promoting Activities for Disabled Persons scale score at analysis baseline (ie, at the end of the rehabilitation stay; range 18-72; the higher the score, the more barriers to physical activity), median (IQR)	20 (19-21)	20 (19-22)	20 (19-21)
End-of-study assessments			
Barriers to Health Promoting Activities for Disabled Persons scale score (range 18-72; the higher the score, the more barriers to physical activity), median (IQR)	28 (24-35)	30 (24-35)	26 (25-28)
12-item Multiple Sclerosis Walking Scale score (range 0-100; the higher the score, the lower the walking ability)			
Value, median (IQR)	45.8 (29.2-79.2)	62.5 (35.4-85.4)	28.1 (16.1-29.2)
Missing information, n (%)	6 (13)	4 (9)	2 (4)
Fatigue Scale for Motor and Cognitive Functions score (range 20-100; the higher the score, the more the fatigue), n (%)			
<43 (no fatigue)	9 (20)	7 (21)	2 (17)
43-52 (mild fatigue)	6 (13)	5 (15)	1 (8)
53-62 (moderate fatigue)	8 (18)	5 (15)	3 (25)
≥63 (severe fatigue)	15 (33)	12 (36)	3 (25)
Missing information	7 (16)	4 (12)	3 (25)
Fatigue Scale for Motor and Cognitive Functions–cognitive fatigue score (range 10-50; the higher the score, the more the fatigue), n (%)			
<22 (no cognitive fatigue)	17 (38)	14 (42)	3 (25)
22-27 (mild cognitive fatigue)	6 (13)	4 (12)	2 (17)
28-33 (moderate cognitive fatigue)	8 (18)	4 (12)	4 (33)

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Characteristics	Study participants (n=45)	Less active study participants (<10,000 steps/d; n=33)	Active study participants (≥10,000 steps/d; n=12)
≥34 (severe cognitive fatigue)	9 (20)	8 (24)	1 (8)
Missing information	5 (11)	3 (9)	2 (17)
Fatigue Scale for Motor and Cognitive Functions–motor fatigue score (range 10-50; the higher the score, the more the fatigue), n (%)			
<22 (no motor fatigue)	6 (13)	5 (15)	1 (8)
22-26 (mild motor fatigue)	4 (9)	2 (6)	2 (17)
27-31 (moderate motor fatigue)	9 (20)	6 (18)	3 (25)
≥32 (severe motor fatigue)	22 (49)	18 (55)	4 (33)
Missing information	4 (9)	2 (6)	2 (17)
General Self-Efficacy Scale score (range 10-40; the higher the score, the more the self-efficacy), median (IQR)	32 (30-36)	32 (29-36)	31 (30-36)
8-item Patient Health Questionnaire depression scale score (range 0-24; the higher the score, the more the depression signs), n (%)			
<10 (not clinically significant depression)	35 (78)	23 (70)	12 (100)
≥10 (clinically significant depression)	7 (16)	7 (21)	0 (0)
Missing information	3 (7)	3 (9)	0 (0)
EQ-5D-5L score, weighted by the French values set (range 0-100; the higher the score, the better the quality of life)			
Value, median (IQR)	63.5 (45.6-78.8)	63 (39.9-74.0)	78.3 (63.4-87.6)
Missing information, n (%)	2 (4)	2 (6)	0 (0)
"How bad was your pain when it was at its worst during the last 7 days?" (visual analog scale; range 0-10; the higher the score, the greater the pain), median (IQR)	3 (0-6)	3 (0-7)	3 (1-4)

[a]Multiple answers possible.

[b]N/A: not applicable.

[c]Asthma, type 1 diabetes, osteoporosis, psoriasis, cancer, rheumatic diseases, elevated cholesterol level, colitis ulcerosa, fibromyalgia, shingles, Meniere disease, and cerebellar syndrome.

Description of Barriers to PA

Figure 1 illustrates the mean scores (on a range of 1-4) for the 18 BHADP items, stratified by participants' PA level (means, SDs, *t* statistics, and *P* values are shown in Table S2 in Multimedia Appendix 1). The following items contained missing values, with the corresponding numbers provided in parentheses: *Lack of convenient facilities* (n=1), *Too tired* (n=2), *Lack of transportation* (n=1), *No one to help me* (n=1), *Concern about safety* (n=1), *Feeling I can't do things correctly* (n=2), and *Difficulty with communication* (n=2). In both comparison groups, *Impairment* (mean 2.5, SD 1 for the less active group vs mean 2, SD 0.7 for the active group), *Too tired* (mean 2.4, SD 0.9 vs mean 2.2, SD 0.9), and *Interferes with other responsibilities* (mean 1.9, SD 0.9 vs mean 2.1, SD 0.9) were among the highest-rated barriers. The means and SDs at the study participants' level are presented in Figure S5 and Table S3 in Multimedia Appendix 1. Most BHADP item scores were higher among the less active group. However, only a few exhibited statistical significance, which were *Feeling what I do doesn't help* (mean 1.6, SD 0.7 for the less active group vs mean 1.2, SD 0.4 for the active group; *P*=.01), *No one to help me* (mean 1.5, SD 0.6 vs mean 1.1, SD 0.3; *P*=.005), and *Lack of support from family/friends* (mean 1.4, SD 0.7 vs mean 1, SD 0; *P*=.003). The *Impairment* item score was nominally higher in the less active group, but this difference was not statistically significant (mean 2.5, SD 1 vs mean 2.0, SD 0.7; *P*=.09). Similar results were observed in the sensitivity analysis based on a cutoff of <7000 or ≥7000 steps/d (Figure S6 in Multimedia Appendix 1). Furthermore, most of the BHADP item scores decreased at the end of the rehabilitation stay compared with before the rehabilitation stay (Figures S7 in Multimedia Appendix 1). However, at the end of the study (ie, at the end of the home phase), they rebounded to the start-of-rehabilitation levels (Figures S7-S9 in Multimedia Appendix 1). The items *Impairment* and *Too tired* improved significantly from study enrollment to the end of the study (*Impairment*: mean 2.9, SD 0.9 at study enrollment vs mean 2.4, SD 0.9 at the end of the study; *P*<.001; *Too tired*: mean 2.6, SD 1 at study enrollment vs mean 2.3, SD 0.9 at the end of the study; *P*=.04).

Barriers and facilitators to PA were additionally surveyed through weekly free-text questions (Figures S10 and S11 in Multimedia Appendix 1). The most frequently reported key words were *work*, *fatigue*, and *weather* (≥15 occurrences) in the question about PA barriers and *weather* and *motivation* (20 occurrences) in the question concerning the PA facilitators.

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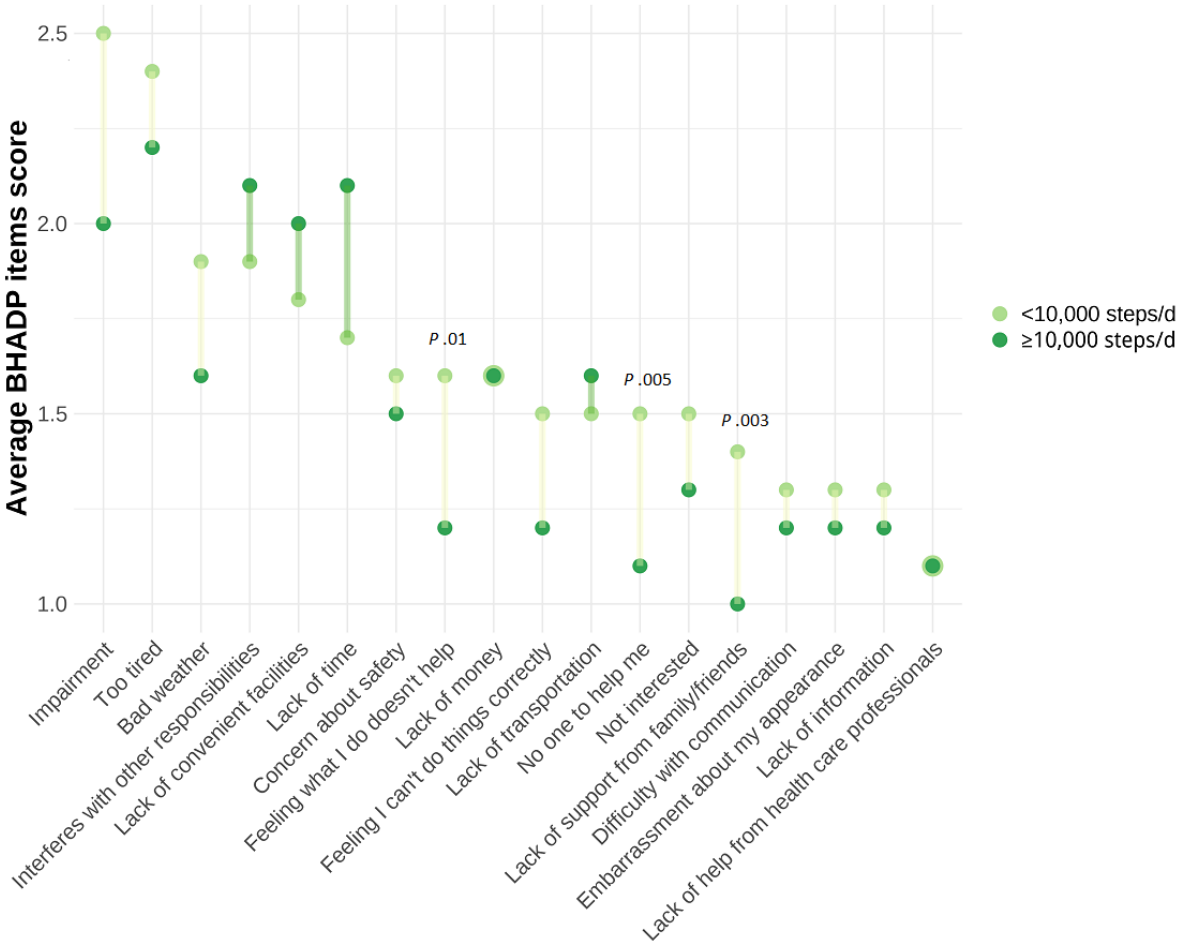
Figure 1. Barriers to physical activity by physical activity level. Average score of the 18 items of the Barriers to Health Promoting Activities for Disabled Persons (BHADP) scale (item score range 1-4) reported at the end of the study by the less active participants (<10,000 steps/d; n=33; in light green) and the active participants (≥10,000 steps/d; n=12; in dark green), in decreasing order for the less active participants. Statistically significant differences (*P*<.05) are reported directly on the graph. Higher scores reflect greater barriers. The figure is based on the complete cases data set.



Associations of Barriers Score

For study aim 2, we intended to examine the correlations among the 18 BHADP items, as well as the associations of the total BHADP score with other patient-reported instruments. The 18 items of the BHADP scale revealed interdependencies among different items (Figure S12 in Multimedia Appendix 1); for instance, *Not interested* in PA was positively correlated with *Impairment* (ρ=0.56; *P*=.02), *Difficulty with communication* (ρ=0.44; *P*=.04), and *Bad weather* (ρ=0.44; *P*=.01). The item *Bad weather* was also negatively correlated with *Interferes with other responsibilities* (ρ=−0.15; *P*=.02). Furthermore, the item *Interferes with other responsibilities* was positively associated with *Lack of time* (ρ=0.6; *P*<.001).

Moreover, given the high importance of the BHADP item *Impairment*, we further explored the associations of the overall BHADP score with specific patient-reported outcomes of fatigue, depression, self-efficacy, and health-related quality of life (Figure S13 in Multimedia Appendix 1). In particular, the total FSMC fatigue score (ρ=0.66; *P*=.002) and the PHQ-8 score for depression (ρ=0.73; *P*<.001) demonstrated a positive correlation with the BHADP score. The EQ-5D-5L score for health-related quality of life (ρ=−0.60; *P*<.001) and the GSE self-efficacy score (ρ=−0.67; *P*<.001) exhibited a negative correlation with the BHADP score. Multivariable, confounder-adjusted regression analyses (Table 2) confirmed the positive relationships of the PHQ-8 (β coefficient=0.90, 95% CI 0.56-1.2) and FSMC (β coefficient=0.16, 95% CI 0.07-0.25) scores with the BHADP score. In other words, an elevated depressive state and increased fatigue were independently associated with an increase in the barriers to PA. Similarly, the adjusted regression analyses substantiated the negative relationships of the EQ-5D-5L (β coefficient=−17, 95% CI −23 to −11) and GSE (β coefficient=−0.49, 95% CI −0.72 to −0.25) scores with the BHADP score. This suggests that higher health-related quality of life and increased self-efficacy are independently associated with a reduction in the barriers to PA. The regression models were re-estimated on the complete cases data set as a sensitivity analysis (Table S4 in Multimedia Appendix 1), which did not change the results substantially.

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Table 2. Linear regression analyses with the Barriers to Health Promoting Activities for Disabled Persons (BHADP) scale score as outcome. Confounder-adjusted unstandardized linear regression models to assess the association of the BHADP score (dependent variable) with the 8-item Patient Health Questionnaire depression scale (PHQ-8), Fatigue Scale for Motor and Cognitive Functions (FSMC), EQ-5D-5L, and General Self-Efficacy Scale (GSE) scores (independent variables), based on the imputed data set (n=45). Notably, as the β coefficients were not standardized, they are not directly comparable across the different regression analyses.

Characteristic	BHADP score vs PHQ-8 score		BHADP score vs FSMC score		BHADP score vs EQ-5D-5L score		BHADP score vs GSE score	
	β coefficient (95% CI)	*P* value	β coefficient (95% CI)	*P* value	β coefficient (95% CI)	*P* value	β coefficient (95% CI)	*P* value
Intercept	29 (19 to 39)	<.001	26 (13 to 39)	<.001	54 (43 to 65)	<.001	50 (38 to 62)	<.001
Age	−0.07 (−0.25 to 11)	.40	−0.01 (−0.22 to 0.19)	.90	−0.02 (−0.20 to 0.16)	.80	−0.01 (−0.20 to 0.19)	.93
Sex								
Female	—[a]	N/A[b]	—	N/A	—	N/A	—	N/A
Male	0.96 (−2.2 to 4.1)	.50	1.7 (−1.8 to 5.2)	.30	1.3 (−1.7 to 4.3)	.40	2.2 (−1.1 to 5.5)	.20
BMI	−0.13 (−0.39 to 0.13)	.30	−0.23 (−0.52 to 0.06)	.11	−0.34 (−0.59 to −0.09)	.008	−0.16 (−0.45 to 0.12)	.20
MS[c] duration	−0.12 (−0.28 to 0.04)	.14	−0.12 (−0.30 to 0.07)	.20	−0.15 (−0.31 to 0.01)	.06	−0.13 (−0.31 to 0.05)	.15
EDSS[d] score	0.52 (−0.65 to 1.7)	.40	0.18 (−1.1 to 1.5)	.80	−0.95 (−2.1 to 0.23)	.11	−0.18 (−1.4 to 1.1)	.80
PHQ-8 score	0.90 (0.56 to 1.2)	<.001	N/A	N/A	N/A	N/A	N/A	N/A
FSMC score	N/A	N/A	0.16 (0.07 to 0.25)	<.001	N/A	N/A	N/A	N/A
EQ-5D-5L score	N/A	N/A	N/A	N/A	−17 (−23 to −11)	<.001	N/A	N/A
GSE score	N/A	N/A	N/A	N/A	N/A	N/A	−0.49 (−0.72 to −0.25)	<.001

[a]Reference category.

[b]N/A: not applicable.

[c]MS: multiple sclerosis.

[d]EDSS: Expanded Disability Status Scale.

Furthermore, we evaluated the relationships between 4 different PA outcome measures and the BHADP score by means of univariate and multivariable linear and logistic regressions (Table 3). The multivariable regressions were adjusted for the confounding variables age, sex, MS duration in years, and continuous forms of EDSS and BMI, assessed at baseline (regression details not shown). Overall, the dichotomized median step counts outcome (<10,000 or ≥10,000 steps/d; models 1, 2, and 3) and the dichotomized median cumulative minutes in MVPA outcome (<150 or ≥150 min MVPA/wk; models 7, 8, and 9) did not reveal statistically significant relationships with the total BHADP score. Similar results were observed in sensitivity analyses using a dichotomized median step counts outcome based on a cutoff of <7000 or ≥7000 steps per day (Table S5 in Multimedia Appendix 1). By contrast, the continuous outcomes median step counts and median cumulative minutes in MVPA exhibited statistically significant relationships with the BHADP score but only after additional adjustment for analysis baseline (ie, end of rehabilitation) step count (models 5 and 6) and MVPA levels (models 11 and 12), respectively. This suggests that an increase in median daily step counts and in median weekly cumulative minutes in MVPA were independently associated with a reduction in the barriers to PA. Specifically, a 1-unit increase in the BHADP score was associated with 218.84 (95% CI 50.86-386.82; model 5) and 210.27 (95% CI 39-381.54; model 6) fewer steps per day. Likewise, a 1-unit increase in BHADP score was associated with 15.04 (95% CI 1.1-28.99) and 14.41 (95% CI 0.1-28.72) fewer weekly MVPA minutes. Sensitivity analyses based on complete cases (Table S6 in Multimedia Appendix 1) and on PA data collected during the penultimate study week instead of the last study week (imputed and complete cases data; Table S7 in Multimedia Appendix 1) resulted in very similar findings, except that the continuous outcome–based linear regression analyses for weekly cumulative MVPA minutes did not exhibit statistically significant relationships with the BHADP score. Moreover, sensitivity analyses based on PA data collected during the penultimate study week revealed a lower decrease in the step count per day per 1-unit increase in the BHADP score. In the case of the imputed data, a 1-unit increase in the BHADP score was associated with 196.01 (95% CI 38.74-353.27; model 5) and 190.09 (95% CI 29.26-350.91; model 6) fewer steps per day.

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Table 3. Imputed linear regressions with physical activity as outcome. Univariate and confounder-adjusted (ie, age, sex, multiple sclerosis duration in years, and continuous forms of Expanded Disability Status Scale and BMI assessed at baseline) multivariable regression models to evaluate the association of physical activity assessed during the last week of the study with the Barriers to Health Promoting Activities for Disabled Persons scale assessed at the end of the study, based on the imputed data set (n=45).

Models	Univariate imputed data analysis	Multivariable imputed data analysis[a]
Last week of the study		
1. ≥10,000 steps/d[b]		
Odds ratio (95% CI)	0.93 (0.82 to 1.06)	0.88 (0.74 to 1.04)
P value	.29	.14
2. ≥10,000 steps/d controlled for steps/d at the end of the rehabilitation		
Odds ratio (95% CI)	0.86 (0.73 to 1.02)	0.82 (0.67 to 1.00)
P value	.09	.05
3. ≥10,000 steps/d controlled for steps/d and barriers score at the end of the rehabilitation		
Odds ratio (95% CI; *P* value)	0.87 (0.71 to 1.05)	0.86 (0.69 to 1.06)
P value	.14	.15
4. Steps/d		
β coefficient (95% CI)	−48.32 (−259.08 to 162.44)	−69.43 (−275.33 to 136.47)
P value	.65	.50
5. Steps/d controlled for steps/d at the end of the rehabilitation		
β coefficient (95% CI)	*−164.28 (−321.17 to −7.38)*[c]	*−218.84 (−386.82 to −50.86)*
P value	*.04*	*.01*
6. Steps/d controlled for steps/d and barriers score at the end of the rehabilitation		
β coefficient (95% CI)	−151.92 (−307.87 to 4.04)	*−210.27 (−381.54 to −39.00)*
P value	.06	*.02*
7. ≥150 min of MVPA[d]/wk[e]		
Odds ratio (95% CI)	0.97 (0.87 to 1.08)	0.97 (0.86 to 1.11)
P value	.59	.67
8. ≥150 min of MVPA/wk controlled for min of MVPA/wk at the end of the rehabilitation		
Odds ratio (95% CI)	0.94 (0.82 to 1.07)	0.95 (0.81 to 1.12)
P value	.34	.52
9. ≥150 min of MVPA/wk controlled for min of MVPA/wk and barriers score at the end of the rehabilitation		
Odds ratio (95% CI)	0.95 (0.82 to 1.09)	0.95 (0.81 to 1.13)
P value	.44	.58
10. Min of MVPA/wk		
β coefficient (95% CI)	−8.67 (−24.07 to 6.72)	−12.19 (−27.28 to 2.9)
P value	.26	.11
11. Min of MVPA/wk controlled for min of MVPA/wk at the end of the rehabilitation		
β coefficient (95% CI)	−11.64 (−24.92 to 1.65)	*−15.04 (−28.99 to −1.1)*
P value	.08	*.04*
12. Min of MVPA/wk controlled for min of MVPA/wk and barriers score at the end of the rehabilitation		
β coefficient (95% CI)	−10.85 (−24.26 to 2.56)	*−14.41 (−28.72 to −0.1)*
P value	.11	*.048*

[a]Adjusted for age, sex, BMI, multiple sclerosis duration, and Expanded Disability Status Scale.

[b]Steps/d corresponds to the mean number of steps per day and per individual.

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[c]Statistically significant effect sizes (P<.05) are marked in italics.

[d]MVPA: moderate to vigorous physical activity.

[e]Min of MVPA/wk corresponds to the sum of minutes of MVPA during the week.

Discussion

Principal Findings

We found that persons with MS with different levels of PA do not face the same barriers to engage in PA. Less active persons with MS express a greater need for general as well as family and friends' support and empowerment to engage in PA. We tested the construct validity of the BHADP scale and found it suitable for use in persons with MS. In addition to evaluating barriers to PA, the scale reflects common MS symptoms such as fatigue and depression, as well as self-efficacy and health-related quality of life. Moreover, an increase in sensor-measured PA level was associated with a decrease in barriers to PA.

Comparison With Prior Work

Overall, our findings are well aligned with previous studies. On the basis of longitudinal electronic surveys and Fitbit measurements in 45 participants, this study investigated the validity and usefulness of the BHADP score to explain real-world PA barriers and their consequences for sensor-measured PA among persons with MS.

We observed that less active persons with MS (<10,000 sensor-measured steps/d) were more likely to have signs of a more advanced disease stage, including a longer MS history, a higher EDSS score, and a higher proportion of secondary-progressive MS cases. Consistently, a recent Australian study observed lower PA levels among persons with MS with more severe symptoms [49]. The less active group also reported higher fatigue levels, as indicated by the FSMC score. This finding is consistent with a recent study that observed an association between increased fatigue and decreased PA [50]. Although many MS-related symptoms and impairments are only minimally modifiable, fatigue can be mitigated to some extent by pharmacological and nonpharmacological measures; for example, in disease management programs, persons with MS learn strategies to better manage their fatigue by adapting their daily routines to match the pattern of their fatigue [51]. Persons with MS can also gain a sense of empowerment through coaching and become better able to exert control over their energy levels [51]. PA can also positively influence fatigue [3] and health-related quality of life [52] once initial fatigue barriers have been overcome. Along similar lines, a subset of participants (7/33, 21%) in the less active group exhibited high PHQ-8 scores that are suggestive of severe depression, whereas none in the active group did. Most likely, this finding suggests that persons with depressive symptoms may struggle more often to be physically active. Nonetheless, several meta-analyses provided initial evidence that PA has the potential to decrease depression symptoms in persons with MS [53-56].

Furthermore, we found that the BHADP items *Not interested* in PA and *Impairment* were positively correlated—a noteworthy finding from a care management perspective. Impairments may reduce motivation for PA, which further decreases engagement in PA and leads to a vicious cycle [50]. The important effect of MS-related symptoms as PA barriers was further underscored in a multivariable regression analysis of validated patient-reported outcomes for fatigue, depression, lack of self-efficacy, and health-related quality of life on the BHADP score.

Moreover, the less active group reported not being sufficiently helped by their families and friends, whereas the active group generally did not cite a lack of assistance as a major barrier. These observations are corroborated by another study, which highlighted a positive relationship between the amount of support from relatives and the level of PA [57].

Study participants reported the weather as both a limiting and a facilitating factor for PA in their weekly free-text assessments. Although the weather is not a modifiable element, persons with MS may benefit from advice on physical activities for rainy, snowy, and hot weather, as well as digital tools such as app-based personalized PA prescriptions for indoor exercises and activities [58].

Finally, our study also offers insights on a methodological level into best practices for sensor-based PA monitoring and PA barrier detection. Specifically, daily step count exhibited an inverse association with the BHADP score but only after adjustment for baseline step count levels. This finding is in line with previous literature, which has also described a relationship between a decrease in step count and an increase in the BHADP score [26]. By contrast, dichotomized analysis outcomes on the basis of the World Health Organization recommendation of 150 minutes of MVPA per week or the widely accepted threshold of 10,000 steps/d performed poorly in our analysis, likely in part owing to the loss of information through dichotomization. These observations suggest that intraindividual changes in PA may be more meaningful measures of PA barriers than absolute thresholds. Moreover, recent literature also suggests that PA <10,000 steps/d can improve health [10,59]. Therefore, we conducted a sensitivity analysis with a dichotomized threshold of 7000 steps/d, which did not materially alter our conclusions [10]. Accordingly, it may be more beneficial to monitor longitudinal within-person PA changes rather than goals set at fixed values.

Limitations

Several limitations should be noted about this study. First, the sample size of the BarKA-MS study was restricted by recruitment potential and feasibility. Our analyses of the association between the BHADP score and the PA level may have been underpowered. The use of dichotomized outcomes in certain regressions further exacerbated the problem. In addition, through the aggregation of the Fitbit data at the daily level, PA fluctuations were missed [60]. PA at the daily level could reveal PA patterns, thus being more informative to better support persons with MS in PA engagement. Moreover, motivated by the explorative nature of the study, the analyses were not corrected for multiple testing. The BHADP scale was

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used to ascertain barriers to PA in persons with MS. However, the PA level is inevitably also influenced by the state of the disease. Therefore, it is highly likely that the items of the BHADP scale reflect both disease- and barrier-related differences simultaneously. In addition, we cannot exclude that personal interactions between persons with MS and staff at the rehabilitation clinic may have impacted perceived barriers also in the home setting (eg, through motivation or specific suggestions for home exercises). Furthermore, by assessing PA variation 4 weeks after a rehabilitation stay, our results are not representative of the long-term effect of a rehabilitation program on PA. Owing to the recruitment setting and the eligibility criteria applied, our results are not generalizable to the entire population of persons with MS in Switzerland. Finally, the presence of an on-site study coordinator during the completion of the baseline surveys and the surveys at the end of the rehabilitation stay may have led to information bias, especially in the well-being–related questionnaires (ie, barriers to PA, depression, walking ability, fatigue, health-related quality of life, pain, and self-efficacy).

Conclusions

In summary, our data underscore the detrimental effect of common MS symptoms, including fatigue and depression, along with lifestyle and motivational barriers, on PA. Overcoming such barriers, particularly through more effective MS symptom management, may promote more active, healthier lifestyles. Furthermore, greater social support from family and friends could facilitate PA engagement in persons with MS. The involvement of close family members and friends in the care process might be a means to increase their support. Our study demonstrates that the BHADP scale is a valid and reliable instrument for assessing barriers to PA among persons with MS. Because of its association with the PA level of persons with MS, we encourage future use of the BHADP scale in combination with wearable fitness trackers to monitor and better support engagement in PA among persons with MS.

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Authors' Contributions

AP, CH, CS, JK, RG, and VvW researched the literature and conceptualized and planned the study. They also applied for and gained the ethics approval for this study. CH and CS managed the implementation of the *Barrieren für körperliche Aktivität bei Multiple Sklerosis-Betroffenen* (Barriers to Physical Activity in People With Multiple Sclerosis) study, ensured good conduct, and collected data. They also acted as the primary points of contact for the on-site study coordinator, RS, and the participants in the home setting. RS oversaw on-site study conduction and data collection, whereas VvW supervised the overall study process. AP, CH, and CS developed and maintained the database and prepared the data. CS performed the data analysis with the statistical support of SRH. CS, SRH, and VvW interpreted the data and wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the submitted version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Methods complement detailing Fitbit data processing, free-text analysis methods, and missing data imputation. Results complement presenting sensitivity analyses based on either the complete case data set or a cut-off of 7,000 steps/d, providing insights into additional study time points and a different data granularity.
[DOCX File , 2073 KB - rehab_v11i1e52733_app1.docx]

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Abbreviations

BarKA-MS: Barrieren für körperliche Aktivität bei Multiple Sklerosis-Betroffenen (Barriers to Physical Activity in People With Multiple Sclerosis)
BHADP: Barriers to Health Promoting Activities for Disabled Persons
EDSS: Expanded Disability Status Scale
FSMC: Fatigue Scale for Motor and Cognitive Functions
GSE: General Self-Efficacy Scale
MS: multiple sclerosis
MVPA: moderate to vigorous physical activity
PA: physical activity
PHQ-8: 8-item Patient Health Questionnaire depression scale

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Original Paper

Enabling People With Intellectual and Sensory Disabilities to Trigger a Tablet's Delivery of Task Instructions by Walking to the Tablet: Proof-of-Concept Study

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Abstract

Background: People with intellectual and sensory or sensory-motor disabilities tend to have problems performing multistep tasks. To alleviate their problems, technological solutions have been developed that provide task-step instructions. Instructions are generally delivered at people's request (eg, as they touch an area of a computer or tablet screen) or automatically, at preset intervals.

Objective: This study carried out a preliminary assessment of a new tablet-based technology system that presented task-step instructions when participants with intellectual and sensory disabilities walked close to the tablet (ie, did not require participants to perform fine motor responses on the tablet screen).

Methods: The system entailed a tablet and a wireless camera and was programmed to present instructions when participants approached the tablet, that is, when the camera positioned in front of the tablet detected them. Two instructions were available for each task step. One instruction concerned the object(s) that the participants were to collect, and the other instruction concerned the "where" and "how" the object(s) collected would need to be used. For 3 of the six participants, the two instructions were presented in succession, with the second instruction presented once the required object(s) had been collected. For the other 3 participants, the two instructions were presented simultaneously. Instructions consisted of pictorial representations combined with brief verbal phrases. The impact of the system was assessed for each of the 2 groups of participants using a nonconcurrent multiple baseline design across individuals.

Results: All participants were successful in using the system. Their mean frequency of correct task steps was close to or above 11.5 for tasks including 12 steps. Their level of correct performance tended to be much lower during the baseline phase when they were to receive the task-step instructions from a regular tablet through scrolling responses.

Conclusions: The findings, which need to be interpreted with caution given the preliminary nature of the study, suggest that the new tablet-based technology system might be useful for helping people with intellectual and sensory disabilities perform multistep tasks.

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KEYWORDS

technology; tablet; task; instructions; intellectual disability, visual impairment, hearing impairment

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Introduction

Background

People with intellectual disabilities tend to have problems carrying out multistep tasks, largely due to difficulties in remembering the different steps included in the tasks and the order in which they should be performed [1-5]. The problems may be even greater in situations where intellectual disabilities are combined with sensory or sensory-motor impairments [6-8]. In spite of the difficulties encountered, fostering the ability to carry out multistep tasks remains a main rehabilitation objective, vital for ensuring that people will be able to achieve functional occupation and have a constructive role within their daily contexts and possibly within vocational contexts [1,9-12]. Such achievement is considered critical for advancing their condition, offering them new socially adaptive opportunities, and improving their quality of life [8,11,13-19].

Given the relevance of enabling people to manage the performance of multistep tasks, a large variety of studies have been conducted with the aim of reaching this goal with the support of technological solutions [1,4,20]. These technological solutions, designed to provide instructions for performing task steps correctly and in the right sequence, present several differences [10,21]. The most obvious differences concern (1) the characteristics of the instructions provided (eg, static pictorial images vs video clips illustrating the steps with or without an accompanying verbal phrase describing the steps) and (2) the way those instructions are made available [1,4].

With regard to the latter aspect (ie, the way instructions are made available), two main approaches can be pointed out. The first approach relies on the use of computer or tablet devices that present instructions for the task steps based on participants' requests. Typically, participants initiate the request by performing a specific action such as touching an area of the computer or tablet screen [5,9,22-24]. The second approach relies on computer, tablet, or smartphone devices presenting the instructions automatically, at preset time intervals, eliminating the need for participants to produce specific request responses [7,25,26]. The intervals between instructions are decided by staff personnel familiar with the participants and the time they require for carrying out the different task steps.

The second approach may be considered advantageous for participants who cannot successfully use the first approach due to challenges in providing appropriate responses on computer or tablet screens (eg, inaccuracy in executing touch and scroll responses required to operate these devices) [27,28]. On the other hand, the presentation of instructions at preset time intervals may not always be consistent (in synchrony) with the participants' performance. Although staff may have estimates of the times required by the participants for carrying out the task steps, the participants' response speed and efficacy may fluctuate within and across days, making the intervals programmed based on those estimates too long or too short [8,16]. This may lead to participants missing some instructions and related task steps or having to wait for the instructions.

A possible way to bypass the shortcomings of the aforementioned approaches may involve the development of a technology system that (1) presents instructions without requiring the participants' performance of fine motor responses on the computer or tablet screen and simply (2) associates instruction presentation with participants' walking toward the system [8,16,27]. Such a system would ensure that participants who struggle with performing accurate motor responses on a computer or tablet screen do not need to use those responses. At the same time, this system would guarantee that instructions are delivered at the appropriate time (directly linked to people's actions) rather than at preset time intervals [8,16,29].

Objectives

This study aimed to set up such a system and carry out a preliminary evaluation of it with 6 participants with intellectual and sensory disabilities. The system consisted of a tablet and a wireless camera and was programmed to present instructions when the participant approached the tablet, that is, as the participant was spotted by the camera positioned in front of the tablet. Two instructions were available for each task step. One instruction concerned the object(s) that the participants were to collect, and the other concerned the "where" and "how" the collected object(s) were to be used. For 3 participants, the two instructions were presented in succession, with the second instruction displayed after the required object(s) had been collected. For the other 3 participants, both instructions were presented simultaneously. Instructions consisted of pictorial representations combined with brief verbal phrases. For each of the two groups of participants, the study was conducted following single-case research methodology.

Methods

Participants

Table 1 lists the participants included in the study (categorized into two groups of 3 based on their use of the task-step instructions) and reports their chronological ages and their Vineland age equivalents for daily living skills (personal subdomain) and receptive communication. The participants, who have pseudonyms (Table 1), were between 23 and 62 years of age. All of them were diagnosed with sensory disabilities. Specifically, Allie had severe hearing loss. Sylvie, Rowan, Demi, and Jolene had serious impairments of their neurovisual system, leading to severe limitations in their visual acuity. Emory presented with severe limitations in her visual acuity as well as severe hearing loss. The use of eyeglasses allowed all participants to discriminate pictorial images of familiar objects on a tablet screen and to navigate easily within familiar contexts. Vineland age equivalents (measured via the second edition of the Vineland Adaptive Behavior Scales [30,31]) ranged from 4 years to 5 years and 3 months for personal daily living skills and from 3 years and 4 months to 4 years and 3 months for receptive communication. All participants attended rehabilitation and care centers, where the psychological services classified their level of functioning within the moderate intellectual disability range. However, no IQ scores were available.

The participants were recruited for the study based on a number of general criteria. First, they were unable to carry out multistep

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tasks without staff guidance or specific step instructions. Second, they could use pictorial representations alone or in combination with simple verbal phrases as instructions for the performance of task steps. Third, they expressed their willingness to use the technology system adopted in this study (and shown to them in advance) for carrying out multistep tasks involving familiar material and areas within their daily contexts. Fourth, they had poor fine motor skills and were considered unable to reliably use a tablet for accessing a series of task-step instructions. Fifth, staff supported their involvement in the study and considered technology-aided task engagement a positive goal for the participants and their contexts.

Table 1. Participants' chronological age and Vineland age equivalents for daily living skills (personal subdomain) and receptive communication.

Participants (pseudonyms)	Chronological age (years)	Vineland age equivalents[a] (years, months)	
		Daily living skills (personal subdomain)	Receptive communication
First group			
Rowan	23	4, 2	3, 4
Allie	62	5, 3	3, 11
Sylvie	48	4, 0	3, 4
Second group			
Jolene	48	4, 4	4, 3
Emory	61	5, 1	3, 11
Demi	49	5, 1	4, 3

[a]Age equivalents are based on the Italian standardization of the Vineland scales [30].

Ethical Considerations

The study was approved by the Ethics Committee of the Lega F. D'Oro, Osimo (Ancona), Italy (P072820235). All procedures performed were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

As mentioned above, the participants had expressed their willingness to use the technology system to carry out tasks involving familiar material. Moreover, staff had indicated that the participants would enjoy performing the tasks provided that difficulties and errors (and thus frustration) would be largely avoided, which was the expectation within this study. While these two points suggested the study would be a positive experience for the participants, it was not possible for them to read and sign a formal consent document. Consequently, their legal representatives were directly involved in the consent process, reading and signing the consent forms on the participants' behalf.

Setting, Sessions, Tasks, Instructions, and Research Assistants

Familiar rooms within the participants' daily environments constituted the setting for the study. Sessions were typically carried out 1 or 2 times per day, 4 to 6 days a week. During each session, the participants were asked to perform 1 task. Tasks consisted of combinations of 12 steps. Each step involved 2 simple actions, which were familiar and meaningful to the participants, for example, "take the toilet paper" and "bring the toilet paper to the men's room." The combinations of steps (and related actions) led to a recognizable and practically relevant outcome, such as setting up a bathroom and cleaning the entrance, arranging the living room and putting away papers and books, and preparing or cleaning the dining room [16]. Tasks could be flexible, that is, they could include different combinations of steps on different days based on practical and environmental conditions [16]. Moreover, a number of steps could be used across different tasks. In total, 9 tasks were available to each participant. Textbox 1 provides a combination of 12 steps that could be included in a task such as supplying the bathroom and arranging the kitchen.

The instructions the tablet provided for the 2 actions involved in each task step consisted of 2 pictures (Figure 1 and Figure 2) accompanied by brief verbal phrases (explained further under the *Technology System* section below). For the first 3 participants listed in Table 1 (ie, Rowan, Allie, and Sylvie), the 2 pictures were presented separately (ie, one at a time in sequence), and each picture was accompanied by a verbal phrase matching it. For the other 3 participants (ie, Jolene, Emory, and Demi), the 2 pictures were presented simultaneously (ie, one next to the other, as shown in Figure 1 and Figure 2), accompanied by a verbal phrase matching them (explained under the *Technology System* section below).

The presentation of the two instructions available for each task step in sequence or simultaneously was based on the participants' history, that is, their use of the pictures within their daily contexts, under the supervision of regular staff personnel. The research assistants were 4 women who held a master's degree in psychology and had experience with the implementation of technology-aided programs with people with intellectual and multiple disabilities as well as with data collection strategies.

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Textbox 1. A combination of 12 steps for supplying the bathroom and arranging the kitchen.

- Take the toilet paper and bring it to the men's bathroom.
- Take the towel and bring it to the ladies' bathroom.
- Take the toothpaste and bring it to the men's bathroom.
- Take the toilet paper and bring it to the ladies' bathroom.
- Take the deodorant and bring it to the ladies' bathroom.
- Take liquid soap and bring it to the men's bathroom.
- Take the aluminum and bring it to the microwave.
- Take paper towels and put them in the kitchen drawer.
- Take the chips and put them on the kitchen table.
- Take the flowers and put them in the kitchen sink.

Figure 1. The 2 pictures represent the actions of collecting the toothpaste and bringing it to the washbasin of the red bathroom.

Figure 2. The 2 pictures represent the actions of collecting 2 bottles from a shelf and putting them in the refrigerator.

Technology System

Basic Components

The technology included (1) a Samsung Galaxy tablet with an internet connection and MacroDroid and CloudEdge apps and (2) a DEATTI wireless (battery-powered) camera with a passive infrared sensor [32]. The tablet was also fitted with (1) pictures and verbal phrases used as instructions for the task steps; (2) positive-feedback pictures and praise words shown after the completion of each task step; and (3) videos with the participants' preferred music, comic sketches, or food preparation presented after the completion of the last task step. The tablet was located in one of the rooms used for the tasks. The camera was positioned about 1.5 meters before the tablet. By walking to the tablet, the participants automatically activated the camera, making it send an input to the tablet via the CloudEdge app. This input was used by the MacroDroid app to make the tablet present task-step instructions.

Instructions Presentation

The first 3 participants (ie, Rowan, Allie, and Sylvie) received the two instructions available for each task step in succession (explained in the *Setting, Sessions, Tasks, Instructions, and Research Assistants* section). With a task step such as "bringing liquid soap from a store cabinet to the sink area of a specific bathroom," for example, the instruction the participants received the first time they approached the tablet consisted of a picture showing the liquid soap inside a store cabinet (or simply the liquid soap) accompanied by the verbal phrase "take the soap." The instruction they received the second time they approached the tablet for that step (while they were carrying the soap they had collected from the cabinet) involved a picture representing the soap on the sink of the red bathroom accompanied by the

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verbal phrase "bring the soap to the red bathroom." Once a step was completed, approaching the tablet led to the tablet's presentation of (1) positive feedback with a picture showing hand clapping, thumbs up, or another representation indicating approval and a praise word, and (2) the first instruction for the following task step. The process continued as described above for all other steps of the task and included the presentation of a 2.5-minute video of a preferred (music, comic, or food preparation) event following the completion of the last step. After the delivery of an instruction, the system had a brief period (15-25 seconds) of inertia to ensure that the participant could go back for a second look at the tablet screen without a change of instruction.

For the last 3 participants (ie, Jolene, Emory, and Demi), the tablet presented the two instructions available for each task step simultaneously. For example, for a step such as "bringing liquid soap from a store cabinet to the sink area of the red bathroom," the tablet presented a picture showing soap (or soap in the cabinet) to the left and a picture showing soap on the sink of the red bathroom to the right and accompanied such presentation with a phrase like "take the soap and bring it to the red bathroom." Returning to the tablet (ie, after completing a step) triggered the tablet's presentation of positive feedback plus praise word followed by the presentation of the instructions for the next task step. The positive feedback and praise word after each completed step, the video of a preferred event at the end of the task, and the idleness of the tablet after the delivery of instructions matched those used for the first 3 participants.

Experimental Conditions and Data Analysis

The study started with a pretest verifying whether the participants could carry out the tasks independent of specific step instructions. After the pretest, each of the two groups of participants had a baseline phase followed by an intervention phase. These phases were implemented according to a nonconcurrent multiple baseline design across participants [33,34]. In practice, the participants of each group received different numbers of baseline sessions before the start of the intervention with the technology system. Pretest, baseline, and intervention sessions were implemented by the research assistants. To make sure that their application of the procedural conditions was accurate (that their level of procedural fidelity was high), two strategies were adopted. One involved their preliminary familiarization with those conditions while the other involved regular feedback on their performance [35]. Feedback was delivered by a research coordinator who had access to video recordings of the sessions.

The participants' data concerning the correctly performed task steps were reported in graphic form. To simplify the graphic presentation, data points were made to represent blocks of sessions. The baseline and intervention frequencies of correct task steps were compared using the "Percentage of data points Exceeding the Median" method [36,37]. This method, which is one of the most practical tools to evaluate single-case research data, served to determine how many data points of the intervention phase were above the baseline median.

Pretest

The pretest included 5 sessions. Each session started with the research assistant asking the participants to carry out a task. The request was made via a simple verbal statement and a general pictorial representation. The statement summarized what the participants were to do (eg, "you can supply the bathroom and set up the kitchen table"). The pictorial representation included a drawing of the areas (bathroom and kitchen table) involved in the task. The research assistant did not intervene if the participants carried out steps involved in the task. If the participants remained passive for 30-60 seconds or carried out a step not involved in the task, the research assistant provided guidance for a task step (eg, helped them to bring the toilet paper to a red bathroom). The session continued until the participants had carried out all task steps or had received the research assistant's guidance for the performance of 2 steps. All the steps omitted as well as those carried out with the research assistant's guidance were counted as noncorrect. At the end of a session, the participants were presented with a 2.5-minute video of preferred music, comic, or food preparation events.

Baseline

The baseline included 7, 8, and 13 sessions for the participants of the first group and 6, 8, and 12 sessions for the participants of the second group. Those sessions served to determine whether the participants were able to use a tablet independently to obtain task-step instructions and then carry out those steps. Each session started with the research assistant placing a tablet on a desk and asking the participants to use it to get instructions for a specific task. Meanwhile, the research assistant demonstrated how to use the tablet (ie, operating horizontal scrolling) to receive the step instructions. If participants were unsuccessful or passive for 30-60 seconds, the research assistant provided guidance (ie, carried out the tablet scrolling for them and ensured that they performed the task step indicated by the tablet instructions). Two instances of guidance from research assistants were allowed per session. A session lasted until the participants had either carried out the last step of the task or failed to progress (eg, due to a new unsuccessful or passive period following the research assistant's guidance instances or due to inaccurate scrolling leading them to skip the instructions or shut the presentation process). At the end of a session, the participants were presented with a 2.5-minute video of their preferred music, comic, or food preparation events.

Intervention

The intervention phase included 97, 83, and 88 sessions for the participants of the first group and 87, 64, and 69 sessions for the participants of the second group. During the intervention, the participants had the technology system that worked as described in the *Technology System* section. The objective was to determine whether the system was suitable to help the participants carry out the tasks correctly. Each session started with the research assistant accompanying the participants to the area where the tablet was available (ie, just before the camera). When the camera detected the participants, the tablet was triggered to produce the first instruction delivery. All the rest was as described in the *Technology System* section. The first 2

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sessions served as introductory sessions in which the research assistant could provide guidance any time the participants showed signs of hesitation or difficulty. During the following (regular intervention) sessions, no research assistant's guidance was available except if a participant asked for it.

Data Recording

Data recording concerned (1) the number of task steps performed correctly (ie, in line with the step descriptions and independent of the research assistant's guidance) within the sessions and (2) the length of the sessions. Data were recorded by the research assistants responsible for the implementation of the sessions. Interrater agreement was assessed by having a reliability observer record the participants' performance of the task steps and the sessions' length in 21% to 23% of the participants' sessions. The percentage of agreement (calculated by dividing the number of sessions in which the 2 raters reported the same number of correct steps and session lengths differing by less than 1.5 minutes by the total number of sessions in which agreement was checked, and multiplying by 100%) ranged between 91 and 100% across participants.

Results

Figures 3 and 4 report the baseline and intervention data for the first group of participants (ie, Rowan, Allie, and Sylvie) and the second group of participants (ie, Jolene, Emory, and Demi), respectively. The black triangles represent mean frequencies of correct task steps over blocks of 2 sessions. Occasional blocks with 3 sessions (at the end of the phases) are marked with an arrow. The figures do not report the 2 introductory sessions carried out at the start of the intervention phase.

During the pretest, the participants' frequency of correct task steps per session was (virtually) zero. Indeed, they could carry out a single step (not necessarily involved in the task presented) or remain inactive. All sessions were interrupted after they had received guidance for 2 task steps. The mean session length was below 10 minutes for all participants.

During the baseline, the participants' mean frequency of correct steps per session varied between about 1.5 (Allie) and 6 (Emory) out of the 12 steps available for each of the tasks. Such frequency reflected their inaccurate (unreliable) use of the tablet (ie, skipping step instructions or blocking the scrolling process and closing the instructions' presentation) with the consequent omission of many task steps. The mean session length was about 6.5 (Jolene) to 14.5 (Emory) minutes. The mean length across participants was about 11.5 minutes.

During the intervention, the participants carried out the tasks successfully, and the mean frequency of task steps performed correctly per session varied between near 11.5 (Jolene and Demi) and above 11.5 (all other participants). The mean session length varied between about 15 (Demi) and 29.5 (Allie) minutes. The mean length across participants was about 19.5 minutes. The session length reported for pretest, baseline, and intervention always included the 2.5-minute preferred video shown at the end of the sessions. The large differences in the session length observed during the intervention (when the frequency of correct steps was similar across participants) mainly reflected differences in the participants' performance speed. The Percentage of data points Exceeding the Median method showed indices of 1 for all participants (ie, all their intervention data points were higher than their median baseline frequency value) confirming the strong impact of the intervention with the technology system on their task performance.

Figure 3. The 3 graphs report the baseline and intervention data for Rowan, Allie, and Sylvie. Each data point represents the mean frequency of correct steps over a block of 2 sessions. Blocks of 3 sessions are marked with an arrow.

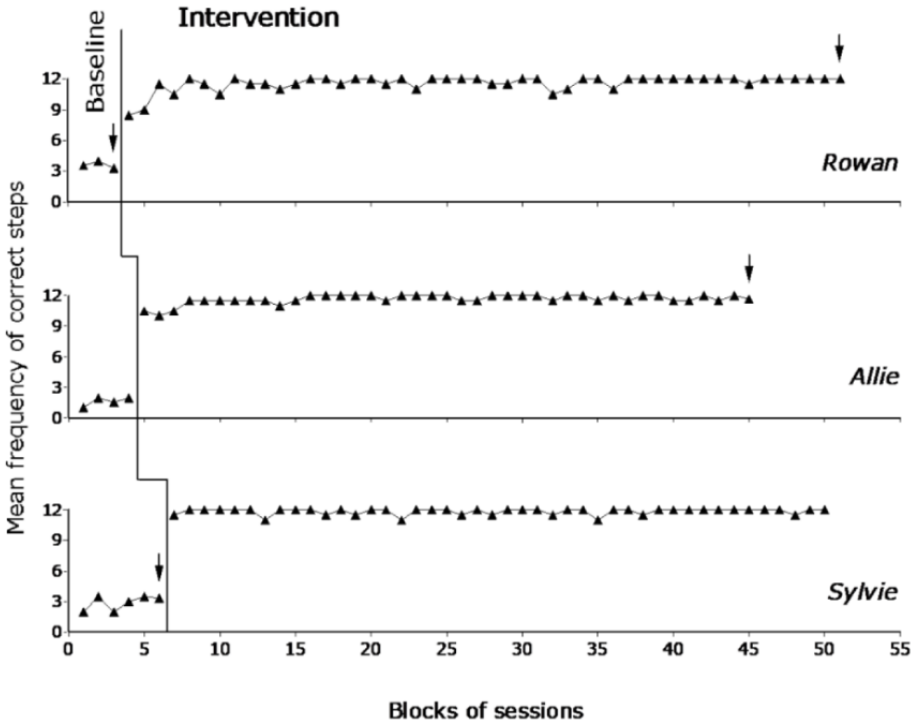

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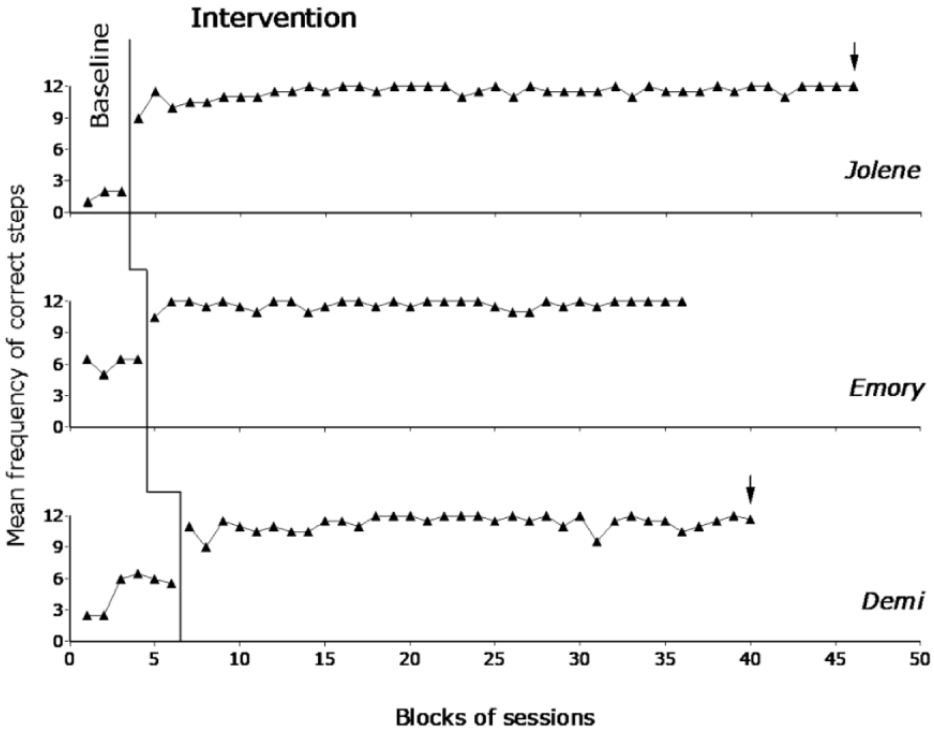
Figure 4. The 3 graphs report the baseline and intervention data for Jolene, Emory, and Demi. Data are plotted as in Figure 3.



Discussion

Principal Findings

The results suggest that the technology system used during the intervention was adequate to help the participants receive step instructions in a timely fashion and without the need to produce specific responses on the tablet. The participants' high frequency of correct task steps and the stability of such frequency across the intervention phase suggest that the instruction process was suitable for them and that they had sufficient motivation to maintain their task performance over time [38-40]. In light of the above, a few considerations may be in order.

First, the new technology system seems to have the characteristics required to bypass the limitations of the two main instruction technology approaches typically used with people with intellectual and developmental disabilities, that is, the approach requiring the participants to seek the instructions through simple responses on the tablet or computer's screen and the approach providing automatic presentation of the instructions, at preset time intervals [1,4]. Indeed, by avoiding the need for fine motor request responses, the new system can successfully help participants who, due to poor fine motor skills, would fail to benefit from the first approach. Moreover, by ensuring a timely presentation of the step instructions based on the participants' walking to the tablet, the new system would avoid any reliance on prearranged instruction deliveries and related risks of instruction neglect in case of performance difficulties or slowness.

Second, the system can be flexible concerning the way the instructions are presented. As viewed in this study, for example, the system can be set to present the two instructions concerning each task step at successive times for people who can handle only one simple instruction at a time (people with poor working memory [41,42]). The system can also be set to present the two instructions of each step simultaneously for participants who are able to handle more complex instruction inputs. Technically, the system could also be set up to present the step instructions in small chunks with people who have a relatively high level of functioning or have become very familiar with the tasks on hand and no longer need an analytic step-by-step instruction process [43-46].

Third, the system can be easily used for supporting tasks that may change across days in terms of the steps included. The most direct and fast way to arrange the sequence of steps included in the task on any particular day is to provide the system with a sequence of numbers representing the codes for those steps [16]. To facilitate the use of the system by staff and caregivers who have limited familiarity with technology, the system could be fitted with a series of tasks and variations thereof that can be selected by writing their names or any other code used in storing them in the tablet memory.

Fourth, the use of a webcam to trigger the tablet to present instructions can be considered a rather simple technology solution [47-50]. The webcam is a small battery-powered device connected to the tablet via Bluetooth, a device that is much simpler and easier to operate than conventional motion sensors, such as the Philips Hue motion sensors [51]. Moreover, the webcam's cost (about US $60) is largely affordable [52]. When using the system within a daily context, one would be advised to locate the webcam and the tablet in a room corner. This would minimize the risk that people sharing the room with the participants can accidentally interfere with the system's functioning.

Limitations and Future Research

The study presents 4 basic limitations, namely, the small number of participants, lack of generalization and maintenance data,

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lack of participants' satisfaction data, and lack of social validation of the technology and its impact. The first limitation reflects the preliminary nature of the study, prevents one from making general statements about the findings reported, and underlines the need for new studies with additional participants [53-55]. The second limitation calls for new studies directed at (1) extending the number of sessions implemented and the intervention period to verify whether the intervention effects last and consolidate over time and (2) carrying out the sessions in different settings (provided these were familiar to the participants) to determine how extensively and profitably the system could be used within daily contexts [39,55-57].

The third limitation necessitates assessing how the participants perceive the intervention program. The assessment could consist of having the participants choose between the sessions with the system and other types of daily occupation. Large levels of preference for the sessions over other types of occupation would suggest participants' satisfaction with the sessions [58-61]. The fourth limitation underlines the need for new studies to include staff and caregivers in the evaluation of the technology and its impact, as these personnel are finally responsible for applying the program and its technology in daily contexts. A practical way to include these personnel in the evaluation could involve (1) the personnel's access to videos reporting the performance of different participants during intervention sessions and (2) the personnel's rating of the videos on points such as the participants' comfort during the sessions, the relevance of their task performance, and the overall acceptability and applicability of the intervention program [62,63].

Conclusions

In conclusion, the results of this study suggest that the technology system used for the intervention program implemented with 6 participants was effective in helping them carry out fairly complex tasks independently and accurately. Although quite encouraging, these results are to be taken with caution, given the limitations of the study mentioned above. New studies should address those limitations and provide the evidence necessary to determine the applicability and impact of the present technology-aided program. New research may also assess the possibility of upgrading and optimizing the technology to facilitate and extend its use across settings and people.

Data Availability

The data sets generated during and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

GEL was responsible for setting up the study, acquiring and analyzing the data, as well as writing the manuscript. NNS, MFO, and JS collaborated in setting up the study, analyzing the data, and editing the manuscript. GA, IO, VC, and LD collaborated in setting up the study and the technology system, acquiring and analyzing the data, as well as editing the manuscript.

Conflicts of Interest

None declared.

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Original Paper

Potential Effects of an Exoskeleton-Assisted Overground Walking Program for Individuals With Spinal Cord Injury Who Uses a Wheelchair on Imaging and Serum Markers of Bone Strength: Pre-Post Study

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Abstract

Background: As many as 60% of individuals use a wheelchair long term after a spinal cord injury (SCI). This mode of locomotion leads to chronic decline in lower-extremity weight-bearing activities and contributes to the development of severe sublesional osteoporosis and high rates of fragility fracture. Overground exoskeleton-assisted walking programs provide a novel opportunity to increase lower-extremity weight bearing, with the potential to improve bone health.

Objective: The aim of the study is to measure the potential effects of an exoskeleton-assisted walking program on lower-extremity bone strength and bone remodeling biomarkers in individuals with chronic (≥18 months) SCI who use a wheelchair.

Methods: In total, 10 participants completed a 16-week exoskeleton-assisted walking program (34 individualized 1-hour sessions, progressing from 1 to 3 per week). Bone mineral density and bone strength markers (dual-energy x-ray absorptiometry: total body, left arm, leg, total hip, and femoral neck and peripheral quantitative computed tomography: 25% of left femur and 66% of left tibia) as well as bone remodeling biomarkers (formation=osteocalcin and resorption=C-telopeptide) were measured before and after intervention and compared using nonparametric tests. Changes were considered significant and meaningful if the following criteria were met: $P<0.1$, effect size ≥0.5, and relative variation >5%.

Results: Significant and meaningful increases were observed at the femur (femoral neck bone mineral content, bone strength index, and stress-strain index) and tibia (cortical cross-sectional area and polar moment of inertia) after the intervention (all $P<.10$). We also noted a decrease in estimated femoral cortical thickness. However, no changes in bone remodeling biomarkers were found.

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Conclusions: These initial results suggest promising improvements in bone strength markers after a 16-week exoskeleton-assisted walking program in individuals with chronic SCI. Additional research with larger sample sizes, longer interventions (possibly of greater loading intensity), and combined modalities (eg, pharmacotherapy or functional electrical stimulation) are warranted to strengthen current evidence.

Trial Registration: ClinicalTrials.gov NCT03989752; https://clinicaltrials.gov/ct2/show/NCT03989752

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KEYWORDS

assistive technology; bone architecture; bone turnover; osteoporosis; rehabilitation; spinal cord injuries; SCI; spinal cord injury; assistive device; wheelchair; exoskeleton device; locomotion; bone strength; risk; fracture

Introduction

Mechanical loading is a key factor influencing bone strength [1]. Indeed, osteocytes detect and respond to mechanical stimuli by triggering an anabolic state that stimulates bone formation and leads to adaptations in bone geometry (known as the "mechanostat principle") [1]. Healthy bones are therefore well adapted to the habitual loads regularly encountered during daily function (ie, concept of specificity) [2]. However, after sustaining a spinal cord injury (SCI), up to 60% of individuals use a wheelchair as their primary mode of locomotion—leading to a chronic reduction in lower-extremity weight bearing and reduced mechanical loading [3]. As a result, these individuals experience an accelerated loss in lower-extremity bone mass, particularly if no mitigation strategies are implemented during the first 18 to 24 months following the SCI [4]. This complication, referred to as sublesional osteoporosis, is associated with an increased risk of fracture, notably at the distal femur and proximal tibia [5].

Bone strength is directly related to fracture risk and can be influenced by several characteristics, such as bone mineral density and content, as well as geometry [6]. Measuring areal bone mineral density by dual-energy x-ray absorptiometry (DEXA) remains widely recommended to assess fracture risk in this population [7]. Indeed, low areal bone mineral density has been associated with increased risks of lower-extremity fractures in individuals with SCI as well as in the general population [8]. However, solely relying on areal bone mineral density to assess bone strength can be misleading since DEXA images display 2D (ie, x- and y-axis) representations of 3D structures (ie, loss of the z-axis) [9]. DEXA condenses structures by superposing images, causing "deeper" bones to artificially appear denser (ie, increased bone mineral density) and may lead to misclassifying individuals with a lower risk of fracture [9]. As such, this limits the DEXA's capability to inform on bone geometry (eg, cross-sectional areas and cortical thickness) [9,10]. Peripheral quantitative computed tomography (pQCT) aims to overcome this limitation by assessing volumetric bone mineral density based on 3D images [11]. Moreover, pQCT can provide additional advantages by analyzing both trabecular and cortical bone compartments separately (ie, bone geometry) and enable the estimation of mechanical properties of strength (ie, resistivity to compression, bending, and torsion).

Although imaging (DEXA and pQCT) can provide an instantaneous "snapshot" of estimated bone strength, it does not directly assess bone turnover (remodeling). Bone turnover rate can provide fundamental information as to whether bone formation or resorption is dominant at the time of measure. Indeed, serum bone biomarkers (eg, osteocalcin and C-telopeptide) may serve as a precursor indication of a positive therapeutic effect of an intervention, even before changes can be measured with DEXA or pQCT. Osteocalcin is secreted by osteoblasts, is a marker of anabolic bone activity, and has been used in previous studies with individuals with SCI [12]. C-telopeptide, which has also been studied previously in this population, is released during bone resorption and used to characterize catabolic bone activity [13]. Since vitamin D levels can impact bone metabolism, 25-hydroxyvitamin D levels should also be measured as a possible confounding factor when characterizing serum bone biomarkers [7].

Recently, the emergence of wearable robotic exoskeletons has led to new opportunities to develop interventions that can significantly increase lower-extremity weight bearing and mobilization. Among others, a goal of such interventions is to increase bone strength and ultimately mitigate fracture risks (and associated complications) in individuals with SCI. Pilot studies have previously demonstrated that exoskeleton-assisted walking programs are feasible in this population with high rates of satisfaction (95.2%), excellent attendance (ie, 229 completed training sessions out of 234 planned training sessions, 97.9%), and relatively low dropout rates (ie, 1 dropout out of 14 individuals recruited, 7.1%) [14,15]. In terms of learnability and ease of use, most individuals can stand and walk with walking aids and minimal assistance from a therapist by the end of the program (18 to 24 sessions) [15,16]. Walking parameters, including speed and distance, have also been shown to progress consistently and safely over the course of a walking program, especially when individualized progression strategies are used [13,15-19]. Increased walking speed and distance may provide a progressive stimulus for bone strength adaptations, equating to increased intensity and volume for these tissues. Body composition improvements have also been documented following exoskeleton-assisted walking programs, including a decrease in total and regional (ie, lower extremities) body fat and an increase in muscle mass [20]. Overall, these results are encouraging; however, the effects on bone have not been comprehensively evaluated to date.

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Thus, the main objective of this paper was to measure the potential effects of a 16-week exoskeleton-assisted walking program on lower-extremity bone density and strength and serum bone turnover markers in individuals with SCI who use a wheelchair [21]. It was hypothesized that immediate positive and meaningful effects would be observed on bone mineral density, mineral content, geometry, and mechanical strength indexes in the lower extremities as well as serum markers of bone turnover (ie, increase in bone formation markers and decrease in bone resorption markers) following the intervention.

Methods

Ethical Considerations

Ethics approval for this study was received on March 14, 2019, from the Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal ethics committee (CRIR-1338-0518). The protocol has been published previously and was registered with the US National Library of Medicine on June 7, 2019 (ClinicalTrials.gov NCT03989752) [21].

Study Design and Participants

This prospective pre- and postinterventional study included adults (≥18 years of age) with chronic (ie, ≥18 months) complete or incomplete SCI. To be included, individuals needed to use a wheelchair as their primary mode of locomotion, understand French or English, and reside (or be able to arrange to reside) within 75 km of the main research site. Individuals were excluded if they had neurological impairments unrelated to the SCI (eg, multiple sclerosis); had a concomitant or secondary musculoskeletal impairment limiting their ability to safely ambulate (eg, hip heterotopic ossification); had a history of fragility fracture within the past year; or had any other condition that may preclude safe lower-extremity weight bearing, walking, or exercise tolerance (eg, unstable cardiovascular or autonomic system and renal insufficiency). Individuals also had to meet criteria specific to the wearable robotic exoskeleton (Ekso GT; Ekso Bionics) used in this study, including maximum anthropometric measures and minimal lower- and upper-extremity range of motion. Inclusion and exclusion criteria are described in greater detail in the published (open access) protocol [21].

Measurement Times and Intervention

Due to constraints imposed by the COVID-19 pandemic (Multimedia Appendix 1), the 4 measurement times in the published protocol were not possible. Measurement times were only possible before the intervention (2 measurements) and immediately after the intervention (1 measurement). A participant's preintervention measurements represented the average value between measurements taken before 4 weeks and immediately before initiating the intervention. Postintervention measurements were solely taken immediately following the end of the intervention (ie, within 7 days).

Following preintervention measurements, individuals engaged in a wearable robotic exoskeleton–assisted overground walking program consisting of 34 sessions (60 minutes per session) over a 16-week period. A published algorithm was used to individualize training volume and progression based on osteoporotic profile determined by DEXA [19]. Individuals were classified in 1 of 3 profiles: osteoporosis, osteopenia, or preserved bone mineral density. The number of steps taken per training session was then modulated, starting at 300, 400, and 500, and progressed weekly by 10%, 15%, and 20%, respectively, according to the assigned profile. For all profiles, individuals began with 1 training session per week and progressed to 3 training sessions per week by the end of the program. To maintain a moderate to vigorous exercise intensity during the sessions, walking speed, resting time, assistive devices (ie, walker or crutches), and assistance provided by the therapist were modulated to ensure a rate of perceived exertion of ≥3/10. All training sessions were supervised by a certified physiotherapist, with the help of a second physiotherapist or a physiotherapy technician if necessary.

The exoskeleton-assisted walking program was performed using the Ekso GT exoskeleton. This ready-to-wear exoskeleton has motorized hip and knee joints and semirigid ankle orthoses. Several sensors integrated into the exoskeleton (accelerometers, gyroscopes, pressure sensors, etc) are used to detect weight transfers and movements. Front and lateral spatial targets are used to guide weight transfer with an audible sound emitted when targets are reached. Step initiation depends on the walking mode used. In "FirstStep" mode, front and lateral spatial targets must be reached, followed by the press of a confirmation button by the therapist for stepping movements to be initiated. In "ProStep" mode, stepping is automatically initiated once front and lateral spatial targets are reached (no confirmation button is pressed). In "ProStep+" mode, the lateral spatial target must be reached (no front target is necessary), and the participant must initiate a hip flexion moment to activate stepping. Additionally, the exoskeleton also provides different levels of assistance, from partial (the participant must generate some lower extremity force, and the exoskeleton assists as required) to maximal (the participant does not generate lower extremity force, and the exoskeleton realizes all movements).

Outcomes

DEXA Measurement

Total body, lumbar, and left hip mineral density and content were measured using DEXA (General Electric Lunar Prodigy; standard mode; version 12.30.008). Calibration was executed daily with a standard phantom prior to each test. Participants were asked to fast for at least 8 hours prior to the assessment. Participants were also asked to empty their bladder if they had not done so within the hour preceding the DEXA. Scans were taken following the standardized protocol recommended by the manufacturer. For all scans, participants lay supine, free of jewelry or any other metallic objects. Clothing worn was noted, and participants were asked to wear the same clothing for repeated scans. For lumbar scans, participants' lower extremities rested on a block to maintain a flexed-hip position and reduce lumbar lordosis, as recommended by the Centers for Disease Control and Prevention [22]. For hip scans, a triangular bracing device attached to the feet maintained the lower extremity in slight internal rotation, as recommended by the Centers for Disease Control and Prevention [22]. Quantitative analysis was provided automatically by the manufacturer's software. Total

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body, L4 lumbar vertebrae, left arm, left leg, left total hip, and left femoral neck bone mineral densities and contents were selected as outcomes of interest. Total body measurements provided an estimate of the whole skeletal system. Lumbar vertebrae and left arm measurements provided comparators for lower extremity measurements, as changes were not expected to occur at these sites. Left leg measurements provided an estimate of the overall response of the lower extremities, which complemented the more specific pQCT measurements (described hereafter). Total hip and femoral neck sites provided a comparator with the broader osteoporosis literature, as these remain standard measurements for all populations with osteoporosis. When applicable, the left side of the body was selected to match with the pQCT scan sites.

pQCT Measurement

All pQCT imaging was realized on the left distal femur and proximal tibia. A standardized scan protocol was developed based on previous recommendations [11]. Calibration was executed daily with a standard phantom prior to each test. For all scans, a voxel size of 0.5×0.5 mm was used, and the scan speed was set to 10 mm/s to optimize resolution for bone and soft tissues. The total length was measured manually for the femur from the lateral femoral condyle to the greater trochanter [11]. To ensure location consistency for repeated scans, scout scans were realized at the knee joint with a reference line placed at the distal limit of the lateral femoral condyle. Following the scout scan, the pQCT was programmed to take one 2-mm slice at 25% of the total bone length calculated from the reference line. For the tibia, the total length was measured manually from the medial malleolus to the medial plateau [11]. To ensure location consistency for repeated scans, scout scans were realized at the knee joint with a reference line placed at the most distal and flattest portion of the tibial plateau. Following the scout scan, the pQCT was programmed to take one 2-mm slice at 66% of the total length calculated from the distal limit of the bone (using the reference line in this study, this equates to 33% from the knee joint). Both sites were selected to optimize for the presence of both bone and soft tissues in the scans.

Prior to quantitative analysis, the quality of all pQCT images was independently assessed by 2 evaluators (AB and MG or JTATL) using a previously published 5-level visual inspection and quality scale, where an image score of 1 indicated high quality and an image score of 5 represented low quality [23]. To further standardize the assessment of image quality, the following criteria were agreed upon between evaluators: score 1, if the image was free of movement artifacts; score 2, if the image was only a few movement artifacts; score 3, if the image had several movement artifacts, but periosteum continuity was not affected; score 4, if the image had several movement artifacts, and periosteum continuity was affected; and score 5, if the image had movement artifacts leading to complete loss of bone continuity. A mean score was calculated for each image. Scans with a mean score greater than 3 were excluded, as such quality of the image has been proposed to be incompatible with quantitative analysis software [23]. Excluded images were treated as missing data, and measurements were computed following an intention-to-treat protocol.

Quantitative analysis of pQCT scans was realized using the manufacturer's software (Stratec XCT-3000; version 6.20). For all scans, contour mode 3 with a threshold set to 130 mg/cm^3, peel mode 2 set to 400 mg/cm^3, and separation mode 4 with an outer threshold of 200 mg/cm^3 and an inner threshold of 650 mg/cm^3 were used [11]. Outcomes of interest were those related to bone mineral density (total, trabecular, and cortical), bone mineral content (total, trabecular, and cortical), bone geometry (cross-sectional areas and cortical thickness), and mechanical strength indexes (bone strength index, stress-strain index, and polar moment of inertia) [7,11].

The software provides 2 measurements for cortical thickness. The first (CRT_THK), referred hereafter as measured cortical thickness, is the mean cortical thickness based on an iterative algorithm that attempts to draw the endosteal and periosteal borders by consecutively comparing neighboring voxels (pixels). Due to occasional failure of the algorithm, particularly in individuals with severe cortical thinning and loss of cortical bone mineral density (ie, many individuals with chronic SCI), the software also provides a second measurement. This measurement (CRT_THK_C), referred hereafter as estimated cortical thickness, is based on a subtraction of endosteal radius from periosteal radius in a theoretical circular model, where total and trabecular cross-sectional areas match those measured. Since measured cortical thickness systematically failed in 2 participants, estimated cortical thickness is also reported in this study.

Estimations of mechanical strength indexes are based on material properties and are calculated as follows. The bone strength index is the product of total bone mineral density squared by total cross-sectional area (ie, bone strength index = total bone mineral density^2 × total cross-sectional area) and is indicative of resistance to compression [10,24]. The stress-strain index (resistivity to bending) is based on the calculation of the cross-sectional moment of inertia (ie, area moment of inertia or second moment of area) [10,24]. The cross-sectional moment of inertia considers the distance of cortical bone from the central axis of the bone. The greater the distance separating cortical bone from the central axis, the greater the resistivity. To calculate the stress-strain index, section modulus (Z) is computed from the cross-sectional moment of inertia in the transversal plane. Section modulus is then weighted against measured cortical bone mineral density. Thus, resistance to bending is influenced by cortical size, shape, and mineral density [10,24]. Polar moment of inertia is based on the calculation of the cross-sectional moment of inertia in the longitudinal plane [10,24]. Thus, resistance to torsion is influenced by cortical size and shape but not mineral density [10,24]. The pQCT-related variables of interest and their cross-relationships are summarized in Figure 1.

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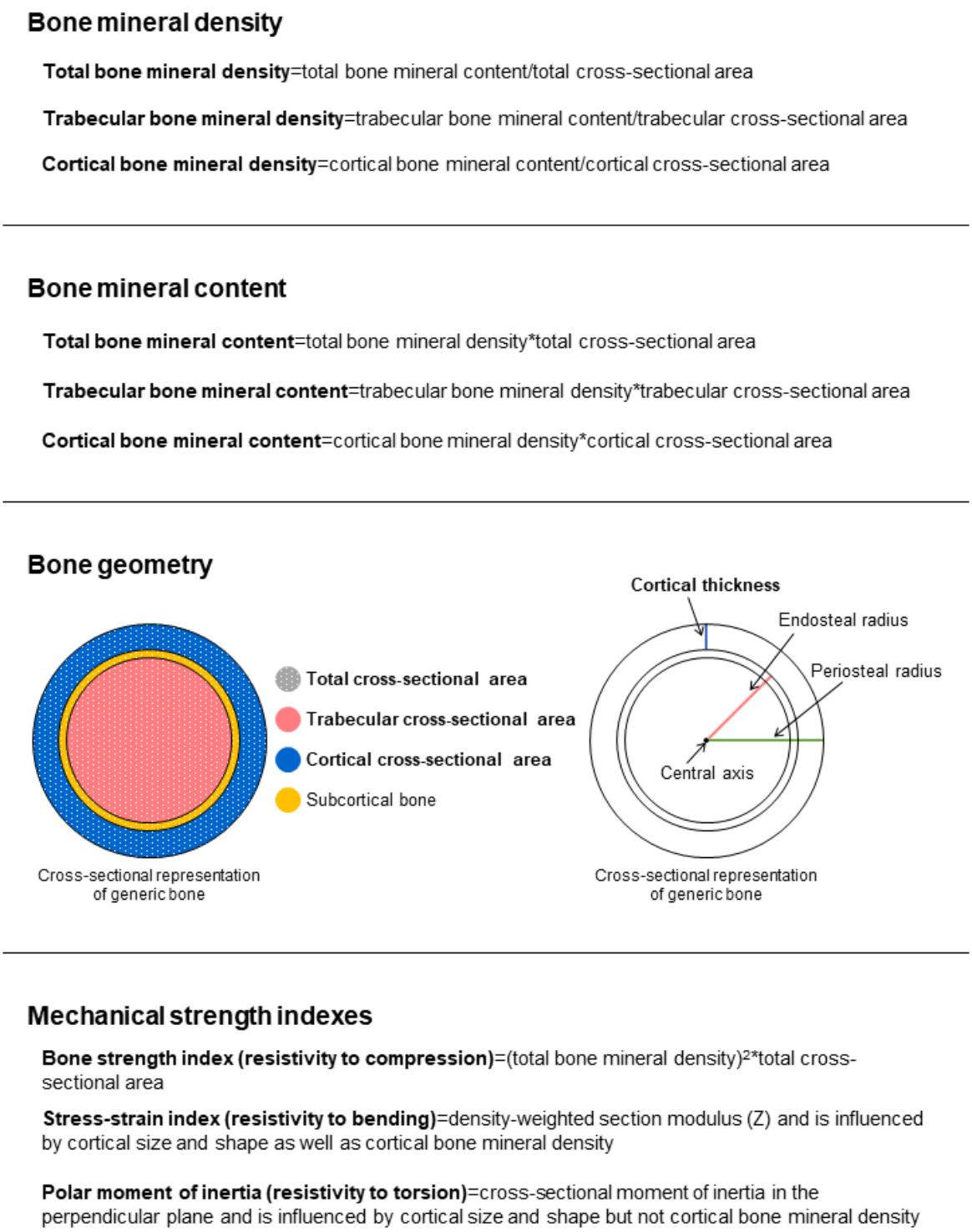
Figure 1. Summary of, and relationships between, outcomes of interest for peripheral quantitative computed tomography.



Blood Samples

Blood samples were drawn in the morning, following an 8-hour fast, by a licensed nurse into gold-top serum separator and lavender-top anticoagulant ethylenediaminetetraacetic acid tubes. Samples were immediately placed on ice and centrifuged within an hour. Serum (from gold-top serum separator tubes) and plasma (from lavender-top anticoagulant ethylenediaminetetraacetic acid tubes) were collected and stored at –80 °C until analysis. Blood samples were transported on dry ice to a university hospital laboratory at the McGill University Health Centre for analysis after the completion of the study. Serum was used to measure 25-hydroxyvitamin D, and plasma was used to measure osteocalcin and C-telopeptide.

Statistics

Descriptive statistics were used to characterize participants. Since the sample size was limited and some outcome measures

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were not normally distributed, nonparametric tests (ie, Wilcoxon signed rank test) were used to compare pre- versus postintervention data. Standardized effect sizes (*r*) were calculated by dividing the *z* value by the square root of the number of observations and interpreted as being negligible (<0.1), small (≥0.1), medium (≥0.3), or large (≥0.5) [25]. Relative pre- versus postintervention median variations (%) were also computed for all outcomes. Given the explorative nature of this study, three criteria needed to be met to reach significance and meaningfulness: (1) the α for statistical tests needed to be <.10 to balance the risk of false negatives due to an anticipated lack of statistical power, (2) calculated effect sizes needed to be large (ie, ≥0.5) for an outcome to be deemed potentially clinically relevant, and (3) relative variation needed to be greater than 5% to be considered as a change exceeding natural variability and potential measurement errors. This threshold has been used in previous work, as the least significant change reportedly varies between 2% and 5% for DEXA and pQCT depending on the location of the scan [12,26]. All statistical analyses were conducted using SPSS (version 28; IBM Corp).

Results

Overview

Characteristics of the participants are summarized in Table 1. Among the 10 participants, only 1 had a very minimal motor function in the lower extremities (lower-extremity motor score: 5 out of 50), although it was not sufficient for active participation of the lower extremities during the exoskeleton-assisted walking program. Therefore, the exoskeleton was programmed to detect body weight shifts and realize stepping movements without active participation of the lower extremities ("ProStep" mode with maximal assistance in the exoskeleton) for all participants.

Table 1. Description of the participants (N=10).

Participant ID	Sex	Age (y)	BMD profile[a]	Walking program progression	Neurological lesion level	AIS[b]	LEMS[c]	Exoskeleton mode (Ekso GT)	SCI[d] duration (y)	Weight (kg)	Height (m)	BMI (kg/m^2)	Total body fat (%)[e]
1	Male	41	Preserved	Fast	T8	A	0	ProStep	9.6	66.7	1.71	22.8[f]	34.1[f]
2	Male	36	Preserved	Fast	T6	A	0	ProStep	11.6	99.7	1.92	27.0[f]	39.5[f]
3	Male	67	Preserved	Fast	T10	A	0	ProStep	12.0	92.3	1.88	26.1[f]	37.8[f]
4	Male	60	Preserved	Fast	T11	A	0	ProStep	3.3	90.6	1.74	29.9[f]	38.7[f]
5	Female	35	Preserved	Fast	C3	C	0	ProStep	3.6	50.2	1.65	18.4	29
6	Male	32	Osteopenia	Moderate	T3	A	0	ProStep	8.6	73.5	1.75	24.0[f]	24.6[f]
7	Female	48	Osteopenia	Moderate	T12	B	5	ProStep	45.5	62.4	1.60	24.4[f]	51.8[f]
8	Female	42	Osteopenia	Moderate	T3	A	0	ProStep	7.7	70.7	1.66	25.7[f]	44.4[f]
9	Female	55	Osteoporosis	Slow	T4	A	0	ProStep	7.8	61.2	1.66	22.2[f]	43[f]
10	Male	47	Osteoporosis	Slow	C5	A	0	ProStep	18.3	81.3	1.86	23.5[f]	42.7[f]
Mean (SD)	N/A[g]	46.3 (10.9)	N/A	N/A	N/A	N/A	N/A	N/A	12.8 (11.6)	74.9 (15.0)	1.70 (0.10)	24.4 (2.9)	38.5 (7.4)

[a]BMD profile: preintervention bone mineral density profile of the left hip as measured by dual-energy x-ray absorptiometry (DEXA).

[b]AIS: American Spinal Injury Association Impairment Scale.

[c]LEMS: lower-extremity motor score on the AIS.

[d]SCI: spinal cord injury.

[e]Total body fat percentage as measured by DEXA.

[f]Identifies obesity using criteria recommended by Paralyzed Veterans of America (BMI≥22 kg/m^2 or body fat>22% in men and >35% in women) [27].

[g]N/A: not applicable.

DEXA Outcome Measures

Outcome measures for DEXA are summarized in Table 2. Only the left femoral neck bone mineral content met all 3 criteria with a *P*=.08, a large effect size (0.55), and a relative increase of 6% postintervention.

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Table 2. Summary of dual-energy x-ray absorptiometry outcome measures (N=10).

Outcomes	Preintervention, median (IQR)	Postintervention, median (IQR)	*P* value	Effect size[a]	Δ[b] (%)
Areal bone mineral densities (g/cm^2)					
Total body bone mineral density	1.159 (1.060-1.277)	1.145 (1.082-1.267)	.80	0.08 (N)	–1.2
Left arm bone mineral density	1.046 (0.909-1.155)	1.073 (0.889-1.221)	.51	0.20 (S)	+2.6
Left leg bone mineral density	1.018 (0.613-0.898)	0.979 (0.442-0.902)	.45	0.24 (S)	–3.8
Left total hip bone mineral density	0.862 (0.756-0.992)	0.832 (0.755-0.989)	.68	0.13 (S)	–3.4
Left femoral neck bone mineral density	0.852 (0.765-0.992)	0.908 (0.770-0.947)	.11	0.50 (L)	+6.6
Bone mineral contents (g/cm)					
Total body bone mineral content	2759 (2377-3499)	2757 (2365-3466)	.33	0.31 (M)	–0.1
Left arm bone mineral content	188 (174-236)	202 (173-241)	.65	0.15 (S)	+7.3
Left leg bone mineral content	393 (300-510)	370 (312-528)	.80	0.08 (N)	–5.9
Left total hip bone mineral content	28.3 (20.8-34.9)	32.1 (20.2-36.7)	.39	0.27 (S)	+13.5
Left femoral neck bone mineral content[c]	4.5 (3.5-6.0)	4.8 (3.6-5.9)	*.08*[d]	*0.55 (L)*	*+6*

[a]Standardized effect sizes interpreted as N=negligible (<0.1), S=small (≥0.1), M=medium (≥0.3), or L=large (≥0.5).

[b]Δ=relative variation between medians (positive indicates an increase in value from pre- to postmeasurement).

[c]Italics format indicates variables meeting the following 3 criteria: statistically significant difference, effect size ≥0.5, and relative median difference ≥5%.

[d]Statistically significant difference (*P*≤.10) for Wilcoxon signed rank tests.

pQCT Outcome Measures

For the femur, outcome measures for pQCT are summarized in Table 3. Although 9 outcomes were statistically significant (*P*<.10), only 3 had large effect sizes and sufficient relative changes to be considered as intervention effects. Bone strength index (resistivity to compression; *P*=.09) and stress-strain index (resistivity to bending; *P*=.01) increased by 9.6% and 11%, respectively, whereas estimated cortical thickness (*P*=.01) decreased by 9.9%. Of note, scans at the femur were not possible for 1 participant (participant 10), as his weight and lack of core stability impeded his ability to safely take and maintain the crouched sitting position necessary to set up the femur into the pQCT.

For the tibia, outcome measures for pQCT are summarized in Table 4. Although 6 outcomes were statistically significant (*P*<.10), only 2 had large effect sizes and sufficient relative changes to be considered potential intervention effects. Cortical cross-sectional area (*P*=.06) and polar moment of inertia (*P*=.01) increased by 7.3% and 5.1%, respectively.

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Table 3. Summary of peripheral quantitative computed tomography outcome measures at 25% of the left femur (n=9).

Outcomes	Preintervention, median (IQR)	Postintervention, median (IQR)	*P* value	Effect size[a]	Δ[b] (%)
Volumetric bone mineral densities (mg/cm^3=)					
Total bone mineral density	355.8 (334.2-470.5)	381.6 (330.8-442.6)	.51	0.22 (S)	+7.3
Trabecular bone mineral density	87.7 (80.5-113.0)	88.5 (83.6-110.0)	.15	0.22 (S)	+1
Cortical bone mineral density	905.9 (805.0-968.1)	938.2 (871.5-981.6)	.04[c]	0.69 (L)	+3.6
Bone mineral contents (mg/mm)					
Total bone mineral content	346 (275-434)	341 (266-429)	.05[c]	0.65 (L)	–1.5
Trabecular bone mineral content	46.6 (37.9-76.7)	48.0 (39.1-78.4)	.95	0.02 (N)	+3
Cortical bone mineral content	275 (224-350)	268 (217-343)	.01[c]	0.89 (L)	–2.5
Bone geometry					
Total cross-sectional area (mm^2)	822 (736-1066)	805 (770-1023)	.14	0.49 (L)	–2
Trabecular cross-sectional area (mm^2)	489 (418-700)	472 (435-659)	.46	0.25 (S)	–3.4
Cortical cross-sectional area (mm^2)	312 (233-394)	305 (221-354)	.01[c]	0.89 (L)	–2.4
Measured cortical thickness (n=7; mm)	4.03 (3.56-4.28)	3.88 (3.31-4.23)	.03[c]	0.83 (L)	–3.6
Estimated cortical thickness (mm)[d]	3.28 (2.89-3.44)	2.95 (2.95-3.35)	*.01*[c]	*0.85 (L)*	*–9.9*
Mechanical strength indexes					
Compression: bone strength index (g/cm^4)	1.35 (1.16-1.60)	1.48 (0.94-1.51)	*.09*[c]	*0.57 (L)*	*+9.6*
Bending: stress-strain index (mm^3)	2240 (2047-2589)	2486 (2356-2706)	*.01*[c]	*0.89 (L)*	*+11*
Torsion: polar moment of inertia (mm^4)	48,002 (43,337-72,759)	48,800 (42,470-71,304)	.02[c]	0.77 (L)	+1.7

[a]Standardized effect sizes interpreted as N=negligible (<0.1), S=small (≥0.1), M=medium (≥0.3), or L=large (≥0.5).

[b]Δ=relative variation between medians (positive indicates an increase in value from pre- to postmeasurement).

[c]Statistically significant difference (*P*≤.10) for Wilcoxon signed rank tests.

[d]Italics format indicates variables meeting the following 3 criteria: statistically significant difference, effect size ≥0.5, and relative median difference ≥5%.

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Table 4. Summary of peripheral quantitative computed tomography outcome measures at 66% of the left tibia (N=10).

Outcomes	Preintervention, median (IQR)	Postintervention, median (IQR)	*P* value	Effect size[a]	Δ[b] (%)
Volumetric bone mineral densities (mg/cm^3)					
Total bone mineral density	666.0 (571.1-772.6)	669.2 (554.0-772.4)	.06[c]	0.60 (L)	+0.5
Trabecular bone mineral density	97.3 (86.0-105.9)	95.0 (81.3-109.5)	.14	0.47 (M)	–2.4
Cortical bone mineral density	984.9 (961.0-1007.9)	956.4 (898.2-1004.8)	.07[c]	0.56 (L)	–2.9
Bone mineral contents (mg/mm)					
Total bone mineral content	326 (288-425)	333 (292-427)	.14	0.47 (M)	+2.3
Trabecular bone mineral content	20.1 (12.5-24.5)	18.0 (13.1-24.4)	.88	0.05 (N)	–10.1
Cortical bone mineral content	283 (264-394)	288 (270-398)	.09[c]	0.53 (L)	+1.9
Bone geometry					
Total cross-sectional area (mm^2)	602 (425-621)	610 (423-660)	.06[c]	0.60 (L)	+1.4
Trabecular cross-sectional area (mm^2)	224 (124-274)	217 (124-295)	.34	0.50 (L)	–3
Cortical cross-sectional area (mm^2) [d]	294 (267-388)	315 (273-420)	*.06* [c]	*0.60 (L)*	*+7.3*
Measured cortical thickness (n=8; mm)	5.22 (4.74-5.67)	5.31 (4.86-5.53)	.12	0.54 (L)	+1.8
Estimated cortical thickness (mm)	4.80 (3.96-5.48)	4.70 (4.26-5.78)	.33	0.31 (M)	–2.1
Mechanical strength indexes					
Compression: bone strength index (g/cm^4)	2.06 (1.67-2.85)	2.03 (1.63-2.88)	.20	0.40 (M)	–1.5
Bending: stress-strain index (mm^3)	1838 (1346-2294)	1828 (1300-2250)	.58	0.18 (S)	–0.5
Torsion: polar moment of inertia (mm^4)	35,706 (23,560-47,987)	37,539 (23,638-49,806)	*.01* [c]	*0.79 (L)*	*+5.1*

[a]Standardized effect sizes interpreted as N=negligible (<0.1), S=small (≥0.1), M=medium (≥0.3), or L=large (≥0.5).

[b]Δ=relative variation between medians (positive indicates an increase in value from pre- to postmeasurement).

[c]Statistically significant difference (*P*≤.10) for Wilcoxon signed rank tests.

[d]Italics format indicates variables meeting the following 3 criteria: statistically significant difference, effect size ≥0.5, and relative median difference ≥5%.

Serum Bone Turnover Biomarkers

Outcome measures for serum bone turnover biomarkers are summarized in Table 5. Only 25-hydroxyvitamin D met all 3 criteria with a *P*=.03, a large effect size, and a relative increase of 11.4% postintervention.

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Table 5. Summary of serum bone turnover biomarkers (N=10).

Outcomes	Preintervention, median (IQR)	Postintervention, median (IQR)	*P* value	Effect size[a]	Δ[b] (%)
Bone formation (µg/L)					
Osteocalcin	18.3 (15.6-19.4)	21.0 (15.3-24.0)	.20	0.69 (L)	+15.1
Bone resorption (µg/L)					
C-telopeptide	0.3 (0.2-0.4)	0.3 (0.2-0.4)	.17	0.43 (M)	–13.8
Others (nmol/L)					
25-Hydroxyvitamin D[c]	74.5 (62.4-111)	83.0 (66.3-129)	*.03* [d]	*0.69 (L)*	*+11.4*

[a]Standardized effect sizes interpreted as N=negligible (<0.1), S=small (≥0.1), M=medium (≥0.3), or L=large (≥0.5).

[b]Δ=relative variation between medians (positive indicates an increase in value from pre- to postmeasurement).

[c]Italics format indicates variables meeting the following 3 criteria: statistically significant difference, effect size ≥0.5, and relative median difference ≥5%.

[d]Statistically significant difference (*P*≤.10) for Wilcoxon signed rank tests.

Discussion

Principal Findings

Results of this preliminary study indicate that the completion of a progressive 16-week exoskeleton-assisted walking program may elicit some beneficial bone adaptations in individuals with chronic SCI who have limited-to-no motor function in their lower extremities and use a manual wheelchair as their primary mode of locomotion.

DEXA Revealed an Increase in Left Femoral Neck Bone Mineral Content, but No Changes in Bone Mineral Densities

Left femoral neck bone mineral content increased significantly and meaningfully following the intervention which is, to our knowledge, a novel and key finding partly supporting our hypotheses. Moreover, a similar trend (ie, *P*=.11) was also observed in left femoral neck bone mineral density (ie, +6.6% with a large effect size). Indeed, since bone mineral content and density are directly related (ie, bone mineral density = bone mineral content / area), it would be expected for both to change together. Directly comparing our results to the literature remains difficult due to the lack of previously published evidence. This is particularly true with regard to bone mineral content, as this outcome has not been reported in the limited available literature with regard to exoskeleton-assisted overground walking and treadmill-based interventions [12,20,28-32].

Nevertheless, with regard to exoskeleton-assisted overground walking, a pilot study conducted in our laboratory did not reveal any significant changes in total body and total leg areal bone mineral densities, which is consistent with this study [20]. To our knowledge, only 2 other studies have reported areal bone mineral density measurements following exoskeleton-assisted overground walking. First, in a pilot study, an upward trend in areal bone mineral density was reported following 8 weeks of training (1 hour per session, 2 sessions per week). However, the authors neither specify in what body region this occurred nor present data to support this claim [28]. Second, in a pilot randomized controlled trial, including 16 participants with SCI (≥2 years) who use a wheelchair, areal bone mineral density (total hip and femoral neck) decreased in the activity-based exercise training group (60 minutes per session, 3 sessions per week for 24 weeks), whereas it remained stable in the exoskeleton-assisted walking group (60 minutes per session, 3 sessions per week for 24 weeks). It was hypothesized that exoskeleton-assisted walking may provide a sufficient stimulus to maintain areal bone mineral density but perhaps not to augment it [29]. Since this study did not include a comparison group, it remains unclear whether the areal bone mineral densities measured in our participants would have decreased further over the course of the study had they not participated in the walking program. However, all participants in this study sustained their SCI at least 3 years before initiating the study and were deemed to have reached a stable state in terms of bone mineral density. To this effect, it is now well evidenced that bone loss is greatest within the first 18 to 24 months following the lesion and tends to slow considerably thereafter [4]. Although a true steady state in bone mass may never be reached, it would be premature to state that the intervention in this study had a protective effect on areal bone mineral density [33]. Such a hypothesis would be best tested by recruiting participants who recently sustained their SCI (ie, no more than 2 years prior) and including a comparison group.

The effects of treadmill-based walking programs have also been reported in the literature using robotic assistance (eg, Lokomat; Hocoma), functional electrical stimulation, or manual assistance [12,30,31]. To our knowledge, no study has reported bone mineral content, and no changes in areal bone mineral density have been previously found [12,30-32]. Since these programs imply the use of partial body weight support, the gravity-related mechanical effects decreased considerably in comparison to overground walking, which may impede the effectiveness of such programs. This is further highlighted by the fact that treadmill-based walking programs have also been tested in combination with pharmacotherapy (ie, teriparatide) and functional electrical stimulation, which should have optimized the potential effects on bone [12,30].

Overall, this study suggests that exoskeleton-assisted overground walking may elicit a beneficial bone response at the hip that can be detected by DEXA. A combination of pharmacotherapy

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(eg, teriparatide), functional electrical stimulation, and overground walking may be needed to provide an optimal anabolic stimulus to significantly increase areal bone mineral density, and this warrants consideration for future research.

Potential Improvements in Bone Strength as Measured by pQCT

A few pQCT outcomes changed significantly and meaningfully following the completion of the intervention. This result supports our hypotheses in part. Four such outcomes increased, suggesting positive bone strength adaptations: femoral bone strength index (compression), femoral stress-strain index (bending), tibial cortical cross-sectional area, and tibial polar moment of inertia (torsion).

With regard to the femur, to our knowledge, the increase in bone strength index is a novel finding [12,20,30-32,34]. However, an increase in stress-strain index has been previously reported in a case study following robotic-assisted treadmill training [34]. Yet, the amplitude of change reported in this previous case study (right femur=+2% and left femur=+0.5%) was much lower than in this study (ie, +11%), and may not have exceeded natural variability or measurement error. Nevertheless, these findings highlight the importance of including both femoral and tibial measurements with pQCT in this population. Since bone is expected to respond in areas of greatest mechanical strain, certain biomechanical concepts may help partially explain the results in this study [33]. First, although the increase in bone strength index would be expected with increased weight-bearing, the design of the exoskeleton may also contribute to greater compression forces at the femur during heel strike. Indeed, the exoskeleton used in this study uses a brace at the proximal tibia, just below the knee, to counteract the forward velocity of the lower limb (and body) during heel strike. Since the individuals in this study had very little-to-no motoricity in the lower limbs, this forward velocity could not be absorbed to the same extent by musculotendinous structures (ie, through eccentric contraction of the quadriceps) and would therefore be mainly absorbed by the skeletal (ie, femur) and ligamentous structures [35]. Second, due to the oblique orientation of the femoral diaphysis, it is possible that the forces with heel strike and unilateral stance during walking provide greater strain (ie, bending force) to the femur than the tibia, which may have also contributed to the results in this study [36]. Overall, these hypotheses warrant further investigation.

With regard to the tibia, changes in cortical cross-sectional area and polar moment of inertia have been previously reported in 2 treadmill-based interventions [12,34]. However, the relatively small amplitudes of changes in these previous studies (ie, –1 to +1.4%) raise questions as to whether these changes can be attributed to more than natural measurement error. In fact, in one of these studies, comparisons with a control group yielded no significant difference for polar moment of inertia (cortical cross-sectional area was not reported in this study) [12]. Interestingly, we have previously hypothesized that the design of current exoskeletons may limit the automatic external rotation of the tibia on the femur (and consequently, the foot) during knee extension [37]. This may have led to increased torsion moments in the tibia, which would not occur during treadmill walking without robotic assistance (ie, knee extension in an open kinetic chain)—and could partially explain the difference in amplitude of change between studies.

Uncertainties Remain Regarding pQCT Outcomes

The fact that the estimated femoral cortical thickness decreased (–9.9%) in this study, which does not align with our hypotheses, could raise concerns regarding the possible negative effects of the walking program on bone strength. Indeed, cortical bone is largely believed to be the primary source of resistance and strength for long bones, such as the femur and tibia [9,10]. To our knowledge, these results have not been previously reported in the femur. In 1 treadmill-based trial, a statistically significant reduction of cortical thickness was reported in the tibia [12]. However, this reduction only occurred 8 months following the completion of the training program and was not statistically different than that of the control group [12]. Of interest, a statistically significant reduction in cortical cross-sectional was also observed in this study, which most likely is explained by natural variability or measurement error, considering the relatively small magnitude of change (–2.4%). Moreover, when compared to men without SCI, individuals with SCI show reductions in cortical cross-sectional area of approximately 34% [38]. Thus, the clinical significance of a 2.4% reduction in this parameter remains questionable. Nevertheless, reductions in cortical thickness and cross-sectional area may suggest that the analysis software assigned a larger proportion of bone as subcortical (identified in yellow in Figure 1), which could be related to changes in density (ie, increased porosity) at the endosteal border due to bone resorption. This possibility cannot be completely excluded from the results of this study, particularly when considering the small sample size and the limited statistical power. Future studies should pay special attention to the possible negative effects on cortical thickness and cross-sectional area at the femur.

Serum Biomarkers Were Not Able to Contextualize pQCT Findings, but an Unexpected Increase in Levels of Serum Vitamin D Occurred

Serum osteocalcin (bone formation) and C-telopeptide (bone resorption) did not change significantly between before and after the intervention. This provides further evidence with regard to the complexity of the interpretation of the pQCT findings, as it is not immediately obvious whether increased bone formation or resorption was occurring following the intervention. These results were not anticipated, as 4 months of treadmill walking combined with functional electrical stimulation has been shown to significantly increase osteocalcin (+6.4%) and reduce C-telopeptide (–7.7%) levels in individuals with chronic SCI [12]. The variations found in this study (ie, osteocalcin=+15.1% and C-telopeptide=–13.8%) present trends of similar direction and of greater amplitude when compared to those previously reported, although the statistical threshold was not reached.

Serum vitamin D (25-hydroxyvitamin D) increased significantly and meaningfully by 11.4% during the intervention. Although higher vitamin D levels have been associated with greater levels of physical activity, this is generally attributed to increased time exposed to the sun in more active individuals [39]. In this study,

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all participants were educated regarding vitamin D supplementation recommendations by Osteoporosis Canada [40]. Participants who were not already taking vitamin D (4/10) were offered 1 year's worth of oral supplementation. Only 1 participant began taking vitamin D supplementation during the 4-week period before initiating training. However, even when removing this participant, the data remained statistically significant (P=.05). A possible explanation for this finding is the fact that most training sessions were delivered during the transition from winter to summer months. It is well recognized that vitamin D levels tend to be lower during winter months in northern countries such as Canada, as individuals spend more time indoors [41]. Thus, it is possible that the timing of the study coincided with an expected increase in vitamin D levels seen in the general population during the transition from winter to summer [41]. Nevertheless, serum 25-hydroxyvitamin D levels remained within optimal ranges (ie, ≥75 nmol/L) throughout the duration of the study [42]. As such, bone turnover and metabolism are not expected to have been significantly affected. Moreover, vitamin D supplementation, on its own, has not been shown to effectively increase bone mineral density [43]. Therefore, it is not expected that the variations in bone markers in this study can be attributed to the measured changes in serum 25-hydroxyvitamin D levels.

Limitations and Future Perspectives

This study has limitations that warrant consideration when interpreting its results. First, the sample size was smaller than that initially planned due to numerous challenges associated with the COVID-19 pandemic. Consequently, this reduced statistical power and increased the chance of potential type 2 errors (ie, false negatives). Moreover, the relatively small sample size impeded the possibility of conducting additional subgroup analysis. For example, it was not possible to compare participants according to clinical characteristics (eg, gender, osteoporotic status, obesity status, and response to intervention). Unfortunately, this limits progress toward a more personalized approach for the proposed intervention. Second, the absence of bone mineral density–based inclusion or exclusion criteria led to the recruitment of 5 participants (50% of the sample size) with "preserved" bone mineral density. Hence, these participants were inherently less inclined to benefit from the walking program in terms of bone health. Third, this study did not have specific inclusion or exclusion criteria for concomitant bone health treatments. However, a complete list of medications was taken for each participant, and they were instructed to inform the research team if any changes in medications occurred during the project. Of note, none of the participants were receiving antiosteoporosis agents at the time of the study. Participants were also asked to maintain their physical activity levels during the duration of the study, including their regular exercise regime. Fourth, this study did not have a control group, as such, results should be interpreted with caution as it is unknown to what extent the absence of (or relatively small) changes measured would differ from natural variability in time. Finally, the intensity and duration of the intervention may have been insufficient. Bone resorption typically lasts 30 to 40 days, whereas bone formation frequently requires an additional 150 days, for a total bone turnover cycle requiring up to 6 months [10]. Therefore, it is plausible that clinically significant changes in bone strength could take up to 6 months, indicating that the 4-month measurement period in this study may not have been sufficient. For instance, interventions of 6 or more months, with stationary cycling assisted by functional electrical stimulation, have measured positive effects on bone mass, whereas shorter interventions have not [44-50]. Moreover, despite being initially planned, no follow-up assessments were authorized due to the COVID-19 pandemic, and the beneficial changes that may have emerged later in relation to the temporality of bone adaptation were not captured.

Future research should focus on larger sample sizes, with a particular interest on individuals most likely to benefit from the intervention (ie, individuals with reduced bone mass). From a pragmatic perspective, large multicentric trials will be most likely required to have a sufficient sample size to detect a 5% change in femoral bone mineral density (pQCT) and compensate for large natural heterogeneity in this population. In fact, using the data in this study, this most likely entails the recruitment of roughly 200 participants based on Lehr equation ($n=8s^2/\delta^2$). Interventions should be of sufficient volume (ie, at least 3 times per week), possibly of greater intensity, and of medium- to long-term durations (ie, at least 6 months) to ensure adequate stimulus and time for complete bone turnover cycles. Follow-up assessments, after the completion of the intervention, are also warranted to assess possible latent adaptations. The addition of a control group also remains relevant to compensate for natural variability and measurement error related to bone imaging and serum sampling. Finally, combining pharmacological interventions (eg, teriparatide) or functional electrical stimulation or both with overground exoskeleton–assisted walking may also warrant consideration.

Conclusions

The results from this paper confirm that a 16-week exoskeleton-assisted walking program may elicit bone adaptations. On one hand, significant and meaningful increases were documented via DEXA and pQCT at both the femur (ie, femoral neck bone mineral content, bone strength index, and stress-strain index) and tibia (ie, cortical cross-sectional area and polar moment of inertia). On the other hand, possible significant and meaningful decreases (ie, femoral cortical thickness) raise concerns. Although positive bone adaptations are emerging, it remains unclear whether completing a 16-week exoskeleton-assisted walking program increases bone strength in individuals with chronic SCI. The need for stronger evidence warrants additional research with larger sample sizes that focus on longer interventions (possibly of greater loading intensity), and combining modalities should be considered (eg, pharmacotherapy or functional electrical stimulation). To do so, national or international collaborations will most likely be required.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Project timeline and effects of the COVID-19 pandemic.
[PNG File , 51 KB - rehab_v11i1e53084_app1.png]

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Abbreviations

DEXA: dual-energy x-ray absorptiometry
pQCT: peripheral quantitative computed tomography
SCI: spinal cord injury

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Original Paper

Quality of Life, Physical Activity Participation, and Perceptions of Physical Rehabilitation Among Community-Reintegrated Veterans With Lower Limb Amputation in Sri Lanka: Convergent Parallel Mixed Methods Study

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Abstract

Background: Lower limb amputation (LLA) impacts physical activity (PA) participation and quality of life (QoL). To minimize the effects of these challenges, LLA survivors need to have opportunities to engage in appropriately tailored rehabilitation throughout their lives. However, in Sri Lanka, where a 3-decade civil war resulted in trauma-related LLA among young male soldiers, access to rehabilitation was limited to the immediate postinjury period. Developing rehabilitation interventions for these veterans requires an understanding of their current health status and rehabilitation perceptions.

Objective: This study was conducted to evaluate the QoL and PA participation of veterans with LLA and explore perceptions of factors influencing their PA participation and expectations for a future community-based physical rehabilitation (CBPR) intervention.

Methods: This mixed methods study combined a comparative cross-sectional quantitative survey with qualitative semistructured interviews in 5 districts of Sri Lanka. QoL and PA participation were assessed among community-reintegrated veterans with LLA (n=85) and compared with a matched able-bodied cohort (control; n=85) using Mann-Whitney *U* and Chi-square tests. PA was assessed in terms of metabolic equivalent of task (MET) minutes per week and was computed for walking, moderate-intensity, and vigorous-intensity activities. PA was classified as sufficiently active, low, or sedentary. The design of interview questions was guided by the Theoretical Domains Framework and followed a phenomenological approach. Interviews were conducted with 25 veterans and were analyzed thematically, and the perceptions regarding PA participation and CBPR were codified using the Consolidated Framework for Implementation Research (CFIR).

Results: Based on the quantitative survey findings, scores for both physical ($P<.001$) and psychological ($P<.001$) well-being and participation in walking ($P=.004$) and vigorous-intensity activities ($P<.001$) were significantly lower among veterans than among controls. A “sedentary” classification was made for 43% (34/79) of veterans and 12% (10/82) of controls. Veterans mostly engaged in moderate-intensity PA inside the house (49/79, 62%) and in the yard (30/79, 38%). Qualitative interviews revealed that barriers to PA exist at individual (eg, comorbidity burden), primary care (eg, absence of community rehabilitation services), and policy levels (eg, limited resources) and facilitators exist primarily at societal (eg, inclusive community) and individual levels (eg, preinjury activity baseline and positive attitudes toward exercise). Expectations regarding CBPR included individualized

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rehabilitation parameters; functional exercises; and involvement of peers, amputee societies, and community health care providers. The nonresponse rate for interviews was 7% (2/27).

Conclusions: The findings of reduced PA participation, poor QoL, and physical and psychological impairments among relatively young veterans reveal the long-term impacts of living with LLA in the absence of long-term rehabilitation. Policy-level changes need to be implemented along with behavior-change strategies to promote PA participation and minimize physical inactivity–induced health issues. Veterans' perceptions regarding future CBPR programs were positive and centered on holistic, individualized, and peer-led activities.

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KEYWORDS

amputation; community-based rehabilitation; lower limb; military; physical activity; quality of life

Introduction

Lower limb amputation (LLA) accounts for over 90% of all amputations [1] and is associated with significant morbidity, mortality, and disability [2]. Chronic conditions associated with increased prevalence of cardiovascular diseases and poor long-term quality of life (QoL) outcomes in the LLA population [3-7] are thought to be in part (as a consequence of reduced mobility and chronic pain) compounded by lifestyle choices (diet, alcohol consumption, and smoking) and limited employment opportunities, leading to lower income and economic insecurity [8-10].

War-related trauma is a major cause of LLA in the military population. In Sri Lanka, with its relatively recent history of a long civil war, this trauma accounts for the majority of LLA cases [11]. More than 20,000 military veterans are estimated to be living with disabilities in Sri Lanka, and LLA, either with or without additional injuries, is thought to be the most prevalent physical disability. Given the age and demography of serving officers, war-related traumatic LLA occurs at a young age. As a consequence, those who survive the injury face a future of having to adjust to living and working in civilian society with both their primary disability and associated secondary conditions.

The long-term impacts of both the primary physical injury and sequential health and lifestyle-related conditions in LLA can, however, be mitigated by engagement in regular physical activity (PA) [12,13]. PA is defined as any voluntary bodily movement produced by skeletal muscles that results in energy expenditure and is performed during any time of the day or night [14]. According to the American College of Sports Medicine (ACSM) and American Heart Association (AHA) guidelines, adults aged 18 to 65 years are recommended to perform moderate-intensity aerobic PA for a minimum of 30 minutes a day for 5 days a week or vigorous-intensity aerobic activity for a minimum of 20 minutes a day for 3 days a week [15].

There are several factors known to affect PA participation following LLA. These include present health conditions, provision of informal (family) and formal (health care provider) support, availability of and access to rehabilitation resources, prosthetic function, physical fitness, personal attitude, and knowledge or awareness of the condition [9,16-19]. Moreover, engaging in PA as part of a physical rehabilitation program is more beneficial than performing PA alone, as physical rehabilitation programs further seek to improve chronic pain [20] and balance [21], and increase cardiopulmonary endurance [22,23].

Sustained PA is a major determinant of recovering and maintaining QoL in the LLA population [3,24]. Previous studies on the QoL of Sri Lankan military personnel injured during the civil war, which were based on the Short-Form Health Survey-36 (SF-36), suggested that the presence of comorbidities and limited use of prosthetics are associated with lower QoL [5,25]. Given the potential to mitigate comorbidities and enhance prosthesis use through increased PA [12,26,27] and the strong positive correlation between PA and QoL [3,13], the promotion of PA is a promising avenue to enhance QoL among individuals with LLA.

Currently, there is no formal or government-led rehabilitation service to promote or maintain adequate PA participation for community-reintegrated veterans following LLA in Sri Lanka [28]. Therefore, implementing a tailored community-based physical rehabilitation (CBPR) program could improve PA participation and overall QoL among them. However, this requires an understanding of their current QoL and PA levels, and perceptions of PA and rehabilitation are crucial for developing a feasible and acceptable intervention.

The purpose of this mixed methods study was to understand the current health status in terms of QoL and PA participation and the perceptions of rehabilitation among veterans following LLA in Sri Lanka for informing the development of a future CBPR program. The quantitative and qualitative objectives were as follows:

1. Quantitative objective: To assess QoL outcomes and the level of PA among veterans with LLA in Sri Lanka.
2. Qualitative objective: To explore the factors influencing veterans' PA participation and their perceptions regarding priorities for and implementation of a CBPR program for individuals living with LLA in Sri Lanka.

Methods

Ethics Approval

This study was approved by the Ethics Review Committee of the Faculty of Medicine, University of Colombo, Sri Lanka (EC-19-074).

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Study Design

A mixed methods study involving a convergent parallel approach was conducted [29], and quantitative and qualitative data collection and analyses were carried out concurrently and independently. Findings from both sets of data were integrated to inform the development of a future CBPR intervention for the underlying population. We defined CBPR as an exercise-based rehabilitation intervention practiced in the community or at the home of the participant [22].

Quantitative Assessment

A descriptive cross-sectional survey with a comparison group was conducted. We included a comparison group as we wanted to compare the outcomes of veterans with those of able-bodied controls (matched to age and sex) living in the same geographical location, having similar socioeconomic and lifestyle contexts, and having access to similar health care resources.

Qualitative Assessment

Qualitative semistructured interviews were conducted using a phenomenological approach. This approach was chosen to encourage the identification of broader emerging themes that crosscut the diverse health, social, societal, and individual factors known to affect engagement in and effectiveness of rehabilitation with regard to PA and QoL. Interviews were designed based on methods described by Creswell [30] in planning and conducting qualitative research and published studies focused on factors influencing PA participation among individuals with chronic disabilities, including LLA [16,19,31].

Study Setting

The study was conducted in the following 5 districts of Sri Lanka (out of 22) identified based on a priori knowledge of the locations of veterans' community settlements: Anuradhapura, Kurunegala, Hambanthota, Badulla, and Rathnapura. These 5 districts in Sri Lanka have the highest number of LLA veterans, comprising more than 50% according to the "Disabled Category Registry" manually updated by the Directorate of Rehabilitation, Ministry of Defense, Sri Lanka [11]. Veterans were living in "Ranaviru Villages," which are located far away from the city center of these districts. "Ranaviru Villages" are residences constructed by the Sri Lankan Army for injured and retired Army veterans. The period of the study was from October 2020 to April 2021.

Participant Recruitment

Quantitative Assessment

We identified potential veterans with LLA (group 1) from the "Disabled Category Registry." We aimed to include 85 participants in each of the groups so as to adequately power the comparison of each outcome [32]. We ensured representation from veterans across all 5 districts, selecting participants proportionally using a stratified random sampling procedure [33,34]. Participants for the comparison group (group 2) were identified from the same village or a neighboring village of their group 1 counterparts using the voter registration list.

We selected veterans who had LLA due to an injury on the battlefield and were living in the community. To ensure that the participants had the required functional level for the proposed CBPR intervention, we included only participants who had unilateral LLA and used a prosthetic limb for walking and standing activities. Veterans older than 70 years and those with comorbidities that interfered with their function beyond that of unilateral LLA (eg, dependence on renal replacement therapy) were excluded.

Qualitative Assessment

For the interviews, we purposively selected participants from group 1, ensuring participation from all 5 districts with regard to transfemoral and transtibial amputations to assess the needs and understand the perspectives of individuals with different functional levels of mobility after amputation [35,36].

Data Collection

Quantitative Assessment

The self-administered SF-36 [37] and International Physical Activity Questionnaire (IPAQ) long-form survey [38] were used to assess QoL and PA participation, respectively. The SF-36 is widely used to measure QoL in terms of physical (physical component summary [PCS]) and mental or emotional (mental component summary [MCS]) components, each expressed as a value between 0 and 100, with a high score representing a better QoL [37]. The IPAQ measures the frequency (days per week), duration (minutes), and level of intensity (vigorous, moderate, walking, or sitting) of PA during the last 7 days [38]. Both questionnaires have established psychometric properties making them ideal for use in the LLA population [25,39,40] and have been validated for use in the Sinhalese population previously [41,42].

Initial contact with the participants was made through Grama Niladhari (GN) and officers of societies of amputee veterans (eg, Ranaviru Sansadaya). GN is a Sri Lankan public official appointed by the central government to carry out administrative duties in a GN division (geographic region), which is a subunit of the divisional secretariat.

Participants of groups 1 and 2 were met by 2 research team members (AW and Dasun Isurinda). AW explained the research, provided participants with study information, and sought consent. AW is a trained physiotherapist fluent in Sinhala, with over 6 years of experience working in both clinical and research capacities within community settings in Sri Lanka. Dasun Isurinda is a practicing physiotherapist with more than 5 years of experience in both inpatient and community physiotherapy settings. The SF-36 and IPAQ were available to participants in paper form in the local language (Sinhala). AW and Dasun Isurinda remained with the participants during the survey completion to answer any questions the participants may have regarding the self-assessment.

Qualitative Assessment

The interview guide was developed using the Theoretical Domains Framework (TDF) [43]. This included knowledge about PA or exercises and exercise programs, intentions for participating in PA, environmental context and resources,

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emotions on life with LLA, and reinforcement through support. The guide was translated by a bilingual research team member (AW) and then back-translated and checked for accuracy by a second researcher (SJ). It was piloted with veterans with LLA who were not included in the final analysis. The pilot resulted in the simplification of the question format. The final survey can be found in Multimedia Appendix 1.

A total of 25 interviews were conducted in the language preferred by the participants (Sinhala) and lasted between 30 and 40 minutes. All the interviews were conducted by the author AW at the residence or home of each participant.

Data Analysis

Quantitative Assessment

All the statistical analyses were performed by author DGD (a qualified statistician; independent of participant allocation and data collection) using STATA/IC for Mac v16.1 (StataCorp). The normality of data distributions was tested with the Shapiro-Wilk test, and data are summarized as mean (SD), median (range), or number (percentage), as appropriate. The Mann-Whitney *U* test and chi-square test were used to evaluate comparisons between groups for continuous and nominal variables, with a significance level of .05.

Data from the IPAQ were processed and reported according to the Guidelines for Data Processing and Analysis of the IPAQ [44]. In the IPAQ, PA is defined in terms of the metabolic equivalent of task (MET) minutes per week, and the questionnaire assesses PA participation in walking, moderate-intensity, and vigorous-intensity activities across 4 domains: work, transport, domestic and garden, and leisure. We computed the PA participation of groups 1 and 2 separately for each of these domains and calculated the total PA level by adding them together. Finally, the level of PA was classified as either sedentary (<600 MET-minutes/week), low (600-3000 MET-minutes/week), or sufficiently active (>3000 MET-minutes/week), based on the total MET-minutes/week [44] for both groups.

Qualitative Assessment

The findings of the qualitative study were reported using the Consolidated Criteria for Reporting Qualitative Studies guidelines [45]. Findings were thematically analyzed using the Consolidated Framework for Implementation Research (CFIR). The aim of using the CFIR was to identify the different organizational levels to which the identified barriers, facilitators, and expectations for a future CBPR intervention belong, in order to gain further insights into the effective design and implementation of the intervention considering each organizational level. The CFIR is a pragmatic meta-theoretical framework that helps to identify determinants of a health care intervention implementation with consideration for context, the complexity of the intervention, individual characteristics, and organizational or system-level factors that may facilitate or inhibit implementation [46-48].

Thematic analysis was used to identify emerging themes from the interview responses [30]. Responses were initially reviewed independently by 2 researchers (AW and Nilu Dullewe, both qualified health care professionals trained in qualitative methods and fluent in the Sinhala language) who read through all the verbatim transcripts to inductively code sentences and keywords. Emerging themes were then codified using the domains of the CFIR. These were then reviewed by both researchers, duplicates were removed, and emergent themes were refined. Any disagreements that developed during the analysis were discussed, and if needed, these were further reviewed by the author AB, a clinical researcher with experience of both the Sri Lankan health care setting and the methods used for analysis.

Integration

The themes identified through qualitative analysis were mapped with the findings from quantitative analysis to enhance our understanding of the factors influencing QoL outcomes and PA participation among veterans. Additionally, themes of the barriers and facilitators to PA were transformed into quantitative scores to understand the importance of each theme and its relevance to quantitative analysis findings.

Results

Participant Characteristics

In total, 170 individuals (85 in each group) participated in the study, and they represented 5 districts. Table 1 presents the sociodemographic and clinical characteristics of groups 1 and 2.

All the veterans were active prosthetic users who had undergone amputation as a result of battlefield trauma more than 10 years ago. Of the 85 veterans, 78 (92%) had transtibial amputation and 7 (8%) had transfemoral amputation. A high prevalence of amputation-associated comorbidities was found among the veterans. These data have been published separately [49].

All the veterans had completed prosthetic training during postsurgical hospital care. Upon discharge, the veterans were advised to follow a lower limb muscle strengthening and stretching routine thrice a week for 6 months by physiotherapists, but only 12 out of the 85 veterans (14.1%) had engaged as recommended, with an additional 4 veterans (4.7%) following the routine on an ad hoc basis. No participants received follow-up from rehabilitation providers, and none were engaged in health care–administered physical rehabilitation. Moreover, 3 veterans (3.5%) pursued self-directed exercise programs involving social media videos to reduce body weight and manage back pain.

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Table 1. Sociodemographic and clinical characteristics of the participants.

Characteristic	Group 1 (n=85)	Group 2 (n=85)
Male gender, n (%)	85 (100)	85 (100)
Age (years), mean (SD)	46.3 (6.0)	46.7 (6.0)
BMI (kg/m^2), mean (SD)	26.2 (3.4)	25.0 (3.1)
War-related traumatic amputation, n (%)	85 (100)	—[a]
Time since amputation (years), mean (SD)	21.7 (5.9)	—
Prosthesis use (hours/day), mean (SD)	14.3 (2.4)	—
Amputation type (unilateral), n (%)	85 (100)	—
Amputation level, n (%)		
Transfemoral	7 (8)	—
Transtibial	78 (92)	—
Marital status, n (%)		
Single	8 (9)	14 (17)
Married	71 (84)	66 (78)
Divorced, separated, or widowed	6 (7)	5 (6)
Highest education level, n (%)		
Grade 6-10	47 (55)	35 (41)
Passed GCE[b] Ordinary Level	23 (27)	28 (33)
Grade 11-13	4 (5)	7 (8)
Passed GCE Advanced Level	3 (4)	6 (7)
Vocational training or diploma	7 (8)	5 (6)
First degree	1 (1)	4 (5)
Current employment status, n (%)		
Employed or self-employed	62 (73)	75 (88)
Not employed	23 (27)	10 (12)
Monthly income (LKR[c]), n (%)		
<20,000	0 (0)	2 (2)
20,000-29,999	15 (18)	19 (22)
30,000-39,000	37 (44)	28 (33)
≥40,000	33 (39)	36 (42)

[a]Not applicable.

[b]GCE: General Certificate of Education.

[c]A currency exchange rate of 1 LKR=0.0033 USD is applicable.

Quantitative Assessment

QoL Outcomes (SF-36 Scores)

QoL scores by SF-36 domains are presented in Table 2. The median cumulative scores of physical health (PCS) and psychological well-being (MCS) were significantly lower in group 1 than in group 2 (P<.001). The difference in the PCS score had a large effect size (r=0.5), while the difference in the MCS score had a medium effect size (r=0.3). For group 1 participants, the poorest QoL scores were related to general health (median 45, IQR 55-35) (Table 2).

In the comparison of QoL outcomes between different amputation levels, only the “general health” domain (under PCS) showed a significant difference, with a lower value for veterans with transfemoral amputation (P=.009; Multimedia Appendix 2).

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Table 2. Comparison of quality of life outcomes (Short-Form Health Survey-36) between group 1 (veterans with lower limb amputation) and group 2 (able-bodied controls).

Quality of life domain	Group 1 (n=85), median (IQR)	Group 2 (n=85), median (IQR)	*P* value[a]
Physical health			
Physical functioning	60 (72.5-45)	90 (100-80)[b]	<.001
Role limitation due to physical problems	50 (75-25)	75 (100-50)[b]	<.001
Bodily pain	67.5 (77.5-55)	77.5 (90-67.5)[b]	<.001
General health	45 (55-35)	60 (70-50)[b]	<.001
Physical health component	54.4 (65.9-44.7)	73.1 (83.4-64.1)[b]	<.001
Mental health			
Role limitation due to emotional problems	66.7 (100-33.3)	100 (100-33.3)[b]	.01
Social functioning	75 (87.5-62.5)	87.5 (87.5-75)[b]	<.001
Vitality	60 (70-50)	65 (77.5-57.5)[b]	<.001
Emotional well-being	52 (60-48)	56 (60-52)	.40
Mental health component	61.8 (71.3-48.9)	72.0 (78.7-60.1)[b]	<.001

[a]Statistical significance was assessed using the Mann-Whitney *U* test for comparisons between group 1 and group 2.

[b]Statistical significance at *P*<.05.

PA Participation (IPAQ Scores)

The total PA level was significantly lower in group 1 than in group 2 (*P*<.001), with a medium effect size (*r*=0.3). Participation in walking, moderate-intensity, and vigorous-intensity activities was lower in group 1 than in group 2, with a significant difference in walking (small effect size of *r*=0.2; *P*=.004) and vigorous-intensity PA (medium effect size of *r*=0.3; *P*<.001) (Table 3). Among 79 veterans, 59 (75%) did not meet the recommended PA level (>3000 MET-minutes/week). Moreover, the "sedentary" level was noted in 43% (34/79) of participants in group 1 and 12% (10/82) of participants in group 2 (*P*<.001) (Table 4).

Of the 79 participants with LLA, the majority engaged in moderate-intensity PA inside the house (49/79, 62%) and in the yard (30/79, 38%). The least participation was in cycling for transport (5/79, 6%) and vigorous PA (recreation, sport, or exercise) in leisure (6/79, 8%) (Multimedia Appendix 3).

When considering the amputation level, participation in walking was significantly lower among veterans with transfemoral amputation than among those with transtibial amputation (*P*=.01), and 4 out of the 5 participants (80%) with transfemoral amputation had PA levels below the recommended guidelines (Multimedia Appendix 2).

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Table 3. Comparison of physical activity participation between group 1 (veterans with lower limb amputation) and group 2 (able-bodied controls).

Variable	Group 1 (n=79), median (IQR)	Group 2 (n=82), median (IQR)	*P* value[a]
Total physical activity level (MET[b]-minutes/week)	1913.6 (3506.9-515.8)	4857.3 (8296.0-1008.4)[c]	<.001
Physical activity domain (MET-minutes/week)			
Work	0.0 (0.0-611.5)	590.6 (0.0-3956.8)[c]	<.001
Transport	0.0 (0.0-207.9)	155.9 (0.0-462.6)[c]	.003
Domestic and garden	756 (401.6-2236.5)	787.0 (265.8-2457.0)	.79
Leisure	0.0 (0.0-140.9)	0.0 (0.0-359.8)	.06
Physical activity intensity (MET-minutes/week)			
Total walking	145.5 (0.0-644.5)	519.6 (64.9-1164.2)[c]	.004
Total moderate-intensity activity	1134.0 (476.4-3039.6)	1260.0 (584.8-3169.7)	.21
Total vigorous-intensity activity	0.0 (0.0-189.0)	126.0 (0.0-3024.0)[c]	<.001

[a]Statistical significance was assessed using the Mann-Whitney *U* test for comparisons between group 1 and group 2.

[b]MET: metabolic equivalent of task.

[c]Statistical significance at *P*<.05.

Table 4. Comparison of physical activity behaviors between group 1 (veterans with lower limb amputation) and group 2 (able-bodied controls)

	Group 1 (n=79), n (%)	Group 2 (n=82), n (%)	Chi-square (*df*)	*P* value[a]
Physical activity behavior			17.66 (2)	<.001
Sedentary	34 (43)	10 (12)		
Low	25 (32)	33 (40)		
Sufficiently active	20 (25)	39 (48)		

[a]Statistical significance was assessed using the Chi-square test for comparison between group 1 and group 2.

Qualitative Assessment

Of the 79 participants in group 1 who completed the assessment of QoL and PA, 27 (32%) were invited to participate in the semistructured interviews, and of these, 25 consented to participate. Accordingly, 25 interviews were conducted, with a total of 7.2 hours of transcription data. Participants were aged 30 to 55 years (mean 46.1, SD 7.4 years). Moreover, 20 (80%) participants had transtibial LLA and 5 (20%) had transfemoral LLA.

Barriers and Facilitators to PA Participation in the Community

Barriers and facilitators were codified to 10 CFIR constructs within the major domains “outer setting,” “inner setting,” and “characteristics of individuals.” Table 5 provides a summary of emergent themes, their relationships with CFIR domains, and how they relate to barriers and facilitators to PA participation. Figure 1 shows the importance of themes as perceived by participants. Related participant quotes from the interviews are presented in Table 6.

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Table 5. Perceived barriers and facilitators to physical activity participation and their associations with Consolidated Framework for Implementation Research domains.

CFIR[a] domain and construct	Theme	Barrier	Facilitator
Outer setting (broader external context in which the behavior or implementation occurs)			
External policies and incentives	Availability of services and incentives	• Absence of community rehabilitation services	• Financial support
Patient needs and resources	Provision of prosthetic services	• Unequal distribution of prosthetic services	• Free of charge prosthetic services
Inner setting (specific context within the organization or system where the behavior or implementation takes place)			
Structural characteristics	Living as clusters in allocated villages	• Isolation from the wider society	• Inclusive community environment
Networks and communications	Kinship with family and peers	• Family commitments	• Family support • Peer support • Soldier societies
Available resources	Adequacy and quality of available resources	• Limited physical space at home • Absence of exercise equipment • Low-quality prosthetic legs	• Calm environment in the village • Adequate space in the village
Access to information and knowledge	Access to necessary information and knowledge	• Lack of access to knowledge and information on rehabilitation professional services	N/A[b]
Individual characteristics (the personal attributes and characteristics of individuals performing the behavior or involved in the implementation)			
Knowledge and beliefs	Knowledge and beliefs on recovery expectations and exercises	• Uncertainty of recovery expectations	• Knowledge of the basic principles of exercise • Preinjury active lifestyle
Self-efficacy	Ability to carry out physical activities and exercises	• Burden of chronic pain and persistent comorbidities • Higher level of amputation	• Active prosthetic use • Age (middle-aged adult)
Individual stage of change	Present stage of change	• Present sedentary lifestyle	• Current engagement in exercise
Personal attributes	Motivation for exercises	• Laziness	• Motivation to be more active and independent • Positive attitude toward exercise

[a]CFIR: Consolidated Framework for Implementation Research.

[b]N/A: not applicable.

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Figure 1. Importance of themes related to barriers and facilitators to physical activity participation as perceived by the veterans.

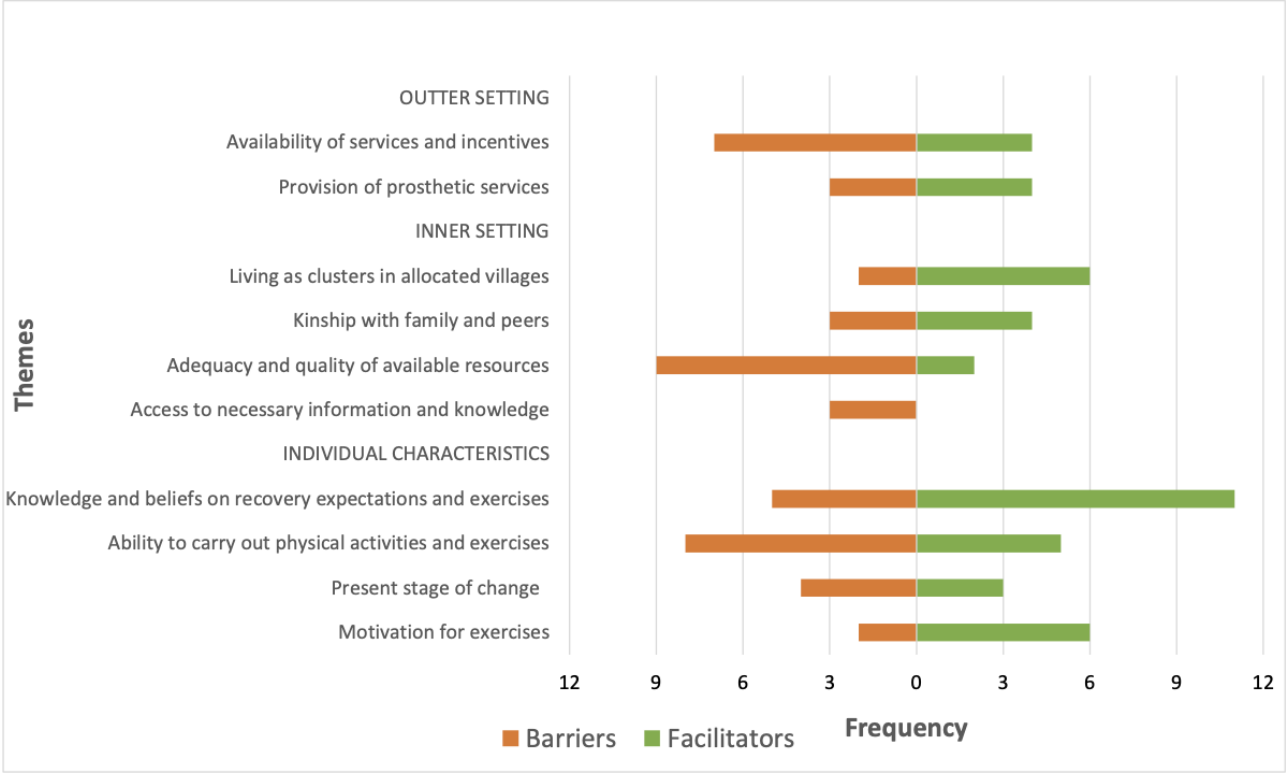

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Table 6. Representative participant quotes for themes related to the barriers and facilitators to physical activity participation.

Theme	Participant quotes
Availability of services and incentives	• "Has anyone told that we've community rehabilitation centers to visit? ...we don't have such rehabilitation services around our area, I don't think we have such in the city even." • "No one has come to me and talked about doing exercises since I discharged from the hospital about 17 years ago." • "The thing is unlike for civil disabled people; we are given a monthly salary with an allowance. So, we don't need to work hard on earning. You know then we have enough time to do some activities at home."
Provision of prosthetic services	• "Last year I was able to get a new prosthetic leg from a mobile social service program. I was directed to this by the president of our society. It is easy for me to work with this new one than the earlier one."
Living as clusters in allocated villages	• "As I think, there are about 24 villages in Sri Lanka that are reserved for veterans. So, all my neighbors are retired soldiers and the majority have the same disability like me. Normally we get together very often, and we can do exercises together."
Kinship with family and peers	• "I have to help my family members, especially my wife. She likes when I help to do household work. So, I should help with that work most of the time. She doesn't care whether I'm doing exercises or not." • "My children don't do their own work, so I have to help them as well, I have to bring them to school, tuition classes and stay there until they finish."
Adequacy and quality of available resources	• "There is no sufficient space at home to do exercises. If we have a separate room to continue exercises, it would be easier. I think none of us have that facility." • "Not having proper equipment is a barrier. I think to follow a physical rehabilitation program properly, we need suitable equipment." • "This prosthetic leg is the only means of mobility for me. But this is so heavy and already worn out. How can I do exercises with this? even it is difficult to walk with this."
Access to necessary information and knowledge	• "Although I want to do exercises, there is no one around to get proper information. But I do some exercises what I feel is good. Sometimes I do exercises to my leg using a sandbag as taught at the hospital."
Knowledge and beliefs on recovery expectations and exercises	• "Currently, I engage in many household activities like gardening and growing vegetables. I don't feel it necessary to do any other special kind of exercise." • "...Yes, I engage in the normal day to day activities as much as I can. So, I think that is quite enough for the body as an exercise..." • "We as soldiers had a good training on physical fitness and we know exercises better than a civil person. I mean before the injury we did exercises as part of our daily schedule in the Army."
Ability to carry out physical activities and exercises	• "The thing is I can't use my body like I used to. Because my body, especially the back and the knee joints, start hurting when I start doing exercises. So, If I do exercises, I will not be able to do my normal routine the next day and sometimes I need to see a doctor after that to take medication for pain." • "For the sake of this prosthetic leg, I can walk when I want even as an exercise, otherwise I would just sit on a chair."
Present stage of change	• "I could manage to do the things and do exercises at this age but what will happen when I am old? I'm doing most of the activities in the paddy field because I have enough strength, because I'm still young." • "You know, most of us just eat and stay at one place and we are used to it, I don't work as we did in the past, and even if I go somewhere, I just use my three-wheeler for that."
Motivation for exercises	• "...I don't do exercises because I feel lazy to do..." • "I don't want to get my health worsen; I don't like to be a burden to my wife and family. You know, usually soldiers like to keep their health in good condition and avoid troublesome diseases like diabetes." • "Although now we are disabled, we fought for the country for many years. At least I want to do my things independently and walk somewhere when I want, without wanting to trouble others."

Outer Setting

Availability of Formal Community-Based Rehabilitation Services

Participants lacked structured CBPR programs and community-based follow-up care from rehabilitation health providers, primarily due to the absence of formal community rehabilitation services like physiotherapy. They believed that having a CBPR program upon discharge from institutional care would have increased their PA participation.

Provision of Prosthetic Services

Prosthetic limbs were the only means of ambulation for the veterans included in this study, and they are needed to engage effectively in PA. Veterans are given free prosthetic legs by nongovernmental organizations to support their independent mobility. However, this service was not available all the time

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and was only available to a few of the participants. People who received this service had the opportunity to replace a worn-out prosthesis with a new one.

Financial Support

Continuous financial support from the government in the form of a monthly salary and disability allowance relieved participants of the burden of earning money for their households, enabling them to dedicate ample time to PA and exercise. However, this support led to sole reliance on the allowance, discouraging them from pursuing any occupational opportunities. This was connected to reduced participation in work-related PA and reduced motivation for PA, which has been described under the subsection "Individual Characteristics."

Inner Setting

Veterans' Residence and Their Kinship

Veterans resided in designated villages allocated for army veterans, providing a peaceful environment with ample space for PA like walking and gardening. Living among peers with similar mental and physical states fostered an inclusive environment, where disabilities were not emphasized, encouraging frequent sharing of thoughts and experiences. Additionally, kinship with family and associated competing responsibilities hindered their engagement in PA.

Adequacy and Quality of Available Resources Required to Engage Effectively in PA

Participants did not have adequate space and equipment to engage in exercise and PA. They believed that exercise would not be effective without proper exercise equipment. The poor functionality of the prosthetic leg combined with skin wounds resulting from its incorrect fitting posed challenges for participating in PA, particularly walking activities.

Access to Information and Knowledge on Professional Services for Rehabilitation

Acquiring proper knowledge and training is crucial for successful and effective engagement in PA. However, participants expressed a lack of access to professionals or services to seek information and guidance on performing exercises at home.

Individual Characteristics

Veterans' Knowledge and Beliefs Regarding Recovery Expectations and Exercises

Participants expressed uncertainty about what to expect in terms of recovery upon discharge from inpatient care. They lacked an understanding of the importance of ongoing exercise engagement for their recovery, with some believing that exercises would not contribute further to their progress. Instead, they perceived activities, such as household chores, gardening, and walking to nearby shops or houses, as sufficient for maintaining a healthy life.

Owing to their active lifestyle before the injury (heavy physical training in the army and representing army sports teams), participants believed that they were familiar with the basic exercise principles. This helped them to engage in at least a few exercises at home even without proper guidance or follow-up.

Veterans' Ability to Perform PA and Exercises

Veterans reported various health comorbidities, including back pain, knee pain, diabetes mellitus, and hypertension, which affected their ability to engage in PA. Veterans with transfemoral amputation perceived lower PA abilities compared to those with transtibial amputation, and they anticipated a worsening situation with age. In contrast, some veterans associated their current physical state positively with engaging in PA. One reason they mentioned was being an active prosthetic user, which made them independent in walking. As they joined the military service at 18-24 years of age and got injured at a young age, their relative age at the time of injury was seen as a facilitator to recovery.

Individual Motivation and Conflicting Priorities

Participants considered engaging in PA and exercise as an extra burden, requiring them to modify their usual lifestyle. Some expressed a lack of motivation for any form of PA, including walking for daily tasks. In contrast, for some participants, consistent engagement in PA was considered crucial among individuals with disabilities. It was seen as a lifelong requirement rather than a lifestyle choice to improve functional levels and reduce the risk of health issues, such as diabetes mellitus and heart disease. They expressed motivation to increase their activity levels and independence, aiming to avoid dependence on family members, including that related to the incidence of chronic health conditions.

Expectations for a Future CBPR Program

Twelve expectations for a future CBPR program emerged, and these were related to 6 constructs under 2 major domains of the CFIR model: "intervention characteristics" and "implementation process" (Figure 2). Most of the themes of expectations were related to "intervention characteristics." Related participant quotes from the interviews are presented in Table 7.

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Figure 2. Perceived themes of expectations for a future community-based physical rehabilitation program and their associations with Consolidated Framework for Implementation Research domains. CBPR: community-based physical rehabilitation.

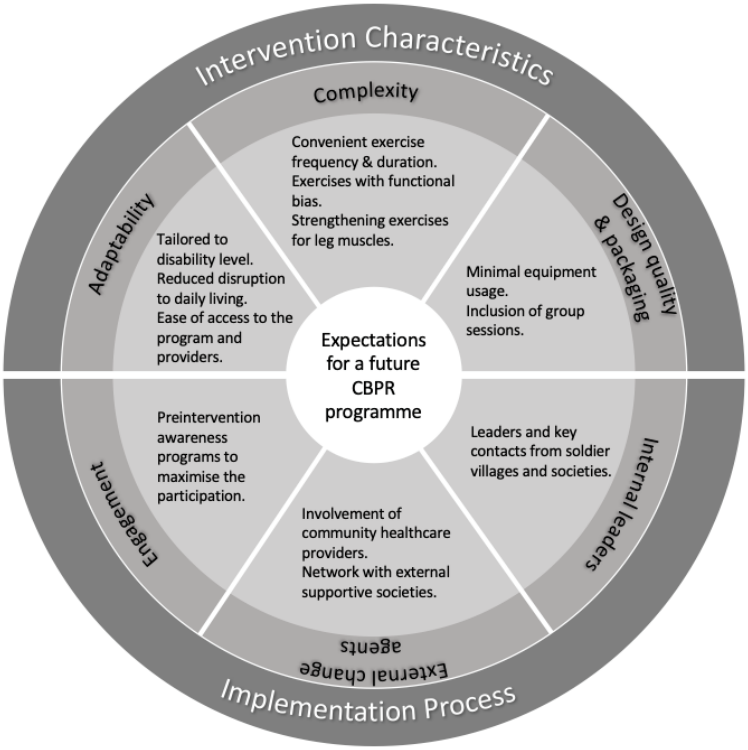

Table 7. Representative participant quotes for themes of expectations for a future community-based physical rehabilitation program.

Theme	Participant quotes
Tailored to functional and disability levels	• "Most importantly the exercise program should not be difficult to follow, especially the activities should match to us. You know, we cannot do activities similar to a normal individual who has both their legs." • "I won't be able to perform difficult exercises, my back starts paining even after simple activities. So, I think I should follow a simple exercise program."
Reduced disruption to daily living and ease of access	• "I would do exercises at home. It is easy for me rather than travelling to a distance hospital without wasting time and money; travelling in public transport is a headache." • "Sometimes I do pushups at home before going to my shop. I can't go anywhere else to do exercises, because I don't have time, I should be there at the shop."
Convenient exercise parameters and components	• "Engaging in a daily exercise program would be very difficult, but 2-3 days per week would be fine." • "All I want is to engage properly in my farming activities, if the program can help me for that, it would be amazing." • "Before anything I want to walk more speedily, I'm getting slow and slow, it is embarrassing." • "I have seen my leg is getting thinner. If we get overweight, it will affect our legs as legs should bear the weight..., I think we should focus more on keeping our legs strong, especially the good leg."
Use of equipment and space and involvement of peer groups	• "I know some form of special exercises like pushups and squats do not need equipment. So, if these kinds of exercises are included in the program, it would be better." • "We live in this village together, so I think we can do exercises together in one common place, it would be more interesting"
Preintervention awareness programs	• "It would be better if you can organize an awareness workshop for all of us before introducing the program. Otherwise, many of the veterans will miss this opportunity."
Involvement of soldier societies and community health care providers	• "There should be a person to contact when we have something to clarify when following the exercise program, actually, we will get many issues." • "Normally, if I need to talk to Army officials for any reason, all I do is contact president of our society and request to pass the message, I'm speaking about that kind of a process." • "All of us are members of the 'Ranaviru Sansadaya' and many of us are active members including me. I participate in almost all the events organized by this society. If you deliver the program through this society, it will surely become successful."

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Intervention Characteristics

Tailored to Functional and Disability Levels

Participants expected the CBPR program to be tailored to their disability, with exercises matching their current functional levels. Exercises to prevent deterioration in existing health, notably back pain and knee pain, were a particular priority for participants with chronic comorbidities.

Reduced Disruption to Daily Living and Ease of Access

Veterans held a favorable perception toward CBPR, perceiving it as easily adaptable to their needs. They expressed a preference for engaging in rehabilitation programs either at home or within their local community, as opposed to attending outpatient clinics at hospitals. This preference was associated with perceived benefits, such as reduced travel burden, lower associated costs, and minimized disruptions to their daily lives.

Convenient Exercise Parameters and Components

Veterans generally suggested a program with 2 to 3 sessions per week, lasting 20-30 minutes each. They favored simple functionally oriented exercises that could be easily incorporated into daily activities, with a preference for specific exercises, such as leg muscle strengthening.

Use of Equipment and Space and Involvement of Peer Groups

Veterans preferred using exercise equipment only when necessary, considering constraints like the lack of equipment at home and financial limitations. They showed interest in using community spaces, such as playgrounds and meeting halls, for group rehabilitation sessions when home space was insufficient. Group participation was favored for the opportunity to learn from one another during the program.

Process of Implementation

Preintervention Awareness Program

Participants stressed the importance of an awareness program led by experts in the field to precede the implementation of a future CBPR program, with the aim of ensuring maximum engagement of veterans in the CBPR program.

Involvement of Soldier Societies and Community Health Care Providers

Veterans highlighted the necessity of key contact from both veterans and rehabilitation providers for each village. This is to communicate the necessary information smoothly and get advice when necessary.

The veterans were members of formal societies like “Ranaviru Sansadaya,” which are associated with enabling participants to stay united as one group of army veterans and connecting them with external organizations to receive help. They anticipated that delivering the program through these societies would help initiate and continue the program successfully.

Integration

Figure 3 presents the joint display of quantitative and qualitative findings. Themes of the barriers and facilitators to PA were identified as factors influencing PA participation among veterans, which were associated with lower PA levels and sedentary behavior observed among the majority of the veterans. Additionally, some of these themes were linked to lower QoL outcomes in both physical and mental health domains. Of the themes that were linked to both QoL outcomes and PA participation, themes, such as availability of services and incentives, adequacy and quality of available resources, knowledge and beliefs on recovery expectations and exercises, and ability to carry out PA and exercises, emerged with high frequencies (Figure 1). Expectations for a future CBPR program, which was identified as a potential solution to improve QoL and PA participation by addressing influential factors, are also presented in Figure 3.

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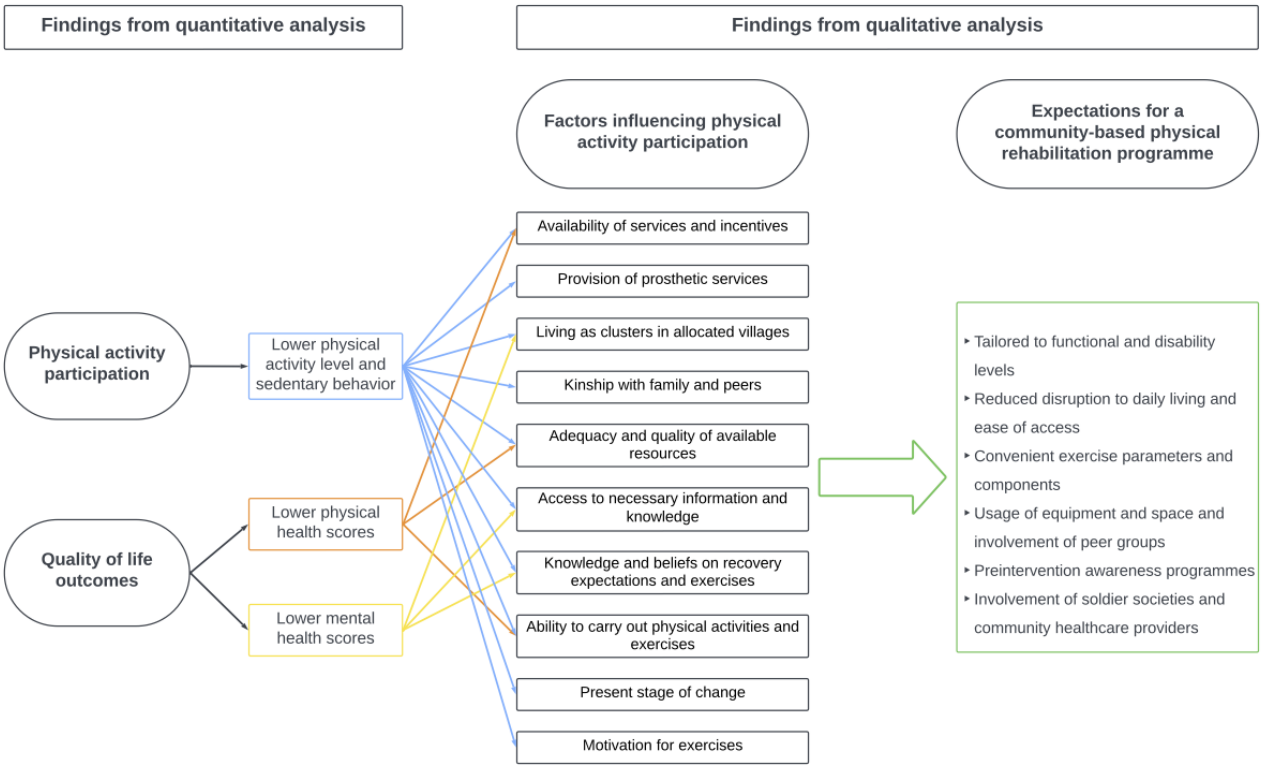
Figure 3. Joint display of quantitative and qualitative findings.



Discussion

Principal Findings

Limited availability of and access to community-based rehabilitation and prosthetic services for survivors of LLA have resulted in poor levels of physical mobility that affect QoL both physically and mentally, including the ability to work, compared with able-bodied members of the society in Sri Lanka. The strongest barriers to PA include low-quality prosthetics and a growing burden of comorbidities, leading to fear and discomfort during PA. A preinjury active lifestyle and a positive attitude toward exercise, especially with family and peer support, were identified as crucial for sustained mobility and long-term rehabilitation. Expectations for a CBPR program included community-based activities tailored to individual disability levels, which are supported by peers and health care providers and are feasible for completion at home.

QoL Outcomes

This study revealed lower QoL outcomes among veterans compared with the findings in a previous study conducted over 20 years ago on the same population [25]. This suggests a decline in QoL over time, possibly attributed to reduced PA participation and rising comorbidities associated with a sedentary lifestyle and poorly managed pain and discomfort [49]. Veterans perceived a decline in their ability to engage in PA and associated it with aging and comorbidities, such as back pain, knee joint pain, hypertension, and diabetes. Consistent with the findings of this study, lower QoL outcomes have been observed among individuals with LLA than among the general population internationally [4,7,50-53].

PA Participation and Influential Factors

Usually, before injury, soldiers have higher levels of PA for their age range compared with nonservice community members. Despite this anticipated higher baseline, survivors of LLA had limited physical function, and their injury was associated with poor functional activity and mental well-being. The survey findings indicated that veterans primarily engaged in moderate-intensity PA, such as gardening, with minimal participation in vigorous-intensity PA, such as sports. Interviews further clarified that veterans perceived activities like household chores, gardening, and walking to nearby shops or houses as sufficient for maintaining a healthy life. However, they failed to meet the recommended levels of PA for an average adult. Their scores were lower compared to scores in similar studies conducted in Australia and the United States, where PA and medium- to long-term community-based rehabilitation programs, including sports activities led by veterans and peer groups, are well established [40,54,55].

Although kinship with peer veterans having similar disabilities was perceived as a facilitator for engaging in PA, living in isolation from the wider society may have contributed to the normalization of their sedentary behavior, which may further be aggravated by the lack of knowledge of recovery expectations and the prevention and management of potential health comorbidities.

Expectations for a Future CBPR Program

Important aspects regarding expectations for a future CBPR program perceived by participants of this study could be described in the following 3 key areas: individualization; function-based exercises; and involvement of key resource persons like peers with LLA, amputee societies, and community

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health care providers. Tailoring intervention components to individual baseline parameters, such as age, disability level, and home environment, is considered essential for participant engagement. Functional exercises are performed with the purpose of enhancing basic everyday motor performance (eg, walking, stair climbing, or sitting and standing up from a chair) and are based on the exercise training principle of specificity [56]. Emphasizing a high functional bias in intervention components reduces the reliance on specialized exercise equipment and allows participants to relate the program to their normal daily activities more easily. For example, use of a graded community walking program and step-ups onto a platform instead of treadmill walking and using bodyweight exercises, such as squats, lunges, and push-ups, to improve muscular strength. The involvement of peers with similar disabilities, amputee societies, and community health care professionals is important in all stages of a community-based rehabilitation program (from design to implementation and follow-up). Similarly, a study highlighted that rehabilitation professionals perceived the involvement of committed and enthusiastic individuals as necessary for the successful implementation and ongoing promotion of PA in the rehabilitation of people with disabilities [57].

Strengths and Limitations

Our study employed both quantitative and qualitative data to investigate PA levels and explore the rationale behind the results and participants' perspectives on potential solutions. The use of theoretical frameworks and adherence to recommended guidelines strengthened our research. However, the generalizability of the findings is limited to male veterans with war-related traumatic unilateral LLA in the community. Nonetheless, our findings shed light on the experiences of a specific disadvantaged group of individuals living in a low-resource setting. Although self-report measures may introduce bias, we mitigated this by using an adequate sample size and a matched control group.

Conclusions

The decline in overall well-being among veterans with LLA in Sri Lanka over time underscores their unmet rehabilitation needs and reveals the long-term impacts of living with LLA in the absence of physical rehabilitation for a young group of veterans. The majority of participants with LLA exhibited insufficient levels of PA owing to barriers, including the absence of community rehabilitation services, limited resources, and a growing burden of comorbidities, such as chronic pain and psychological distress. A future CBPR intervention that is individualized to meet the needs of survivors, with a focus on functionality-biased exercises, and is led by and delivered with peer societies and community health care providers is considered fundamental for successful implementation and adoption. Among the participants, high receptivity in the implementation climate, peer support, a preinjury active lifestyle, and motivation and positive attitudes toward exercise emerged as strong indicators of engagement in a future CBPR program.

Implications for Rehabilitation Practice and Policy

Improving PA participation to recommended levels and enhancing QoL in both physical and psychosocial aspects should be prioritized in the design and implementation of CBPR interventions targeted at individuals with LLA in similar contexts. As the studied population lived with amputation for more than 10 years and the majority had a low to sedentary level of PA, behavior change mechanisms should be incorporated in the intervention components aimed at improving PA participation [58,59]. For effectively addressing the identified challenges, it is required to ensure fair access to community-based rehabilitation services, provide veterans and their families with essential knowledge, and foster support networks through policy-level changes.

Recommendations for Future Research

Future studies should aim to identify the determinants of low QoL and PA participation observed among veterans in this study. Additionally, it is crucial to establish specific PA and exercise parameters effective for improving health outcomes within this LLA subgroup, which need to be considered in a future CBPR program. To enhance the feasibility of future CBPR interventions, inclusive representation of various stakeholders, including health care providers, social workers, and family members, through future qualitative studies is recommended. Furthermore, the feasibility and cost-effectiveness of such CBPR interventions in low-resource settings should be assessed in high-quality randomized controlled trials. As this study was conducted in military community settlements where the majority of veterans with LLA live, the living environment and associated factors like social support and access to rehabilitation services would be different from those of civilians with LLA. In addition, the causes of amputation (traumatic vs vascular), preamputation job roles, and PA levels between military veterans and civilians are generally different. Therefore, repeating the examinations conducted in this study in the civilian population with LLA is crucial for effectively adapting the proposed CBPR program to this population.

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Conflicts of Interest

AW received salary support from the Wellcome award 224048/Z/21/Z during this study. All other authors declare that they have no competing interests.

Multimedia Appendix 1
Interview guide.
[DOCX File , 17 KB - rehab_v11i1e52811_app1.docx]

Multimedia Appendix 2
Comparison of quality of life and physical activity participation between veterans with transfemoral amputation and those with transtibial amputation.
[DOCX File , 17 KB - rehab_v11i1e52811_app2.docx]

Multimedia Appendix 3
Participation in specific forms of physical activities in group 1 (veterans with lower limb amputation).
[PNG File , 170 KB - rehab_v11i1e52811_app3.png]

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Abbreviations

CBPR: community-based physical rehabilitation
CFIR: Consolidated Framework for Implementation Research
GN: Grama Niladhari
IPAQ: International Physical Activity Questionnaire
LLA: lower limb amputation
MCS: mental component summary
MET: metabolic equivalent of task
PA: physical activity
PCS: physical component summary
QoL: quality of life
SF-36: Short-Form Health Survey-36

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Understanding the Sociocultural Challenges and Opportunities for Affordable Wearables to Support Poststroke Upper-Limb Rehabilitation: Qualitative Study

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Abstract

Background: People who survive a stroke in many cases require upper-limb rehabilitation (ULR), which plays a vital role in stroke recovery practices. However, rehabilitation services in the Global South are often not affordable or easily accessible. For example, in Bangladesh, the access to and use of rehabilitation services is limited and influenced by cultural factors and patients' everyday lives. In addition, while wearable devices have been used to enhance ULR exercises to support self-directed home-based rehabilitation, this has primarily been applied in developed regions and is not common in many Global South countries due to potential costs and limited access to technology.

Objective: Our goal was to better understand physiotherapists', patients', and caregivers' experiences of rehabilitation in Bangladesh, existing rehabilitation practices, and how they differ from the rehabilitation approach in the United Kingdom. Understanding these differences and experiences would help to identify opportunities and requirements for developing affordable wearable devices that could support ULR in home settings.

Methods: We conducted an exploratory study with 14 participants representing key stakeholder groups. We interviewed physiotherapists and patients in Bangladesh to understand their approaches, rehabilitation experiences and challenges, and technology use in this context. We also interviewed UK physiotherapists to explore the similarities and differences between the 2 countries and identify specific contextual and design requirements for low-cost wearables for ULR. Overall, we remotely interviewed 8 physiotherapists (4 in the United Kingdom, 4 in Bangladesh), 3 ULR patients in Bangladesh, and 3 caregivers in Bangladesh. Participants were recruited through formal communications and personal contacts. Each interview was conducted via videoconference, except for 2 interviews, and audio was recorded with consent. A total of 10 hours of discussions were transcribed. The results were analyzed using thematic analysis.

Results: We identified several sociocultural factors that affect ULR and should be taken into account when developing technologies for the home: the important role of family, who may influence the treatment based on social and cultural perceptions; the impact of gender norms and their influence on attitudes toward rehabilitation and physiotherapists; and differences in approach to rehabilitation between the United Kingdom and Bangladesh, with Bangladeshi physiotherapists focusing on individual movements that are necessary to build strength in the affected parts and their British counterparts favoring a more holistic approach. We propose practical considerations and design recommendations for developing ULR devices for low-resource settings.

Conclusions: Our work shows that while it is possible to build a low-cost wearable device, the difficulty lies in addressing sociotechnical challenges. When developing new health technologies, it is imperative to not only understand how well they could fit into patients', caregivers', and physiotherapists' everyday lives, but also how they may influence any potential tensions concerning culture, religion, and the characteristics of the local health care system.

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KEYWORDS

rehabilitation; wearables; upper-limb rehabilitation; user-centered design; qualitative; interviews; experiences; attitudes; perceptions; digital health; health technology; wearable; user centered design; design; home; stroke; recovery; affordable; low income; low resource; Bangladesh; physiotherapy

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Introduction

Background

Every year, more than 55 million people globally experience a stroke, which results in around 5 million deaths [1,2]. Those who survive the stroke may lose limb function in the upper limbs [3], which impacts motor control and can lead to long-term or permanent disability [2,4,5]. As a result, stroke patients cannot perform daily living activities such as eating, picking, and placing, and may become dependent on caregivers [4,6].

Stroke patients often undergo upper-limb rehabilitation (ULR) to improve their range of movements [7], which can help them lead independent lives and reduce reliance on caregivers. This rehabilitation is possible in hospital-based and home-based setups [8,9]. Traditional rehabilitation is conducted in a controlled environment in the hospital and includes action observation and mental imagery [8], task-specific training, and constraint-induced movement therapy with trained support personnel [9]. In contrast, home-based ULR focuses on everyday activities that reduce the requirement to visit hospitals [10]. However, access to rehabilitation can be an issue, especially in the Global South. For example, 97.25% of stroke patients in Bangladesh have limb weakness and require rehabilitation [3], and health inequalities mean that rehabilitation services are almost nonexistent [11,12]. Lack of rehabilitation or low engagement and compliance with it can lead to permanent disability, exacerbating poverty and inequality as people and their caregivers cannot work, creating a long-term dependency on caregivers [11]. Furthermore, patients often do not engage with home-based rehabilitation [13], may lose interest in repetitive exercises [14], or may incorrectly perform the exercises for fear of pain [7], negatively impacting the progress of their treatment. Factors such as low physical activity and self-efficacy, stress, lack of support, and adherence to physical treatment can further affect the treatment [7,15].

Novel technologies have been used to support rehabilitation in home-based settings, including virtual reality environments [16], wearable devices [17,18], or robotic devices for measuring upper-limb movements and improving the extension and flexion range of the arms [19-21]. Furthermore, electrical stimulation has been used to stimulate weak limbs [22]. However, these solutions are often complex, large, and expensive [23] and are difficult to integrate in everyday routine. As such, they are not appropriate for home use or low-income communities, especially in the Global South. Wearable technologies are a promising alternative, as they are small and can be worn at home. In recent years, several projects have explored the use of wearable devices to support rehabilitation [24-27] and patient monitoring [28], although their accuracy in identifying differences in upper-limb exercises is limited, and they have not been tested in the home environment. Therefore, there is a pressing need to develop affordable, low-cost ULR tools for stroke patients that support the integration of physiotherapy exercises within community health settings and at home to support recovery and increase the independence of stroke patients.

Aims and Approach

This project aimed to gather contextual and design requirements for affordable, low-cost wearables to support poststroke ULR. In particular, we wanted to understand how ULR is perceived and practiced in Bangladesh and to compare the approach with the practice of physiotherapists from the United Kingdom. While these countries are economically different and are characterized by different cultures, understanding current rehabilitation practices in both settings and differences in approaches would highlight the unique needs of key stakeholders, including Bangladeshi physiotherapists and patients, and help to inform the design of low-cost ULR wearables.

As there is limited research on the user experience of rehabilitation devices in Global South settings (with most studies focused on the technical aspects, eg, Anowar et al [26]), we decided to follow the person-based approach [29] and prioritize understanding the needs of different stakeholder groups, as this is the first step in developing digital health interventions. By starting with qualitative research, we aimed to understand users' experiences, their needs, and challenges they face when providing or receiving physiotherapy. This step is necessary when developing any new technologies or technology-based interventions as it allows researchers to identify a wide range of issues and discuss them in depth [29]. In our case, it would help to explore the challenges stroke patients face as a motivation to identify specific requirements for technology before spending time and resources on development [29]. Therefore, in this paper we report the results of interviews conducted with physiotherapists, caregivers, and patients.

Methods

Study Design

As this was the first step in the design process [29], the aim of the study was to understand the wider context within which users operate and to identify requirements for technology considering different stakeholders' perspectives. Therefore, semistructured interviews were used as the main research method, as they help to understand a given topic in depth and allow researchers to ask follow-up questions while ensuring key topics are covered [30]. Furthermore, as they are a source of rich contextual data, fewer participants are required, especially when conducting an exploratory study with the aim to identify a broad range of related issues [30].

Recruitment and Participants

We used a purposeful and targeted recruitment approach [31] to recruit representatives of all key stakeholder groups. We used our extended networks and local institutions to reach out to physiotherapists and recruited 4 Bangladeshi physiotherapists through medical colleges in Dhaka and 4 British physiotherapists through our contacts at the School of Healthcare Sciences at Cardiff University and the Stroke Association. Five of them were women, and 3 were men. They were aged between 35 and 50 years and had 8 to 14 years of experience working as physiotherapists; they all had experience with ULR. One British physiotherapist had an additional 14 years of experience as an academic.

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Through Bangladeshi physiotherapists, we recruited 3 patients who underwent ULR in the past and 3 caregivers for people who had had a stroke. Patients were aged between 26 and 55 (SD 14.8) years; 2 were men. They underwent rehabilitation for stroke (male; 55 years), hand injury due to an accident (male; 35 years), and carpal tunnel syndrome (female; 26 years). We recruited 1 informal and 2 formal caregivers. The informal caregiver (a housewife) was recruited together with her husband (a patient). The 2 formal caregivers were recruited through formal phone calls to the Caregiver Institute in Bangladesh, where they both worked as caregiver trainers, while the informal caregivers received no such training. The caregivers were aged 40 to 55 years. Table 1 shows an overview of the participants.

Table . Overview of participants and types of sessions in which they participated (n=14).

Session type and participant ID	Participant type	Gender	Format	Country
First round of individual interviews				
PT1	Physiotherapist	Female	Videoconference	United Kingdom
PT2	Physiotherapist	Female	Videoconference	United Kingdom
PT3	Physiotherapist	Female	Videoconference	United Kingdom
PT4	Physiotherapist	Female	Videoconference	United Kingdom
First group discussion				
PT5	Physiotherapist	Male	Videoconference	Bangladesh
PT6	Physiotherapist	Female	Videoconference	Bangladesh
Second group discussion				
PT7	Physiotherapist	Male	Videoconference	Bangladesh
PT8	Physiotherapist	Male	Videoconference	Bangladesh
Third group discussion				
P1	Patient	Male	Videoconference	Bangladesh
C1	Caregiver	Female	Videoconference	Bangladesh
Second round of individual interviews				
P2	Patient	Male	Videoconference	Bangladesh
P3	Patient	Female	In person	Bangladesh
Fourth group discussion				
C2	Caregiver	Male	In person	Bangladesh
C3	Caregiver	Male	In person	Bangladesh

Procedures

We conducted the interviews between March and October 2021. Given the physiotherapists' busy schedules, they were given an option to attend individual or group sessions, depending on their preference and availability. Data were collected by 1 researcher in the United Kingdom and 3 researchers in Bangladesh. Semistructured interviews with physiotherapists were conducted remotely via Zoom (Zoom Video Communications, Inc) and lasted approximately 60 minutes. They were attended by 1 to 2 physiotherapists at the time; all British physiotherapists were interviewed individually, while 4 Bangladeshi physiotherapists joined in pairs. Regardless of the number of participants present, we followed the same protocol during both individual and group interviews.

After explaining the procedures and obtaining informed consent, the interviews started with questions about general experiences in delivering physiotherapy and the difficulties patients face. We then discussed standard practices in ULR following a stroke, focusing on exercises and movements that could be done at home and rehabilitation options available to patients after they leave the hospital. Finally, we talked about their current use of technology and the possibilities of developing a rehabilitation device, its features, and required factors for suitable home-based ULR.

Interviews with patients and caregivers were also semistructured and followed similar procedures; participants also had an option to attend an individual or a group interview and to decide whether they wanted to be interviewed in person or via videoconference. We interviewed 1 patient and their caregiver together via videoconference, 2 caregivers together in person, 2 patients individually via videoconference, and 2 others individually in person. When interviewing participants in person at their homes, we followed COVID-19 safety protocols, that is, we wore masks and maintained distance. Videoconference interviews were conducted through Zoom or Google Meet. The interviews covered similar topics to physiotherapist interviews: their experiences with rehabilitation, their preferences, and their use of technology in this context.

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Ethical Considerations

The research was approved by ethics committees at North South University and Cardiff University (COMSC/Ethics/2021/025). Consent forms for Bangladeshi participants were available in Bengali and English and for the British participants, only in English. British physiotherapists received £20 (US $15.08) shopping vouchers, while Bangladeshi participants received BDT 1000 (US $12) each for their participation; this discrepancy was dictated by the local rates and approved by the ethics committees.

Analysis

The sessions with British physiotherapists were conducted in English and transcribed by a local transcription service. In contrast, Bangladeshi interviews were conducted in Bengali and then transcribed and translated by the researchers who collected the data. In total, we collected and transcribed about 10 hours of audio recordings, which resulted in a rich corpus of data comprising 87 pages (about 60,600 words). The analysis of both sets of interviews was conducted separately but followed the same procedures.

We used framework analysis [32] to analyze the data. The aims formed the basis of the framework used in the analysis of the physiotherapist interviews, and codes of interest included current approaches to physiotherapy, frequently used rehabilitation exercises, use of technology as part of the treatment, common barriers, and comments about a potential wearable system and its desired functionality. Then, based on reading the first few interview transcripts, the framework was updated and used to code the first 2 interviews from both the United Kingdom and Bangladesh. We used the web version of Atlas.ti (Atlas.ti Scientific Software Development GmbH) to code the transcripts, and coding was done by 1 member of the British research team and collaboratively by 3 members of the Bangladeshi research team. While coding the transcripts, we remained alert to potential insights and identified potential broader themes, which were then discussed by the research team during weekly meetings and incorporated into the final coding framework. Another member of the British research team then coded all British interviews, while the Bangladeshi team coded all of them; we then swapped and British team members reviewed the coded Bangladeshi transcripts and vice versa. After the coding was complete, we reviewed and summarized the content of each code and combined the ones with similar content. We then used the codes as columns in the framework table and the participants as rows, which enabled comparisons across the data and allowed us to identify themes.

We used a similar approach to analyzing patient and caregiver interviews, although in this case the coding guide for the physiotherapist interviews was used as a starting point and was adapted to accommodate codes unique to this participant group. All interviews were coded by the Bangladeshi team, who also summarized the framework table. The results were then discussed with the British team, and we identified the main themes together. Finally, we discussed all results to identify overarching themes, which we report in the next section.

Results

Overview

Our goal was to understand the rehabilitation practices and existing challenges of health professionals, patients, and caregivers. We also aimed to identify the contextual and design requirements for a low-cost wearable to support physiotherapy at home. We report 4 themes that have implications for remote therapy and developing rehabilitation devices for use at home.

Theme 1: Sociocultural Factors Affecting Rehabilitation Practices

The interviews highlighted the impact of sociocultural practices on physiotherapy in Bangladesh. For example, access to therapy requires sensitive gendered consideration in Bangladesh, as varying genders of the physiotherapist and patient matter. As a result, families often discourage receiving support from a different gender, even if no other support is available:

> *In Bangladesh, gender is another issue. Women do not take therapy from male therapists, and male patients do not take therapy from female therapists. Sometimes families discourage us from doing that. Older patients usually feel or consider the cultural barriers.* [PT5, physiotherapist, man, Bangladesh]

Our results also showed that if physiotherapists and patients were of different genders, this could introduce additional unexpected barriers ranging from dismissal to potential harassment, which can negatively affect the treatment and discourage patients from engaging with rehabilitation or physiotherapists from attending certain patients. In addition, we noticed a widespread belief and clear expectations of what a physiotherapist should look like, with patients preferring physiotherapists of certain physical characteristics:

> *Another perception in Bangladesh is physiotherapists should be healthy, tall, and stronger. So, I am small in size, which is why patients sometimes do not accept me. They openly express it, "How can you help with my movements?" And family members also tell us like, "Send someone healthy".* [PT6, physiotherapist, woman, Bangladesh]

Family support can also significantly impact the success of rehabilitation. For example, when family members help the patient too much with everyday activities, it can reduce their opportunities to engage in everyday actions that are beneficial to their overall rehabilitation and could discourage patients from engaging in formal exercises, hampering their independent movement in the long term. Both British and Bangladeshi participants mentioned this issue:

> *I have worked with Indian communities around that area, and it was interesting that they did too much for their older people or people who were unwell. They do not let them do anything...their culture is to care for their elderly.* [PT4, physiotherapist, woman, United Kingdom]

In addition, often the family's religious beliefs have an impact on the rehabilitation process. For example, if the family strongly

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believes it is up to God whether someone will recover, they may discourage rehabilitation or not provide any support at home:

> *Parents think if Allah wants, only then these kids can walk. They always ask us when their children can walk, but they don't cooperate. We always tell them that muscular dystrophy patients cannot walk, but they don't believe this. The mom of that family already works as a caregiver in a center, and should know this, but she never provides support to her baby.* [PT6, physiotherapist, woman, Bangladesh]

However, despite potential barriers that family can introduce, it also plays an essential role. Participants from both countries reported that family members often helped with rehabilitation exercises or made sacrifices to enable the treatment. For example, one caregiver reported:

> *At the beginning [of the COVID-19 pandemic], his elder brother massaged him for around 2 hours daily.* [C1, informal caregiver, woman, Bangladesh]

Theme 2: Dimensions of Physiotherapy Practices in Rehabilitation

We also identified differences in the approach to therapy. The interviews with British physiotherapists revealed that they often took a holistic view of the treatment. They reported focusing not just on the immediate movements related to ULR but the broader context in which the patient operates, including functional movements (eg, completing everyday tasks such as getting dressed or eating), their mental health, and their general buy-in and understanding of the need for treatment.

> *I think you would get disappointed if you were to aim at improving wrist flexion, for argument's sake. When it's the whole quality of life, you want to look at. So, it's making it more holistic.* [PT2, physiotherapist, woman, United Kingdom]

In contrast, Bangladeshi physiotherapists came across as more pragmatic by focusing on ensuring the patient had the building blocks needed for functional movements further down the line. For example, they emphasized focusing on a few significant movements, such as flexion, pronation, extension, and supination for the wrist, elbow, and shoulder. They also encouraged simple exercises like pinching to help activate muscles.

> *We do an exercise such as grabbing a page sheet with two fingers together and pulling it. Stroke patients' muscles don't have enough strength to do it. They are called intrinsic muscles; through this exercise, we activate them. If you can put the sensor in the fingertip, it is good.* [PT5, physiotherapist, man, Bangladesh]

Therefore, Bangladeshi physiotherapists seemed less concerned by patients' buy-in and expected them to practice the exercises, even if they involved repetitive movements. While they understood the benefits of holistic treatment, they preferred to focus on quick wins and targeted treatment to facilitate engagement. This was seen as more practical and helped regularly assess the progress of the patient, as it could be matched with their muscle power grades.

> *In Stroke patients' rehabilitation, the movements we are following depend on several stages with several movements. It depends on muscle power. When muscle power is 0, that means the patient is completely paralyzed. This time we do the movements for the paralyzed patient. We have a total of 6 grades: 0-5. In grade 1, the patient can move a bit. Grade 2 is similar but has better movement than grade 1. In grade 3, the patient can move hands against gravity a bit. In 4 and 5 grades, patients can move their hands far better. This time they do not require help.* [PT7, physiotherapist, man, Bangladesh]

Theme 3: Challenges of Home-Based Rehabilitation During and Beyond the Pandemic

While we were not explicitly interested in the impact of the COVID-19 pandemic on rehabilitation, it was impossible to ignore it, as it has exacerbated existing challenges to providing physiotherapy at patients' homes and introduced new ones. Our participants highlighted issues related to movement accuracy, repetition, and COVID-19 contamination risks related to home-based support.

> *During the lockdown, our centers were closed.... We are now trying to give home service so patients can at least continue the therapy at home. However, patients also do not allow physios to their homes due to COVID-19. Therefore, they can't take therapy and get negatively impacted.* [PT6, physiotherapist, woman, Bangladesh]

Caregivers also reported that patients and people they looked after were hesitant to meet with physiotherapists due to COVID-19 concerns, both at the rehabilitation center and at home. For example, 1 informal caregiver shared her patients' distrust and fear of catching the virus, which stopped them completely from engaging in physiotherapy:

> *Physios move around. They will not treat only a single patient. That is why we feared COVID infection because my patient was vulnerable, and he still is. We tried to keep ourselves safe as much as possible. If COVID were not there, the treatment would go better.* [C1, informal caregiver, woman, Bangladesh]

As the rehabilitation had to be delivered at home during the pandemic, it increased costs and further reduced the affordability in Bangladesh ("The cost was double or thrice for the home service." [C1, informal caregiver, woman, Bangladesh]). As a result, our participants reported strategies that required balancing the affordability of the treatment with its effectiveness, such as bypassing physiotherapists and hiring nonprofessionals in their community to support physiotherapy at home:

> *The same things happen in the house also. A maid does the movements they observe from therapists. So, the family discourages the therapists from coming home and paying a small amount to the maid [nonprofessional] to do the movements. This is bad*

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> *for accuracy.* [PT6, physiotherapist, woman, Bangladesh]

Apart from potential COVID-19 issues, unsupervised rehabilitation at home in general poses several risks. For example, our participants highlighted the risk of patients overdoing their exercises when practicing on their own. This may happen when they want to leave physiotherapy centers early and continue the exercises repeatedly without experts' opinions. Furthermore, the physiotherapists explained that inaccurate movements, done without regular supervision, could hamper recovery or even lead to negative outcomes:

> *When the patient can walk somehow at home, all are happy...this patient can completely get well if he is treated by an expert. That is why, the movement should be accurate, and otherwise the postures will be permanently changed for the patient.* [PT6, physiotherapist, woman, Bangladesh]

In addition, home-based rehabilitation is often overseen by informal caregivers, usually family members. However, due to their lack of expertise, they may incorrectly support the movements, or patients may misunderstand what they are supposed to be doing if they rely on video prompts, which also can have negative long-term consequences.

Theme 4: Attitudes Toward Rehabilitation Technologies

There was a clear difference in familiarity and exposure to rehabilitation technologies among the physiotherapists in the United Kingdom and Bangladesh. The British physiotherapists mentioned a wide range of rehabilitation devices they use at work, including rehabilitation gloves and functional electric stimulation. They also reported that, in general, patients liked using gadgets, which improved motivation and engagement:

> *Saebo Glove helps to increase that movement and from a functional point of view, being able to use that glove around the house, it was a lot more helpful because you could use it in function with that little bit of extra help.* [PT1, physiotherapist, woman, United Kingdom]

In contrast, Bangladeshi physiotherapists said they did not use or have wearable solutions, although they did use electrical rays and stimulators to stimulate muscles and nerves. At the same time, both caregivers and patients reported their interest in using wearables in rehabilitation. For example, C2, a professional caregiver trainer, explained that a wearable system with feedback would ease the activities of caregivers and therapists. Patients also shared the potential of using wearables that might detect wrong movements and provide feedback, which would improve movement accuracy. They also believed that it would be more beneficial if the device could detect the injured area and let patients know what is happening through the wearable. For example, P2 explained:

> *If a device can detect which areas have been injured, it will be more beneficial because therapy depends on different sections of injury. And try to add options to let people know what to do. Because normal people are not educated enough to find the treatment.* [P2, patient, man, Bangladesh]

However, despite the potential benefits, the cost of rehabilitation was an issue, and this applied to both countries. While wearables such as the SaeboGlove (Saebo, Inc) "are really good" (PT1, physiotherapist, woman, United Kingdom), they can be "prohibitively expensive" (PT3, physiotherapist, woman, United Kingdom) for patients who may want to use them at home. We also found that using technology to support rehabilitation caused discomfort and anxiety for some of the patients. For example, Bangladeshi physiotherapists mentioned that their patients thought that technology was too complicated or scary. This was echoed by the patients. For example, P3 said:

> *When they diagnosed me, they applied many devices to me. I was so scared to see them. It's like, why so much equipment? When they told me I must take the therapy, I remembered the diagnosis system. I again got scared. I prefer everything to be natural.* [P3, patient, woman, Bangladesh]

Discussion

Principal Results

Our results highlight the impact of sociocultural factors on rehabilitation in Bangladesh. In particular, the family plays an important role in supporting patients, and through their involvement they may enable or hinder the treatment. Furthermore, people have personal preferences regarding physiotherapists' gender, which can negatively impact the treatment if male patients do not want to engage with female physiotherapists. We also show differences in approaches to rehabilitation, with Bangladeshi physiotherapists focusing on individual movements that are necessary to build strength in the affected parts, and British physiotherapists favoring a more holistic approach that covers functional movements and considers patients' mental well-being. Finally, our participants reported that COVID-19 exacerbated the challenges of home-based rehabilitation. During the height of the pandemic, physiotherapists were not able to access their patients' homes, which resulted in limited access to rehabilitation, interrupted treatment, and increased costs.

Nevertheless, participants were optimistic about the potential of using wearable technologies at home, although they had concerns regarding the complexity and cost of such devices. Availability of affordable devices can be useful in low-resource regions like Bangladesh as well as in high-income regions such as the United Kingdom, considering the high cost of existing solutions. We have learned from our participants that any device intended to be used in the home would need to support and monitor hand and finger movements and provide feedback on their accuracy. More importantly, it would need to be affordable. Our results echo previous research that shows a simple, affordable wearable can be good enough to identify certain movements [18] and that such a device can be developed using cheap components [24-27]. However, technical requirements are only one aspect. The success of rehabilitation relies on consistent engagement [13], and that consistency means that

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the device should be suitable for home-based use to fit into patients' lives.

Sociotechnical Considerations: How to Fit ULR Technologies Into Everyday Life

Overview

While our results suggest that a wearable device could help with rehabilitation in home-based settings, they also highlight several sociotechnical challenges that need to be addressed first. Even the best technology can fail if the target users do not want or are unable to use it [30], and this is particularly important if it can (intentionally or not) challenge or affect cultural norms or religious customs [33,34]. Below we discuss the key trends identified in our data and conclude with a set of practical considerations for developing ULR technologies for low-resource settings.

Designing for Gendered Norms and Expectations

Our results showing that gendered expectations toward physiotherapists can limit patients' access to treatment are in line with earlier work that shows differences in treatment based on patients' gender [35]. Furthermore, Stenberg et al [36] consider gender to be a social construct that is shaped by norms and social context, which affects rehabilitation at every stage: from the experiences of physiotherapists and patients to how the care is accessed and provided. While a person's religion in itself does not affect stroke rehabilitation [37], it does influence familial relationships and expectations, playing an important role in ULR. As such, any rehabilitation device or system – both its functionality and design – should consider the values and expectations of its target users and their families and needs to be acceptable to both patients and their caregivers. Finally, any new technologies introduced into the home, even with the best intentions, may encounter barriers related to the home environment (including issues with finding the right location) [38] and could potentially result in increased workload as they would need to be operated and maintained. Given that most informal caregivers in Bangladesh are women [11], these effects could also disproportionately affect them. Therefore, any home-based rehabilitation technologies need to take all the above factors into account.

Designing With Technological Literacy and Acceptance in Mind

We also identified some apprehension and discomfort related to technology use among patients and caregivers. At the same time, participants were open to try out new things, although they acknowledged their limited literacy. This echoes previous research on patients' and physiotherapists' experiences with technology [39-41]. For example, research on remote rehabilitation during the COVID-19 pandemic highlighted issues with technology literacy [40]. One way to address this issue could be through supplementary materials, such as videos [42]: when presented with a blended physiotherapy intervention that included home-based components, participants appreciated videos representing the exercise [43]. Another way could be through exposure to new digital technology. This could be done through exhibitions, online consumer rating websites, or user networks [39], or it could be done on an individual level. One of our participants mentioned being scared of various rehabilitation technologies (see P3's quote in the Theme 4 section), but if the technology had been carefully introduced, the experience could have been less stressful. Research shows that human intermediaries (eg, health professionals and family members) can help people use novel technologies and make the experience of using them less intimidating [44].

In addition, to improve acceptance, the design needs to reflect target users' values and culture [45-47]—an approach that has been taken when designing other types of rehabilitation technologies. For example, Villada Castillo et al [48] designed a virtual reality game for ULR among stroke survivors in Colombia that used cultural references and traditional Andean activities to make it more accessible to older participants. While it may be easier to design a game informed by cultural references than a wearable device, understanding users' aesthetic preferences could help with adoption. For example, Wu and Munteanu [49] developed a wearable device for fall risk assessment in the form of a belt. Using a familiar object made participants more comfortable with technology and ensured regular engagement, although they did request different styles and designs. Similarly, in a study focused on designing wearables for Anishinaabe older adults with dementia from the Manitoulin region of Northern Ontario [50], participants did not like the "big and clumsy" prototype and suggested designing it so that it resembled familiar objects, such as bracelets. These examples suggest that making a simple ULR device that draws inspiration from contexts familiar to end users could make it more accessible and help to minimize literacy issues if it resembles familiar objects.

Designing for Different Approaches to Treatment

Third, we identified differences in physiotherapy practices and implications of different treatment approaches, which can be explained by limited resources and logistical issues related to delivering physiotherapy at home and accessing health care facilities [11,12]—all of which were exacerbated by the COVID-19 pandemic. However, the Bangladeshi physiotherapists' focus on fundamental movements could make it easier to develop low-cost wearables that can recognize them [18,26]. It may also make integration of rehabilitation in everyday life easier, as the simple movements (and therefore any wearable device that supports them) do not require a lot of space or a complicated setup, although they may still require renegotiation of social relationships and additional care work [38]. This raises the question of who should be the target user for rehabilitation technologies: the patient who will use them or the informal caregivers who will help the patient put them on, use them, and maintain them? Ideally, the needs of both groups should be addressed.

Designing for Low-Resource Settings

Finally, while our focus was on low-cost wearables, "cost" in the context of rehabilitation technologies can be understood as "value for money" [39], especially when even the cheapest device may be too expensive for some Bangladeshi patients or not worth purchasing if the home environment or family situation do not afford regular use. As such, another point worth considering is device ownership—perhaps the device should

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be developed for physiotherapy settings with recommendations from both caregivers and physiotherapists, and physiotherapists could lend it to patients and provide at least minimal training to users and their families. Furthermore, having a rented device could work as an additional motivator and provide a sense of accountability, which may be necessary given low adherence to rehabilitation treatments [13,14].

Practical Considerations and Design Recommendations

Based on the above discussion, we highlight the following practical considerations and recommendations that will help designers and developers to create ULR devices for end users in the Global South and other low-resource settings: First, ensure the device is simple and easy to use so that patients and caregivers can operate it without a complex setup. Second, avoid procedures for use that require a significant effort and time investment on the side of the user. Third, identify the minimum required movements that would benefit the patient while still being relatively simple to execute. Fourth, in addition to functional requirements, do not overlook requirements such as maintenance, charging, and storage. All these steps add to the existing workload and could lead to nonuse and eventual abandonment if they do not align with target users' daily routines. Fifth, use low-cost components that are good enough to recognize target movements (eg, flex sensors and an accelerometer can work well [18]); consider energy consumption and battery life. Sixth, when developing the device, engage users, especially women, in a co-design process to ensure the design and functionality of the device reflect their lived experiences and align with their sociocultural values. This will also help to come up with designs that are more contextually and culturally acceptable and less intimidating.

Strengths and Limitations

The involvement of physiotherapists, patients, and caregivers was the strength of our study as it helped to identify the needs and opinions of a range of key stakeholder groups. The interviews with UK physiotherapists helped to compare physiotherapy practices and better understand the needs of delivering treatment in the home and what may and may not be possible in the Bangladeshi setting. Finally, our focus on Bangladesh and understanding the needs of our participants provide insights that could be beneficial when developing ULR technologies aimed at other Global South settings with limited resources and similar sociocultural considerations.

Due to COVID-19 mobility restrictions, we experienced difficulties with accessing participants and could not recruit as many stroke patients and informal caregivers as we initially aimed. To expand our participant pool, we decided to cover other types of conditions that also require ULR, which may have impacted our results. Furthermore, the experiences of the pandemic might have affected the way participants thought about home-based rehabilitation and their responses. However, given that we were interested in the general approach to ULR, patient experiences with home-based rehabilitation, and the role and concerns of caregivers, the results still provide relevant insights as participants were asked to describe their real experiences. As discussed in the Results (in the Theme 3 section), participants openly shared their COVID-19 experiences and how their rehabilitation was affected by the pandemic, which we took into account when forming the practical considerations.

We interviewed 14 participants in total. We acknowledge that the data cannot be generalized, but the sample size is typical for an in-depth formative study (see, for example, Stawarz et al [51,52]) and is sufficient to identify key design considerations [53] and provide a further understanding of the complexities and social and economic context of home-based ULR. Following the person-centered approach [29], the next step in our research program is to organize in-depth design workshops with a larger number of poststroke patients and their formal and informal caregivers and to develop demonstrator prototypes that can be tested in their homes to gather further insights.

Conclusions

A qualitative study with physiotherapists, patients, and caregivers focused on their experiences helped us to identify several sociocultural challenges and considerations that should be taken into account when developing ULR technologies for the home in low-income countries. While it is possible to build a low-cost wearable device for ULR, these sociotechnical challenges need to be considered together with functional requirements, as interpersonal relationships involving patients, physiotherapists, and caregivers (and other family members) can affect access to and quality of care.

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Conflicts of Interest

None declared.

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Abbreviations

ULR: upper-limb rehabilitation

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Original Paper

Consumer Perceptions of Home-Based Percussive Massage Therapy for Musculoskeletal Concerns: Inductive Thematic Qualitative Analysis

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Abstract

Background: Musculoskeletal pain is a prevalent concern among diverse populations, from the average individual to the elite athlete. Handheld percussive massage therapy devices like massage guns have gained much popularity in both medical and athletic settings. Its application has been prominently recognized in injury prevention and rehabilitation. The expansion of the market to provide handheld percussive therapy devices with varying features and price points has encouraged professional and novice use. While percussive therapy holds similarities to more studied therapeutic modalities, like vibration therapy and soft tissue mobilization, there is limited evidence-based information on the indications and contraindications.

Objective: This study aims to use a qualitative analysis of consumer perceptions to understand the perceived therapeutic potential of percussive massage therapy as a home-based intervention for musculoskeletal concerns of everyday users and elite athletes. Additionally, we aim to gain insight on valuable characteristics supporting its therapeutic potential as well as pertinent limitations.

Methods: The TOLOCO massage gun (TOLOCO) was identified as the best-selling percussive massage therapy device on Amazon. We performed an inductive thematic qualitative analysis on the top 100 positive comments and the top 100 critical comments of the device between June 2020 and April 2023 to determine 4 relevant themes.

Results: The 4 themes identified upon qualitative analysis were pain management, versatility, accessibility, and safety and user education. Consumer reviews indicated use for this percussive therapy device in adolescents, adults, and older people across a spectrum of activity levels. Consumers reported the therapeutic potential of percussive massage therapy in managing wide-ranging musculoskeletal concerns like acute pain, chronic pain, nonsurgical injury rehabilitation, postsurgical injury rehabilitation, and injury prevention. Consumers highlighted the versatility of the device to address person-specific needs as a key feature in supporting its perceived therapeutic benefits. Additionally, consumers frequently commented on the affordability and availability of this device to increase accessibility to home-based care. Some critical reviews emphasized a concern for the quality of the device itself. However, this concern did not translate to the overall modality of percussive massage therapy. Of note, despite strong approval for its therapeutic potential, consumer reviews lacked evidence-based insights on appropriate usage.

Conclusions: Home-based percussive massage therapy holds value with its perceived efficacy in pain management for acute and chronic conditions, as well as in injury prevention and rehabilitation. As a low-cost and readily available device for everyday users and high-performing athletes, percussive massage therapy works toward establishing increased health care accessibility and optimizing health care usage. This home-based intervention can serve to reduce the significant personal and economic burden of prevalent musculoskeletal concerns. However, the limited scientific research on percussive massage therapy raises concerns about the lack of evidence-based care and indicates the need for future studies.

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KEYWORDS

home-based therapy; injury prevention; massage guns; musculoskeletal pain; pain management; percussive massage therapy; rehabilitation; self-management; sports medicine

Introduction

Musculoskeletal pain can significantly impact the physical and mental well-being of a wide range of individuals [1,2]. Not only that, but musculoskeletal pain has also been shown to increase the economic burden on both the individual and the health care system [3-5]. Thus, handheld percussive massage therapy has continued to gain popularity for its application in musculoskeletal pain, injury prevention, and recovery in both the medical and athletic realms. The use of this therapeutic mechanism transitioned beyond the office setting to home due to a vast array of manufacturing companies like Therabody and Hyperice. Now, Amazon's platform offers a wide variety of percussive massage therapy devices with different features and price points. In increasing accessibility to percussive massage therapy, Amazon opens the market for professional and novice use.

Percussive therapy is said to have originated in the mid-20th century by Robert Fulford and involves the delivery of high-velocity and low-amplitude oscillating forces to the body [6]. It is proposed to be a notable method of myofascial release [7]. The myofascial system works by distributing tension across a network of connective tissue covering muscles, bones, and organs [8,9]. Due to the continuity of this system, tissue overload or repetitive strain injuries in one region of the body can create dysfunctional biomechanics, impairments in functional movement patterns, and referred tension in other regions of the body [8]. In acting as a myofascial release modality, percussive massage therapy can potentially serve to renew the fascial tissues and manage their restrictive distortions.

Percussive therapy is suggested to incorporate components of more well-studied therapy modalities like vibration therapy and conventional massage [10]. Vibration therapy is said to elicit its therapeutic impact on muscle fibers and proprioception, with health outcomes demonstrating improvements in elasticity, mobility, lymphatic and blood circulation, and swelling [11]. Soft tissue, a common modality of conventional massage, has shown similar health benefits with regard to improvements in circulation, range of motion, and muscle relaxation [12,13]. Its suggested mechanism of action involves reducing friction between fascial layers, improving muscle fiber patterns, and reducing the buildup of abnormal hyaluronic acid molecules in implicated regions [13]. In combining these approaches, percussive therapy has been postulated to promote biomechanical and molecular functioning by improving circulation and lymphatic flow, increasing range of motion, and reducing pain perception and adhesions [8,10]. There are limitations present in detailing the physiological mechanism of percussive therapy itself, given the lack of current evidence-based research.

Today, percussive massage therapy is widely used and has the capacity to mimic conventional therapeutic approaches by serving as a possible self-myofascial release modality. This paper primarily aims to analyze consumer perceptions of the massage gun, a well-known percussive massage therapy modality, in order to gain further insight on its therapeutic potential as a home-based intervention for musculoskeletal concerns of both the everyday user and high-performing athletes. Additionally, this paper seeks to gather information on valued characteristics that support its therapeutic potential as well as pertinent limitations that comment on its necessity for improvement.

Methods

Study Design

This study used an inductive thematic qualitative analysis to explore consumer perceptions of the therapeutic potential and limitations of home-based percussive massage therapy. Qualitative analysis has been deemed a suitable methodology for drawing insights and perspectives from the human experience [14,15]. The authors used an inductive thematic framework to derive data-driven insights and perspectives on this topic without predetermined input [16].

Data Source

Through Amazon's search engine, the TOLOCO massage gun was identified as the best-selling handheld massage gun on Amazon. Given the consumer trend toward web-based shopping platforms in combination with Amazon's diverse market and large influence in e-commerce, the authors found Amazon to be an appropriate data source for consumer reviews [17-19]. The authors performed a qualitative analysis on consumer reviews of this device between June 2020 and April 2023 to interpret consumer perceptions of home-based percussive massage therapy [17,19,20].

Data Collection

The inclusion criteria for this qualitative analysis required the consumer review to be a verified purchase by Amazon, fall between the June 2020 and April 2023 time frame, and include a written review alongside its rating. The authors applied the indicated inclusion criteria to 35,985 total ratings and 7516 verified purchase consumer reviews. The top 100 positive and top 100 critical comments of this subset were used for analysis [17,19,20]. Positive and critical categories were predetermined by Amazon itself. A total of 4 positive consumer comments were discarded as the content was categorized incorrectly or lacked a formal review. Additionally, 2 critical comments were discarded as the content was categorized incorrectly or was incomprehensible. Reviews written in languages apart from English were translated through Amazon's translate feature. Data was stored on a cloud-based platform. All information was deidentified before data storage and use. Consumer reviews were left unedited for authenticity.

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Data Analysis

An inductive thematic qualitative analysis was performed on consumer reviews of the TOLOCO massage gun on Amazon. On initial analysis of consumer reviews, the authors manually developed a codebook based on pertinent key points and common patterns [16]. Some code examples included: "muscle recovery," "postsurgical care," "accessories," "multiple modes," "price point," "self-therapy," "user manual," "battery defect," and "longevity." After the development of this initial codebook, a secondary analysis was conducted to ensure appropriate coding adjustments for all transcripts. The final codebook consisted of a total of 40 codes. After completion of coding, an analysis was carried out on the codebook itself in order to derive 4 distinct themes of percussive massage therapy. Subthemes of the 4 overarching themes were also generated. For example, the theme "accessibility" included subthemes of "affordability" and "availability." The authors performed a third review of consumer transcripts and applied the relevant identified themes and subthemes to each [15]. Quotes that were found to best represent each theme and subtheme were used to better illustrate consumer perceptions of percussive massage therapy.

Ethical Considerations

The data for this qualitative analysis were gathered from publicly available information. Thus, this research was deemed exempt from the University of California, Los Angeles institutional review board. This study does not qualify as human subjects research and therefore does not require further informed consent or compensation. All public data were deidentified before use. Generative artificial intelligence was not used in the context of this paper.

Results

Findings

The TOLOCO massage gun had a 4.5-star rating with 35,985 total ratings and 7516 verified purchase consumer reviews. Of those 7516 reviews, there were 5936 positive reviews and 1580 critical reviews. In analyzing the top 100 positive reviews and the top 100 critical reviews, 4 pertinent themes were identified: pain management, accessibility, versatility, and safety and user education. Consumer demographics such as age, gender, and location were not readily available unless specified within the consumer review itself.

Theme 1: Pain Management

Pain management was one of the most common positive indications for this device based on consumer reviews, with 51 positive comments discussing some form of therapeutic purpose. Under pain management, consumer reviews suggested the handheld percussive therapy device be adapted to a diversity of patient circumstances, including daily pain, chronic pain, nonsurgical injury management, postsurgical injury management, and injury prevention. Table 1 details information derived from both positive and critical reviews for each category encompassing pain management.

Table 1. Consumer perceptions of percussive massage therapy in pain management.

Type of pain	Consumer perceptions
Acute aches and pains	I can't wait for my next Charley horse calf spasm. I am going to jab this gun at max setting into that contacting calf muscle and turn it into tenderized sirloin. Also works well at blasting away muscle knots and tensions in my trapezius area. I am a side sleeper, spend long hours at desk and driving which causes problems. This blasts away deep tissue knots and tension away. I sleep better and wake up with greater range of motion.
Chronic pain	I used to be a black diamond skier in my youth, and unfortunately, all those young and reckless checks that I wrote when I was younger are being cashed now. I wish I had a time machine so I could go back and tell that idiot how much arthritis I would have when I got older because of the crazy stunts I pulled. Anyway, to wrap things up I absolutely 100 percent strongly recommend these percussion guns to help with all kinds of aches and pains.
Nonsurgical injury rehabilitation	I have been seeing massage therapists for several months to work on a strained muscle and my T-band and a tight psoas muscle. She used this device to help break up the huge knot in my leg that she and another therapist have been working on for several months. This massage gun did the trick! So, I bought one to have at home as I gently start exercising my leg muscles again.
Postsurgical injury rehabilitation	Just had a hip replacement and the muscles in my leg and hip knotted up. Got this bad boy and wacked my leg and hip till I couldn't stand it anymore 3 days later it was gone.
Injury prevention	I'm training for a 10K and I know my legs are going to be sore and I'm excited to have this to help manage that over the next few months.

Some consumers mentioned being introduced to this percussive therapy device by health care providers. This prompted consumers to conduct their own research to identify the appropriate at-home percussive therapy device to best meet their health needs. One positive review stated:

> *A couple of months ago, I didn't even know massage guns existed. Enter a physical therapist who used one of these on my leg during a session. I was so impressed by how much it helped that I started doing some research and found this gun.*

In analyzing the top 100 critical reviews, 17 commented on the product's capacity to contribute beneficially toward their pain management regimen. A total of 10 consumers felt dissatisfied with the product's pain management capabilities. Despite the number of critical reviews analyzed, only 1 indicated that percussive massage therapy devices were overall not the best product for them. In critical reviews, common input suggested this particular device was either lacking in intensity or too powerful—issues that might be mitigated by more cushioned attachments, improved quality, or a similar device by a different manufacturer.

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Theme 2: Versatility

Versatility was the second-most commonly discussed key feature of the TOLOCO massage gun. Consumers discussed its various applications supported by the 15 attachment heads and speed adjustability. These various attachments allow for targeted massage of different muscle groups. Both the speed adjustability and the many attachments gave consumers the opportunity to personalize their user experience. Not only that, but consumer experiences also highlighted how the versatility of this percussive therapy device reaches varying populations, age groups, and person-specific needs. For instance, a consumer discussed its benefits for different needs in their own household:

> *We have a household full of athletes, and the gun proved invaluable in losing up knots and returning blood flow to aching muscles. Our daughter (a dancer), used in two to three times a week, and I would use it after 4+ hour rides (bicycling).*

Overall, consumers appeared to agree that the versatility of this device contributed to its therapeutic potential.

Theme 3: Accessibility

Of the top 100 positive reviews, 29 consumers discussed accessibility as a key feature of this handheld percussive therapy device. Accessibility was referenced when consumer reviews discussed aspects of either affordability or availability. Regarding affordability, a consumer commented:

> *I was recommended by my physiotherapist to use a percussion massage gun to loosen up my calves and shoulders, but I couldn't justify paying $300 or more for a Theragun.*

Another consumer even compared this budget-friendly model to those seemingly more expensive and stated:

> *I have the Theragun mini and this gun outperforms the Theragun big time. Waaaay quieter, feels smoother, the attachments are game changing. I was nervous due to the low price, but so far it's been light years better than my Theragun and light years cheaper.*

While not all consumers agreed with this statement, most positive reviews suggested it to be a quality product for its price point.

Most critical reviews commented on the longevity of the device, with consumers stating that they experienced battery or internal defects resulting in product malfunction. In this case, some consumers indicated that they opted for a product replacement as they found percussive therapy to be a cost-effective and ideal method of managing musculoskeletal pain. For instance, a consumer stated:

> *After a couple weeks it started making a high-pitched humming sound. Amazon was fantastic about sending me a replacement very quickly. It's too bad because these are priced very well, and they seem to be built well.*

Other consumers returned the device because they found the overall quality to be a point of concern.

Theme 4: Safety and User Education

The final identified theme upon qualitative analysis was safety and user education. While not a direct component of the therapeutic potential and limitations of the device, it is a notable mention to establish better practices for its use. This comprised guidance from both the manufacturer and other consumers as well as established safety features. Consumer recommendations were based on personal knowledge, experiences, or errors, as demonstrated in Table 2. However, no consumer reviews commented on the use of direct evidence-based guidelines to facilitate usage of this device.

Table 2. Consumer-based recommendations regarding safety and education of percussive massage therapy.

Consumer experience	Consumer recommendations
Personal knowledge	I would advise doing some due diligence and research to make sure you get the right model and brand for you that suits your needs. I also recommend starting slow, with shorter sessions so you don't overdo it. Muscles can release some chemicals (lactic and Uric acid) during massage and if they aren't used to these it could make you a little sore at first. It's like going to a chiropractor. At first it can feel worse, then it feels better. Same kind of thing here but it can be mitigated with a slower titration of time spent daily on massage.
User experience	Caution is in order when working around thin muscle tissue near bone and joints, since the 12 mm travel distance of the TOLOCO Massage Gun can cause discomfort quickly if there is insufficient tissue depth to lessen the impact on hard structures.
User error	It would not charge but I finally figured out that I grabbed the wrong charger. So user error, it is still working great now.

Consumer reviews indicated the product manufacturer established safety components, including a user manual and an automatic shutdown feature. Consumers found the user manual to assist in appropriate and optimal product usage by indicating detailed information on how to use the device and its fifteen attachments. The automatic shutdown feature of the TOLOCO massage gun turned off the device after 10 minutes of use to protect both users and the device. A consumer commented:

> *Speaking of the 10-minute limit, both devices recommend limiting your sessions to 10 minutes at each sitting. This is partly due to physiological reasons and to prevent you from overworking your muscles. But also, you need to give the motor on these kinds of devices some rest to prevent overheating. The Toloco has an auto-shut off function that turns the device off after 10 minutes of continuous use. I appreciate this feature as it protects my device.*

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In critical reviews, however, a consumer noted their frustration with the 10-minute automatic shutdown feature and stated:

> *The biggest thing about it that bugs me is that it shuts off every 10 mins or so and requires me to turn it back on again. This shouldn't be a problem for people using it less than that, but I use it for an hour at a time and it gets really annoying having to turn it on over and over again.*

Discussion

Overview

This qualitative analysis of consumer perceptions of the TOLOCO massage gun on Amazon commented on the generalized therapeutic potential of handheld percussive massage therapy. While this paper focused on an individual percussive therapy device and comments on specific features of said device, this qualitative analysis served to gain insight on the therapeutic potential and limitations of using generalized percussive massage therapy as a home-based intervention for musculoskeletal concerns. The qualitative analysis of consumer reviews demonstrated use for this device in adolescents, adults, and older people. Its use was displayed across a spectrum of activity levels, ranging from bedridden to sedentary to high-performing athletes. In analyzing the top 100 positive and top 100 critical verified purchase reviews, 4 pertinent themes were identified: pain management, versatility, accessibility, and safety and user education. Both positive and critical consumer reviews suggested this percussive therapy device addressed wide-ranging musculoskeletal concerns, including daily pain, chronic pain, nonsurgical injury management, postsurgical injury management, and injury prevention. Critical reviews regarding the device's pain management capacity were primarily regarding device-specific features and suggested identifying an alternative percussive therapy device. The critical reviews highlighted the variability of personal preferences or needs rather than the generalized inability of percussive massage devices to have a therapeutic function. Positive consumer reviews emphasized the budget-friendly nature of the TOLOCO massage gun as a key feature in improving accessibility to the device and therefore its therapeutic potential. However, critical consumer reviews commented on the concern for product quality at lower price points in comparison to their more expensive counterparts. Regarding the final theme, safety and user education, consumer reviews demonstrated this aspect through product-specific safety features, manufacturer manuals, and peer-to-peer guidance. While not directly commented on by consumers, it is apparent that no consumer mentioned evidence-based guidelines for facilitating the use of this device.

Musculoskeletal pain, whether acute or chronic, is a common complaint in the health care system [21,22]. Such pain increases in prevalence with aging and lifestyle factors, such as occupation or lack of physical activity [22]. Both the personal and economic burden of musculoskeletal pain have been demonstrated globally across diverse populations [2,22-24]. For instance, the increasing presence of work-induced musculoskeletal pain in individuals without preexisting conditions has been discussed among nurses, postal workers, agricultural workers, and office workers [24-27]. One can suggest that this concept be readily translated to alternate occupations that also involve long working hours and significant lifting, standing, or sitting, thus being applicable to a vast majority of individuals. Occupation-related musculoskeletal pain is a pertinent common thread among the average individual and is one example that directly increases health care usage and expenditures [2,22]. Not only that, but also such pain increases both absenteeism and presenteeism and therefore negatively impacts employers financially [2]. For the individual, work-related musculoskeletal pain significantly impacts quality of life both physically and mentally [22]. This emphasizes the need to identify appropriate intervention modalities, particularly in the realm of home-based care.

While the mechanism of percussive therapy at the molecular level has not been well defined, its plausible application and health outcomes have been demonstrated by various studies. For athletes, percussive therapy has been found to improve muscle endurance and delay muscle fatigue without compromising muscle performance [10,28]. Some studies have also commented on the capacity of percussive therapy to improve explosive muscle strength, a valuable dynamic for athletes, while other studies claim no significant association in this domain [6,29]. The benefits of percussive therapy can impact everyday users in addition to high-performing athletes. The everyday user may include individuals from ageing or working populations as well as those with orthopedic needs. For instance, working populations—whether involving extended computer usage, long standing hours, or heavy physical labor—experience increasing strain on the body [30-32]. Initially, this strain may present as acute aches and pains, but repeated exposure can increase the potential for greater chronicity of pain [30-32]. Percussive massage therapy can serve as an adequate home-based musculoskeletal pain intervention for the everyday user. In reducing stiffness, increasing muscle relaxation, and improving muscle tone, percussive therapy encourages the flexibility of muscles and tendons and therefore establishes a better range of motion [6,29,33-35]. Not only that, but also in reducing the tension of muscles and tendons, it additionally works to alleviate perception of pain and thus yield psychosocial benefits [6,29]. The TOLOCO massage gun demonstrated the capacity of percussive massage therapy to be an easily accessible therapeutic modality that is readily available within one's own home. Thus, it gives users the opportunity to take their health into their own hands as well as augment medical rehabilitation for improved health outcomes. A breadth of users found this percussive massage therapy device to be a resourceful tool in their pain management regimens. Additionally, some consumers discussed alternative uses for the device in the context of myalgias secondary to chemotherapy, menstrual pains, and migraines.

It is imperative that we consider the biopsychosocial approach to care when addressing musculoskeletal pain. Acute or chronic pain is recognized as a contributing factor to an individual's mental health [36-39]. Pain post orthopedic intervention can be associated with long-term disability, increased restrictions in work or daily living, and decreased satisfaction overall [39]. These points of association may explain elevated depression rating scores in this population [39]. Alternately, in considering

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a population of high-performing athletes dedicated to their athletic identity and role in sport, it is apparent that there is an association between sport-related injury and mental health [36-38,40,41]. Over the course of 5 academic years, from 2009-2010 to 2013-2014, over 1 million injuries were estimated within the National Collegiate Athletic Association [42]. Given the rising competition and pressure, it is likely that this number has continued to rise. Sport-related injuries both short-term and long-term, negatively impact current and previous elite athletes [36-38,40]. In understanding the interconnectedness between musculoskeletal pain and perceived stress, anxiety, and depression, it is crucial that we analyze possible points of intervention. For instance, the psychological aspect of chronic low back pain may encompass decreased self-efficacy and autonomy [43]. Home-based percussive massage therapy, when appropriate, can possibly serve to encourage patient connectedness to care and increase patient confidence in caring for themselves. This concept highlights the potential of home-based percussive therapy as one branch of biopsychosocial interventions in patient care.

A total of 2 prominent handheld percussive massage therapy devices on the market are the Theragun by Therabody and the Hypervolt by Hyperice. Both products tend to range between US $100 and US $500—a price range that might not be considered affordable by all. As the therapeutic percussive therapy device continued to gain popularity, numerous manufacturers such as TOLOCO joined the expanding market to produce low-cost products and therefore improve its accessibility. In comparison to the listed prices of the more well-known brands, TOLOCO lists its product at approximately US $50 and intermittently includes discounted prices or coupons. The expansion of this market to include low-cost items is important because, by improving the affordability of these products, one can say it simultaneously increases health care accessibility. Not only that, but also this accessibility allows numerous consumers of varying backgrounds to find personal therapeutic purposes in the device. Additionally, it is imperative to recognize how the burden of musculoskeletal pain disproportionately impacts low-income populations [44-47]. While social determinants of health impede one's ability to access comprehensive care, it also increases an individual's risk to such conditions and amplifies the burden of disease [45-48]. The gaps in accessing health care providers, psychosocial support, and health resources perpetuate the disparities experienced by these communities and have negative implications for health outcomes [46,48]. Therefore, creating cost-effective, home-based interventions for musculoskeletal ailments may act as a therapeutic modality for wide-ranging populations and serve as one plausible method of bridging the gap between the health care system and vulnerable populations.

While this percussive massage therapy device has specific safety and user education components, including a user manual and automatic shutdown feature, it is imperative to further evaluate the safety and efficacy of such unregulated, at-home modalities. Previous case reports have discussed the consequences of inappropriate usage of these devices, which include rhabdomyolysis, vertebral artery dissection, and lens dislocation alongside secondary acute angle-closure glaucoma [49-51]. When considering at-home therapy options such as percussive massage therapy, users may not have essential medical knowledge and therefore may be unaware of certain anatomical structures including tissue, bones, and vasculature. They may also not fully understand the possible interaction of this percussive modality with their own underlying conditions. Of note, one user of the TOLOCO massage gun commented on their frustration with the 10-minute automatic shutdown and discussed disregarding the safety feature in place. This highlights the possibility of a lack of user education as well as unregulated use of the device. The authors of the noted case reports equally advocated for detailed evaluation of the safety of such devices in order to better define guidelines for indications and contraindications [49-51]. More comprehensive user education of at-home percussive massage therapy may dissuade such inappropriate usage and consequential traumatic complications while contributing to greater beneficial impacts.

Limitations

This qualitative analysis was conducted on consumer perceptions of a single percussive massage therapy device, despite the abundance of such products on the market. The TOLOCO massage gun was selected based on statistics suggesting that this particular product was the best-selling on Amazon. However, this does not indicate that it is the best-selling percussive massage therapy device in the current expanded market. The variability of these products with regard to their affordability, additional features, longevity, and programming may contribute to consumer perceptions. With this analysis primarily investigating this product from the perspective of serving as a home-based therapeutic modality, it might be implied that not all users have the same background knowledge and understanding of how to use the device optimally. Given that this was a retrospective study on consumer reviews, this analysis only includes perceptions from a snapshot in time from individuals who were willing to comment on the capabilities of and concerns about the product's usage. In using public data for this qualitative analysis, the authors were unable to facilitate further conversation, gain clarification, or identify sociodemographic characteristics among consumers. Additionally, this analysis does not provide objective or longitudinal data to further define indications or contraindications for percussive massage therapy. Though percussive massage therapy devices are deemed quite popular and beneficial based on consumer perceptions, there is currently limited scientific research available on their underlying physiologic mechanisms. Thus, further exploration with regard to its safety and efficacy is imperative.

Future Research

Previous studies have been conducted on the possible effects of percussive massage therapy. A study demonstrated that localized vibrations induced by massage guns at 38 Hz and 47 Hz can increase circulation to the region and therefore aid in the muscle recovery of healthy young athletes [52]. In the strength and conditioning setting, the use of massage guns allowed for increased muscle strength and explosive muscle performance secondary to delayed fatigue while also reducing musculoskeletal pain perception [6,10,28,53]. Another study

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using ultrasound diagnostics found that the use of massage guns on the thoracolumbar fascia resulted in a reduction in echo intensity in that region due to the movement of hyaluronic acid toward the fascial rim and thus improved lubrication and gliding between fascial layers [54]. While these studies have demonstrated the possible effects of percussive massage therapy and postulated potential reasons for these effects, they were unable to conclusively define the physiologic mechanisms. A study surveyed health care professionals about their perceptions and use of massage guns; however, it also emphasized the lack of current evidence-based guidelines [33,55]. Thus, future research is needed to investigate the underlying mechanisms of percussive massage therapy to better outline its safety and efficacy. Second, this research may create better guidelines to optimize care for different populations and prevent at-home users from sustaining further injury. In the future, it may be valuable to conduct further research on the integration and cost-effectiveness of mobile health apps and sensing technology in conjunction with home-based percussive therapy devices.

Conclusions

Handheld percussive massage therapy devices such as the TOLOCO massage gun hold potential value as a home-based therapeutic modality. The qualitative analysis of consumer perceptions revealed 4 pertinent themes: pain management, versatility, accessibility, and safety and education. Per consumer insight, percussive massage therapy was shown to address pain management for wide-ranging musculoskeletal needs in diverse populations. In providing an opportunity for consumers—from elite athletes to the everyday user—to play an active role in their own health, handheld percussive massage therapy can navigate the intersection of physical and mental well-being and thus encompass a biopsychosocial approach to care. Additionally, this home-based intervention has the potential to work toward addressing the significant economic burden of musculoskeletal pain by reducing and optimizing health care usage and expenditures. In considering the diversity of user needs and circumstances, this at-home modality addressed a pertinent health care concern in that it improved accessibility to care by presenting as both an affordable and readily available device for consumers. The variability of device models with low-cost price points introduces a possible platform for health equity in this domain of care. While this provides users with the opportunity to essentially play a larger role in their own care, future research on the safety and efficacy of home-based percussive massage therapy is imperative and can ultimately serve to promote evidence-based guidelines, further its technological development, and expand its therapeutic potential.

Data Availability

Data sharing is not applicable to this article as no data sets were generated or analyzed during this study.

Conflicts of Interest

None declared.

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Original Paper

Evaluating the Experiences of Occupational Therapists and Children Using the SensoGrip Pressure-Sensitive Pen in a Handwriting Intervention: Multimethods Study

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Abstract

Background: The acquisition of handwriting skills is essential for a child's academic success, self-confidence, and general school performance. Nevertheless, an estimated 5% to 27% of children face handwriting challenges, where the ability to modulate pressure on the pencil and lead on the paper is a key motor component.

Objective: We aimed to investigate the experience with and usability of the SensoGrip system, a pressure-measuring pen system with personalized real-time feedback about pressure modulation, in a clinical setting with children and occupational therapists (OTs).

Methods: A multimethods study was conducted, incorporating qualitative interviews and questionnaires with children, user diaries, focus group discussions, and a usability questionnaire with OTs, along with a questionnaire for parents.

Results: The study involved OTs (n=8), children with handwriting difficulties (n=16), and their parents (n=16), each of whom used the SensoGrip system in up to 5 therapy sessions. OTs reported that the SensoGrip system helped to focus the child's awareness on handwriting pressure and to measure it objectively. The system received high acceptance and usability ratings from the OTs—usefulness: median score of 4 out of 7; ease of use and ease of learning: median score of 6 out of 7; and satisfaction: median score of 6 out of 7. Participants appreciated that it fosters pressure awareness and motivation to draw and write.

Conclusions: The SensoGrip pressure-sensing system with real-time feedback is a promising tool for pediatric occupational therapy. It supports children with handwriting difficulties to adjust their pressure application during the task. In the future, controlled quantitative trials are warranted to further examine the system's impact.

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KEYWORDS

handwriting; handwriting pressure; pen; children; occupational therapy; assistive technology; tablet; app

Introduction

Background

The development of handwriting skills is not only important for building children's self-confidence but is also considered a fundamental element for academic success [1,2] and educational achievement [3]. Numerous studies have indicated that many children encounter challenges in acquiring handwriting skills. According to a review by Hartingsveldt et al [4], the prevalence of handwriting problems ranges from 5% to 27%. Handwriting is a multifaceted task that requires the integration of motor, sensory, perceptual, praxis, and cognitive functions [5,6]. An essential motor aspect involves the precise control of pencil pressure and pressure of the lead on the paper, as excessive

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pressure on the pen when writing can cause muscle fatigue. Children with handwriting problems have less capacity for idea generation, planning, and revision when they have to focus on the handwriting mechanics [7]. The aim of teachers and occupational therapists (OTs) is that children obtain readable, fluent, and efficient individual handwriting without becoming tired [8]. A survey of 2000 German teachers revealed that sustained writing was a problem for >60% of children in elementary or secondary school, most often based on handwriting-associated cramps (73%) and incorrect pencil grip (68%) [8]. Lin et al [9] observed that children exhibit difficulties in pressure adjustment when learning graphomotor skills. Previous studies have already measured grip or tip pressure (pressure of the pen on the writing surface) using a pen with built-in sensors [10,11]. However, these systems were built for research purposes only. There is a need to investigate the role of pressure in pencil use in a natural setting and to provide direct feedback mechanisms for the children. Biofeedback is a method for changing unconscious movements and perceptions into conscious ones and has already been used in the context of a handwriting training device by the company, "Schneider," and their pen, "Base Senso." Biofeedback is known to be effective in the treatment of many musculoskeletal conditions and has been shown to, for example, improve the measures of balance and patients' exercise techniques [12].

However, to the best of our knowledge, currently, there is no tool that records the child's pressure and provides individualized feedback to the child and OT. Further limitations of the currently commercially available technologies include the following: very high acquisition costs; insufficient calibration accuracy; usability issues, as training is required to use the app; incomplete recording of key measurement parameters; and lack of feedback [13].

The SensoGrip Project

The SensoGrip project was launched with the aim of creating a pressure-sensitive pen, focusing on user-centered conception, development, and evaluation. Previously, we had conducted a comprehensive evaluation to understand the needs of all relevant stakeholders, steering the further development process [14]. The project was supported by an interdisciplinary team that included professionals from occupational therapy, physical therapy, special education, medical informatics, computer science, and mechanical engineering. We adopted an iterative development process complemented by simultaneous testing phases to continuously refine the features.

The SensoGrip System

The SensoGrip system consists of 2 components: a smart SensoGrip pen and the SensoGrip mobile app. The pen weighs 24 g, is 140 mm long and 14 mm in diameter, and has a roller pen refill (Figure 1).

Figure 1. The SensoGrip pen with activated feedback LED and the SensoGrip app with line graphs for grip pressure (red) and tip pressure (blue).

The SensoGrip pen contains 2 sensors to measure the pressure applied on the grip area (grip pressure) and the pressure applied by the pen on the paper (tip pressure) respectively. An LED ring is placed between the distal end of the grip area and the pen tip. The LED provides visual feedback about the applied pressures according to the individual settings in the mobile app.

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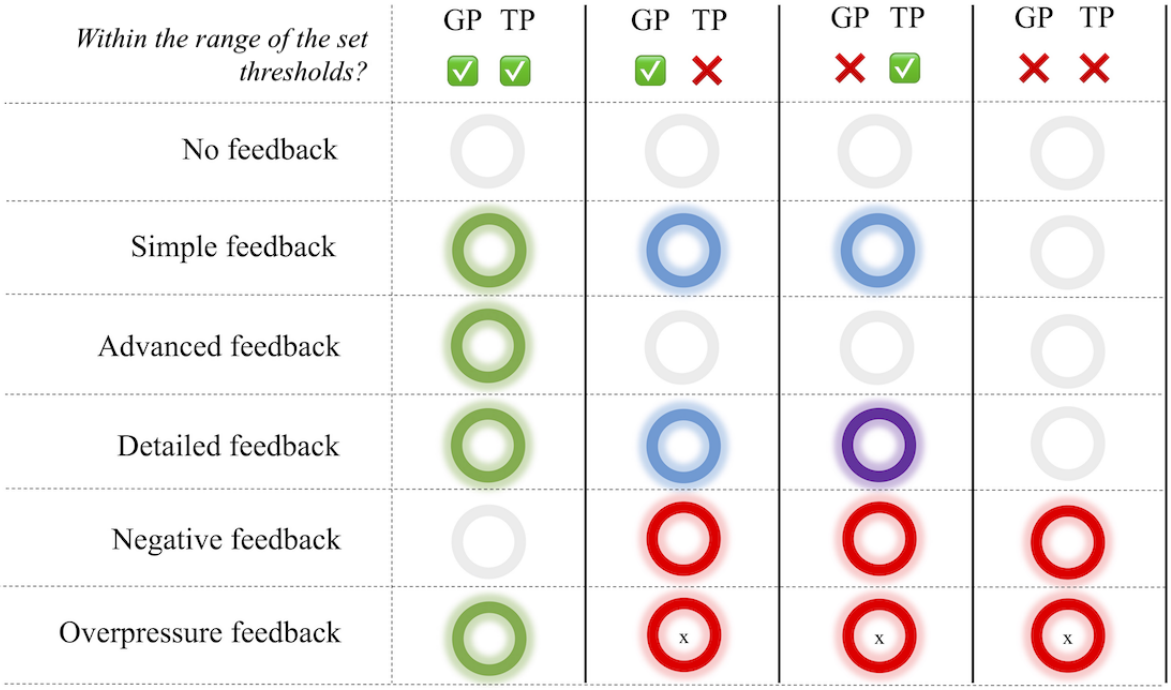
The battery of the pen can be recharged using a standard micro-USB cable.

The SensoGrip app runs on the Android operating system on a customary tablet. It allows for the creation of customer profiles with individual settings and displays real-time or recorded measurements. On the basis of the individual needs and preferences of the child, different feedback modes can be chosen (Figure 2). Upper and lower thresholds are set by the OT to choose the pressure range within which the selected feedback is displayed by the LED. The thresholds are set for the grip pressure and tip pressure separately. Colors for different feedback modes can be chosen individually.

Figure 2. Feedback modes offered by the SensoGrip system. Depending on the mode selected in the SensoGrip app, the LED ring of the SensoGrip pen lights up in individually chosen colors. GP: grip pressure; TP: tip pressure; x: only if pressure is very high.



The app provides real-time visualization of pressure data through numerical displays and line graphs for both grip and tip pressures, as illustrated in Figure 1. Users have the option to capture these data alongside a video of the writing hand in action. For ease of analysis, the app allows the display of customizable threshold lines on the graphs, which can be toggled on or off as needed. All recorded data remain retrievable for future reference. In addition, the interface supports the simultaneous comparison of graphs from different sessions. For reporting or further analysis, users can export these data directly into a PDF document.

Aim

This study is part of a pilot study involving a single-case experimental design [15] to assess the effectiveness of the system. The findings concerning the effectiveness of the system, as derived from the Single-Case Experimental Design study, will be discussed in a subsequent publication. The study was registered on ClinicalTrials.gov (NCT05014854). The aim of this paper was to present data about the usability, acceptance, and perceived impact of the SensoGrip system.

The following research questions were used to guide this study:

1. How is the usability characterized?
2. What hurdles exist in the actual use of the individual components?
3. How are the acceptance factors of the system evaluated by the target groups?
4. What is the perceived impact of the system?
5. What are the intended and unintended effects of the system on the target groups?
6. Does the system positively influence children's motivation and adherence?

Methods

Overview and Procedure

The study was conducted between July 2021 and October 2021 in Vienna and Lower Austria, Austria, across various private practices of OTs. Each participating child engaged in 3 to 7 therapy sessions, during which the OTs integrated the SensoGrip system into therapy. OTs received comprehensive training from the research team. This training included a range of essential skills, such as operating the SensoGrip system, creating patient profiles, fine-tuning feedback settings, interpreting the graphical representation of pressure data, and familiarizing themselves with the procedures for assessment and data upload. Although OTs were expected to incorporate the SensoGrip system into every therapy session for a minimum of 10 minutes, they were granted the flexibility to use it more extensively as needed. The research team supplied a manual containing a variety of recommended therapeutic activities tailored to the SensoGrip

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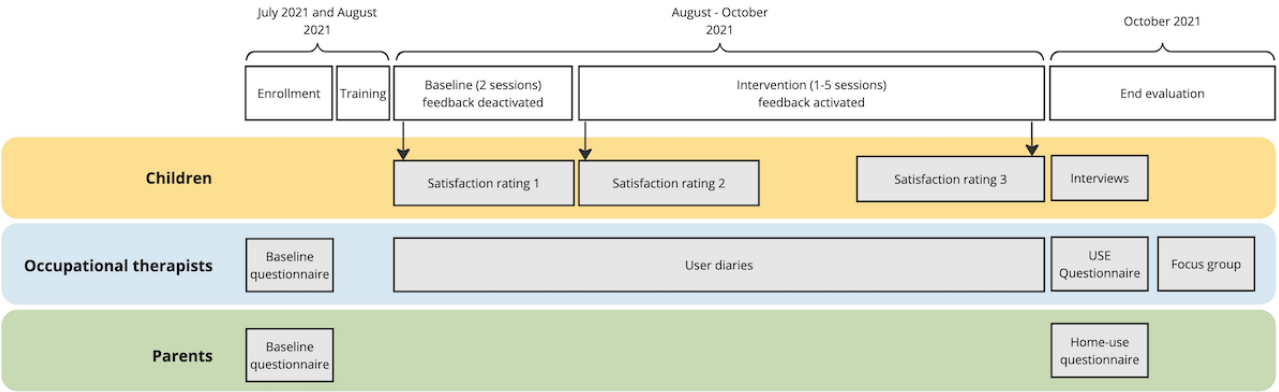
system. Moreover, the OTs were empowered to personalize the system settings, including the calibration of pressure thresholds for both finger and tip feedback and the selection of feedback types and colors. The integrity and consistency of the intervention's implementation were carefully tracked through the collection of user diaries, analysis of use data from the SensoGrip pens, and evaluations conducted during posttherapy focus groups and interviews.

To assess the usability and user acceptance of the SensoGrip system and to gain early insights into the perceived impacts of use, a multimethods design was implemented (Figure 3).

Figure 3. Study overview and timeline. USE: Usefulness, Satisfaction, and Ease of Use and Ease of Learning.



To obtain a comprehensive understanding of the SensoGrip system's impact, we included a variety of data collection methods. We conducted qualitative interviews with children and captured their satisfaction with a child-friendly smiley rating scale. OTs provided baseline data about the child's handwriting issues; regularly documented SensoGrip use, their observations, and the systems' performance in user diaries; rated its usability using a questionnaire; and participated in a focus group. Parents provided information about the child's handwriting at home through a baseline questionnaire. They also described their experiences with the SensoGrip system when it was used in the home setting. The methods were chosen carefully to meet the respective needs of the study participants in terms of time, effort, and place and to achieve a combination of qualitative and quantitative results for triangulation.

Participants

Recruitment and Enrollment Procedure

Participants were recruited using the snowball sampling technique [16], in which initial contacts with OTs in private practices were established through multichannel outreach. This included distributing emails to all pediatric OTs registered in the region, engaging with OT-specific Facebook groups, and leveraging the personal networks of the project team. In addition, OTs were encouraged to use their professional and social networks to further distribute participant invitations. We structured participation into teams or dyads composed of an OT and ≥1 children under their care, with the option to involve the children's parents or legal guardians. Inclusion in the study was contingent upon meeting the established criteria, and upon indicating interest, OTs were provided with detailed participation checklists and consent documentation. Once eligibility was confirmed and consent was obtained, OTs, their paired children, and the children's legal guardians were formally enrolled in the study.

Children

Children aged between 5 and 10 years and exhibiting difficulties in handwriting, especially in handwriting pressure adjustment were eligible. Children belonging to this age group were selected as the target group because they are in the developmental period during which children typically acquire foundational handwriting skills. OTs assessed the eligibility based on a handwriting pressure checklist, where at least 2 stated criteria had to be present. The checklist contained 6 indicators of excessive writing pressure, 4 indicators of insufficient writing pressure, and 1 criterion for high fluctuations in writing pressure (Multimedia Appendix 1). Children had to be able to follow verbal instructions and maintain attention in graphomotor activities for at least 10 minutes and had to have adequate emotional regulation and age-appropriate psychosocial skills. Children who were not able to hold a pen, owing to stiffened joints or excessive or insufficient muscle tension, could not participate in the study. Children's eligibility to participate in the study was assessed by their individual OT, who then selected children for the study from their patient group. Before starting the assessment and intervention, children and parents (or legal guardians) signed an informed consent form.

Occupational Therapists

OTs were eligible to participate if they had at least 2 years of professional experience in evaluating and treating graphomotor difficulties in children. In addition, they had to provide occupation-based therapeutic services aimed at addressing handwriting challenges. OTs were not eligible if they rejected using technical tools in therapy or stated that they are not used to handling everyday technologies such as smartphones. For a collaborative dyad to be formed within the study, each participating OT was required to enlist at least 1 child from their clinical practice. Informed consent was mandatory; OTs were required to sign an informed consent form before enrolling in the study.

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Parents or Legal Guardians

Parents or legal guardians were eligible to participate if their child consented to use the SensoGrip system at home between therapy sessions. A prerequisite for participation was proficiency in basic, everyday technology use. Informed consent was obtained before their inclusion in the study.

Assessments

A comprehensive set of tools was used to collect both qualitative and quantitative feedback from OTs, children, and their parents.

User Diaries (OTs)

OTs maintained a user diary to record the use of the SensoGrip system, experiences and thoughts about the system, and issues with its usability and functionality. These recordings were a central element, as they allowed to observe several therapy sessions of each child retrospectively without directly participating in the sessions themselves. After each session of use, the OTs self-assessed to check whether any technical issues occurred (yes or no and which?), whether the feedback felt reasonable (yes or no and why?), whether they found the SensoGrip system useful (yes or no and why?), whether the system was intuitive to use (yes or no and why?), and how much they enjoyed using it (5-point Likert scale). In addition, the OTs maintained notes about how the SensoGrip system was integrated into the therapy session. The diary was developed by the project team, and the understandability and quality were assessed along with an OT before starting the trial.

Usability Questionnaire (OTs)

At the end of the intervention period, the usability of the SensoGrip system was assessed by the OTs via the standardized Usefulness, Satisfaction, and Ease of Use and Ease of Learning (USE) questionnaire [17,18], translated into German by the research team (Multimedia Appendix 2). It consists of 30 items, attributed to dimensions such as usefulness, ease of use, ease of learning, and satisfaction, which are rated on a 7-point Likert scale (1=do not agree at all; 7=totally agree).

Smiley Rating Scale (Children)

Children self-assessed their satisfaction with the SensoGrip system using a 6-point smiley rating scale. Children were asked “How much did you enjoy writing with the SensoGrip pen?” in the first therapy session of the intervention, in which feedback from the pen was deactivated to not influence the baseline measurements for the single-case experimental design study, and in the first therapy session in which feedback was activated. After the final session, they were asked, “How good can you write with the SensoGrip pen?” and “How much do you like the SensoGrip pen?”

Questionnaires (Parents)

Before initiating the study, parents or legal guardians were asked to complete a detailed questionnaire designed to understand the child’s handwriting practices at home. It covered several topics, including the frequency and duration of writing activities at home, handwriting legibility, pressure and speed during writing, challenges encountered, and the acceptance and use of tools for writing and learning, along with any related social and emotional concerns. Furthermore, when the SensoGrip pen was used at home between therapy sessions, parents or legal guardians provided end-of-study feedback through a subsequent questionnaire. This follow-up sought to assess their perceptions about the pen’s effectiveness, user-friendliness, and overall impact in the home environment.

Interviews (Children)

After the intervention, child participants were interviewed individually by 2 experienced team members, both women, with a background in pediatric occupational therapy. These interviews were deliberately scheduled immediately following the final therapy session at the OT’s office to mitigate any additional stress for the children, a particularly vulnerable group. Parents or legal guardians were allowed to attend the interview, if this was deemed beneficial. The semistructured interviews (Multimedia Appendix 3), which were pretested with age-matched children, explored a range of topics: the children’s enjoyment in using technical tools in general, their previous experience with handwriting, their evaluation of the SensoGrip system’s functionality, the advantages they perceived from its use, their willingness to continue using the system, their suggestions for its improvement, and their 3 most and least effective aspects. The interviews were audio recorded and varied in duration between 10 and 30 minutes per child. In an effort to minimize any potential discomfort, the children were not asked to confirm the accuracy of the interview content.

Focus Group (OTs)

OTs participated in a structured focus group interview designed to elicit a comprehensive evaluation of their experiences with the SensoGrip system. The choice of focus group format was intentional; it was selected for its capacity to yield nuanced insights through collective discussions among the OTs. The focus group was facilitated by 2 experienced research team members with a background in pediatric occupational therapy. To ensure a setting that minimized distractions, the focus group was conducted in a quiet meeting room at the university and lasted 108 minutes. An additional researcher documented field notes to capture nonverbal behaviors and observations. The semistructured guide (Multimedia Appendix 3) included open-ended questions along with prompts and probes and covered the following topics: prevalence of handwriting difficulties and, especially, handwriting pressure difficulties in praxis; common concepts and methods for addressing those issues; integration of the SensoGrip system into OT praxis; perceived benefits and barriers when using the SensoGrip system; effects of pressure feedback about children’s handwriting and behavior; ease of learning the SensoGrip system; assessment of the SensoGrip system regarding design and functionality; and suggested improvements for SensoGrip pen and app. The guideline was developed by the research team. A pilot test was not conducted, but the questions were intensively discussed within the team to ensure that the research questions were addressed. If an OT was unable to attend the focus group owing to scheduling conflicts, an individual interview was conducted. This ensured comprehensive inclusion of their insights regarding the SensoGrip system. Consistent with the focus group methodology, this interview adhered to

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the established guidelines and was audio recorded to capture the OT's feedback accurately. In contrast, the focus group session was video recorded, allowing for precise attribution of comments to the respective contributors. Subsequently, the findings from the study were shared in a public forum, and all the involved OTs were encouraged to attend. This presentation served as an opportunity for participant validation, where OTs could review and comment on the reported results—a process known as member checking.

Data Analysis

Questionnaires and User Diaries

User diary data were systematically compiled into an Excel (Microsoft Corporation) spreadsheet, enabling a detailed analysis of the technical and usability challenges encountered during the SensoGrip system's operation. Statistical analysis included the calculation of the median and the minimum and maximum scores from the children's smiley rating scale. Similarly, we computed the median values for the usability ratings derived from the USE questionnaire's subscales. The frequency distributions of these ratings, along with the smiley rating scale scores, were then visually represented through graphical illustrations.

Qualitative Data

Content analysis based on the procedure suggested by Kuckartz [19] was performed on completely verbatim transcripts of the focus group and interviews by 2 researchers using the software, MAXQDA 2022 (VERBI Software, 2021). This method allows a combination of deductive and inductive coding. Deductive codes were based on the topics that guided the interviews: functionality, stability, usefulness, usability, ease of learning, barriers, performance expectancy, effort expectancy, social influence, hedonic motivation, facilitating conditions, intention to use, effect on handwriting pressure, transfer into daily living, effect on motivation and adherence, effect on therapeutic efficiency, and support in documentation. Then, inductive codes were differentiated into many subtopics such as design, usability, and barriers. The 2 researchers collaborated intensively in the coding and analysis phases to increase objectivity. Working in tandem, they cross-examined each other's coding decisions and interpretations during the analysis and discussed discrepancies to reach consensus. This approach aimed to reduce individual bias and enhance the reliability of the findings.

Ethical Considerations

The SensoGrip system is defined as a class-1 active medical device according to Rule 12 of Directive 93/42/EEC [20]. Therefore, the evaluation of the system qualified as a clinical trial and was successfully approved by the ethics committee of the City of Vienna under the number EK-21-042-0321. In addition, the study was registered at the Austrian Federal Office for Safety in Health Care [21] as required by national law. The study was monitored on an ongoing basis by a physician and a monitor. No adverse effects occurred.

Results

Description of Participants

Overall, 8 OTs (n=7, 88% women; n=1, 13% men) participated in the study. They were aged between 28 and 51 (mean 37.6, SD 7) years and had between 4 and 30 (mean 13.5, SD 8.2) years of experience in pediatric occupational therapy. All (8/8, 100%) used a smartphone or mobile tablet with 3 to 5 apps (4/8, 50%) or >5 apps (4/8, 50%) on a regular basis. The participating OTs' acceptance of technology was rather high (Multimedia Appendix 4).

Overall, 16 children (n=3, 19% girls; n=13, 81% boys) were enrolled in the study (Table 1). They were aged between 5 and 10 years. Of the 16 children, 14 (88%) wrote with their right hand, 1 (6%) wrote with the left hand, and 1 (6%) did not have a preferred hand for writing at the time of the study. Their reasons for referral to OT were developmental coordination disorder of fine and gross motor coordination, unspecified developmental disorder of motor function, difficulties in concentration, dyspraxia, sensory integration disorder, autism spectrum disorder, and adaptive disorder.

Of the 16 parents, 9 (56%) reported that their child's hand grew tired when writing, 7 (44%) reported that their child had to shake their hand for relaxation when writing, and 1 (6%) reported that their child verbalized pain regularly when writing. Of the 16 parents, 10 (63%) thought that fatigue had an influence on the handwriting of their child, 9 (56%) found prolonged writing to be a relevant factor, 7 (44%) perceived that the pen their child was using influenced the handwriting, and 1 (6%) mentioned that time pressure negatively affected handwriting. Of the 16 parents, 4 (25%) rated their child's handwriting as illegible, 2 (13%) as sloppy, and 1 (6%) as often smudgy. Of the 16 children, 8 (50%) had trouble in maintaining alignment with the line when writing, 3 (19%) imprinted their handwriting on the next page, and 4 (25%) produced very large letters when writing. Of the 16 children, 8 (50%) used special aids for writing such as grip aids with or without molds, weighted writing utensils, or special ergonomic pens. Of the 16 parents, only 2 (13%) confirmed that the aids were helpful. Of the 16 children, 4 (25%) enjoyed their use and 1 (6%) explicitly did not like it. Of the 16 parents, 5 (31%) acknowledged that handwriting problems frequently led to conflicts at home.

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Table 1. Overview of children's baseline data.

Child's ID	Sex	Age	Handedness
C1	Male	6 y and 11 mo	Right
C2	Male	6 y and 6 mo	Right
C3	Male	7 y and 8 mo	Right
C4	Male	6 y and 6 mo	Right
C5	Male	9 y and 4 mo	Right
C6	Male	6 y and 0 mo	Right
C7	Male	7 y and 8 mo	Right
C8	Male	5 y and 10 mo	Left
C9	Male	5 y and 9 mo	Right
C10	Male	6 y and 9 mo	No preference
C11	Male	5 y and 8 mo	Right
C12	Female	9 y and 3 mo	Right
C13	Female	10 y and 11 mo	Right
C14	Male	6 y and 2 mo	Right
C15	Male	8 y and 4 mo	Right
C16	Female	8 y and 5 mo	Right

Relevance of Handwriting Pressure in OT Practice

According to the participating OTs, the prevalence of handwriting problems among children in their common practice is approximately 30%, and one-third of these children also shows signs of inappropriate handwriting pressure. Problems of handwriting pressure adjustment rarely occur in isolation; they occur in combination with other difficulties related to handwriting grip and letter formation. OTs select therapy approaches to target appropriate handwriting pressure adjustment that include activities to improve body perception in general and occupation-based activities such as drawing and writing with different materials. Common activities mentioned were coloring by hatching with varying intensity or applying padding of varying modalities under the paper. All OTs emphasized that they used a child-centered approach in terms of child-initiated color or topic selection.

Application of the SensoGrip System in the Study

Of the 16 children, 12 (75%) used the SensoGrip system in 5 therapy sessions, 3 (19%) used it in 3 sessions, and 1 (6%) used it only in 1 therapy session. On average the total use time was 77 (SD 34; range 10-135) minutes per child. Reasons for discontinuation of implementing the SensoGrip system were based on unforeseen therapy termination (1/16, 6%) or the child's pencil grip being very immature (2/16, 13%). The children used the SensoGrip system in a variety of writing and drawing exercises, ranging from playful activities to more structured tasks such as free drawing, tracing, copying, and writing. OTs supported the children in monitoring the feedback from the LED indicator on the pen and in adjusting the pressure on the pen and paper. In addition, the accompanying mobile app was introduced, offering an interactive experience where they engaged in creating specific graph patterns. By varying the pressure on the pen, children learned to manipulate the graphical representations, striving to achieve either high or low pressure readings or to maintain consistent pressure levels. OTs reviewed the children's handwriting pressure with them, using the graphical data recorded in the mobile app after various writing and drawing activities. In a home setting, 31% (5/16) of the children continued to use SensoGrip between therapy sessions. According to the parents of these 5 children, 1 (20%) child used it daily, 2 (40%) used it multiple times per week, and 2 (40%) used in weekly. Some OTs opted not to send the SensoGrip pen home owing to concerns about potential loss or damage or worries that the pen might not be used as intended or returned for subsequent sessions.

OTs' Evaluation

Regarding the USE questionnaire's usefulness subscale, OTs reported a median score of 4 (IQR 3-6) out of 7, indicating a moderate level of perceived utility of the SensoGrip system (Figure 4). During the focus group discussions, OTs gave high ratings to the tablet's graphical representation of handwriting pressure, valuing it as a particularly useful tool for objectively assessing a child's performance and informing therapeutic strategies. They noted the advantages of the system's real-time visual pressure feedback, which was well received by both OTs and children alike. OTs also expressed appreciation for the customizable settings, which allowed them to tailor the feedback to each child's specific requirements. A notable benefit reported was the SensoGrip pen's utility in the home environment, where children could continue practicing even when the OT was not present:

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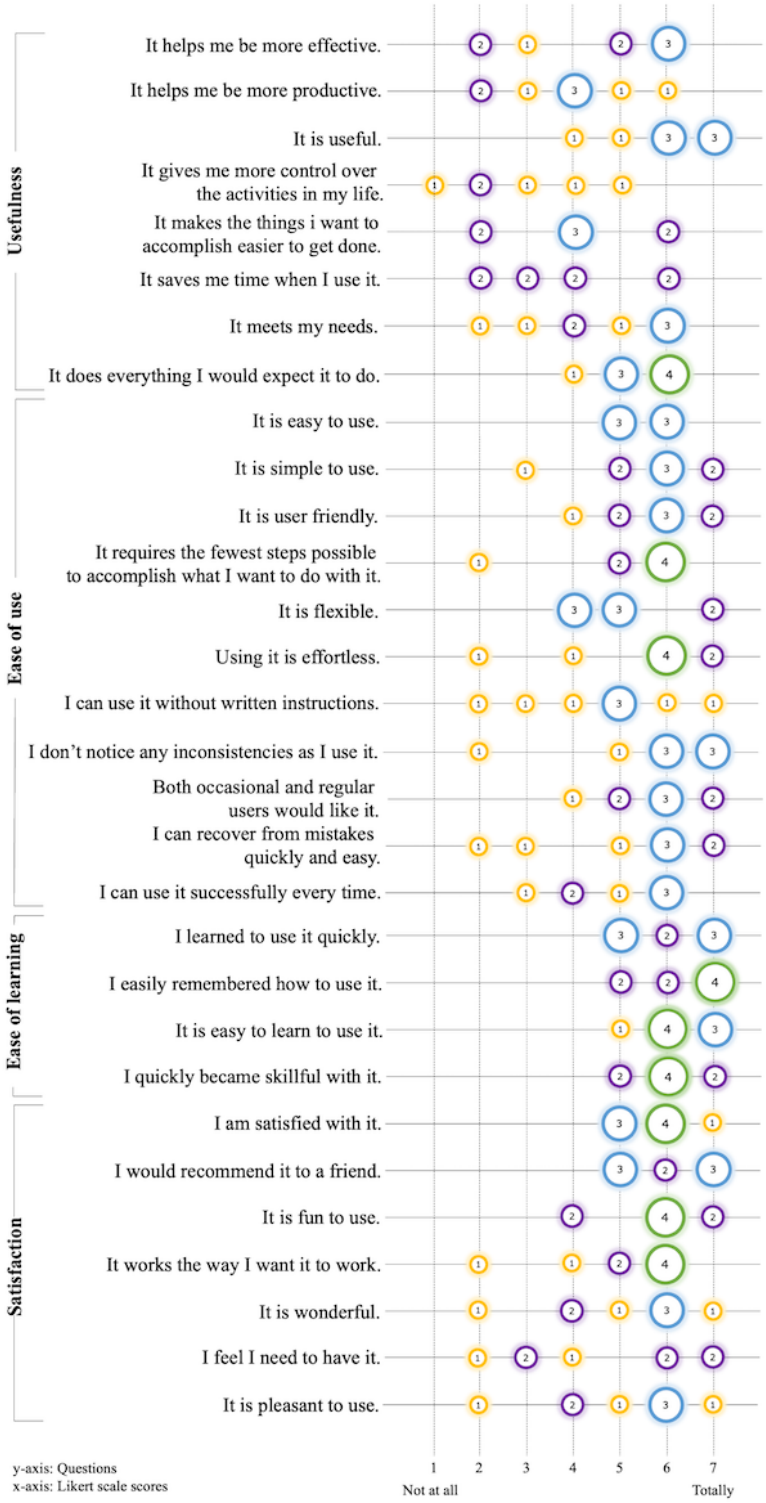
Figure 4. Ratings of the Usefulness, Satisfaction, and Ease of Use and Ease of Learning questionnaire. Bubbles indicate the number of participants who rated the respective score for the respective question. Missing numbers indicate skipped questions.



> *I think it is great when they take it home. You just set everything up and say, for example, "This week try to make it light up as much as possible when you do your homework."* [OT 3]

OTs assigned high ratings to the SensoGrip system's ease of use (median 6, IQR 5-6) and ease of learning (median 6, IQR 6-7), each receiving a median score of 6 out of 7 on a Likert scale, which suggests a high level of usability of the system (Figure 4). They found the graphical analysis of pressure to be intuitive to use and the customization to be straightforward. However, determining the optimal thresholds for each child using the graphical interface proved challenging for some. An OT expressed a preference for adjustment based on numerical pressure values rather than graphical data. To further improve the system's usability, the OTs recommended enhancements, such as ensuring the mobile app's functionality even when the

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pen is not connected or is charging. This would facilitate uninterrupted access to settings and data. They also proposed a feature to provide isolated feedback about either the finger or tip pressure, which would allow a focused approach to correcting specific pressure issues. Further suggestions included more sophisticated data comparison tools, such as visualizations showing the duration for which a child maintains pressure within the set thresholds and box plot analysis. In addition, a filtering function to extract particular data points was suggested. For future iterations, OTs advocated for the development of an automated progress analysis feature and integration of interactive games into the SensoGrip mobile app to enrich the SensoGrip experience.

The OTs provided a median score of 6 (IQR 5-6) on the satisfaction subscale of the USE questionnaire on a 7-point Likert scale (Figure 4). They pointed out that although they had stated many suggestions for improvement, they would like to use the SensoGrip system in its current development state:

> *On the other hand, if it would be possible to buy this pen, I would do it.... It is actually a good product.* [OT 5]
>
> *It is really usable the way it is.* [OT 2]

Overall, the OTs noted that the use of the SensoGrip system helped to focus the child's awareness on handwriting pressure and to measure it objectively. An OT expressed that the system helped to identify the specific situations in which the handwriting pressure increased. OTs perceived improvement in handwriting pressure in some children, based on observation. Nevertheless, some children did not benefit from the system. OTs hypothesized that differences in impact might depend on the age of the children:

> *It was my impression that the older child, which is in the first grade, improved it's handwriting pressure. His problem was that he was holding the pen too loosely. And now it is more adequate, and the tracing became better. The younger children's handwriting pressure did not really change.* [OT 4]

Children's Evaluation

During the interview, 69% (9/13) of the children mentioned that they thought the SensoGrip system was useful. They reported an increased awareness of their handwriting pressure when using the SensoGrip pen, which they felt contributed positively to their writing:

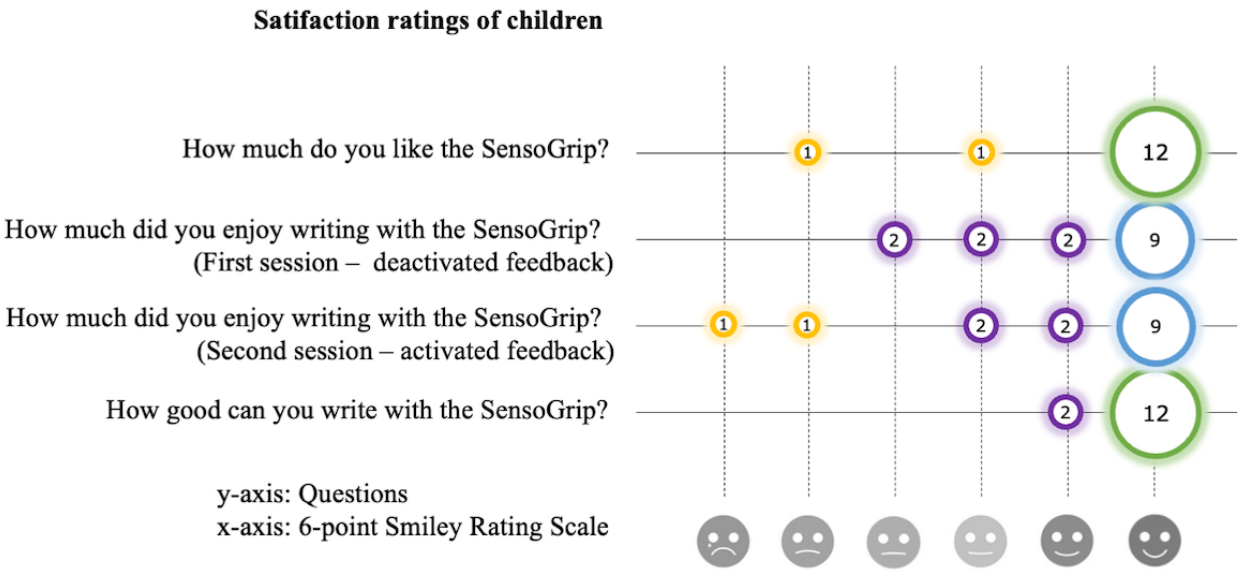
> *It really helps me figure things out. Like, when the pen lights up, I know "oh, the pressure is very low here."* [C15; aged 8 y]
>
> *When I do it right, the light turns green. And when I push too hard, then it turns purple.* [C13; aged 10 y]
>
> *When I push very hard and then soft, the line goes up and down. Then again harder and softer, and so on.* [C3; aged 7 y]

Other children did not perceive any differences when writing with the SensoGrip pen or preferred using their normal pen:

> *No, not necessarily. I can still write better with a pencil.* [C14; aged 6 y]

Children assessed their satisfaction with the SensoGrip system using the smiley rating scale (Figure 5).

Figure 5. Children's satisfaction ratings on a 6-point smiley rating scale. Bubbles indicate the number of children who rated the respective smiley for the respective question. Missing numbers indicate missing answers.



Overall, 80% (12/15) of the children gave the highest possible rating when asked how much they like the SensoGrip system. Furthermore, 86% (12/14) of the children rated the question, "How good can you write with the SensoGrip pen?" with the highest score (Likert scale score=6), and 14% (2/14) of the children rated with the second highest score (Likert scale score=5). In the interviews, they explained that it was "quite easy to write with the SensoGrip (pen)" (child 2 and child 3; aged 6 y) and that it was "easy to hold" (child 15; aged 8 y). However, some children encountered issues when using the SensoGrip pen: a child mentioned that they had trouble keeping the LED light on (child 15; aged 8 y), a child reported that the ink stained their fingers (child 14; aged 6 y), a child found the LED light not sufficiently bright (child 3; aged 6 y), and another

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child had difficulties in maintaining a firm grip on the pen (child 3; aged 7 y).

Overall, children reported a medium to high level of enjoyment when using the SensoGrip system. The median rating was 6 (4.25-6) on a 6-point Likert scale (minimum=1; maximum=6), where 6 represents maximum writing enjoyment (Figure 5).

Overall, 92% (12/13) of the children thought that the SensoGrip pen was "cool" or "fun," and 75% (9/12) of them said that they would enjoy continuing to write with the SensoGrip pen. Only 8% (1/13) of the children mentioned that the feedback puts them "out of control" and that it would not help them with writing (child 14; aged 6 y). They most enjoyed the LED feedback, the sensor technology, and working with the app's graph:

> *...That we could draw hills in the app. And the colored light. And that it was so pleasant for my fingers. That were my three favorites.* [C3; aged 7 y]
>
> *...I could see if I am doing it right.* [C13; aged 10 y]
>
> *...It feels good in my hands. The light. The feedback. And that it helped me with writing.* [C1; aged 6 y]

Some children expressed improvement in writing during the interviews:

> *Now I can write much better.* [C1; aged 6 y]
>
> *Earlier I pushed the pen a little harder on the paper and I can see that it is now different.* [C13; aged 10 y]
>
> *My hand felt a little bit lighter when I was holding the pen like this.* [C15; aged 8 y]

Parents' Evaluation

Among the 5 parents who had the SensoGrip pen used at home, 3 (60%) found the SensoGrip pen to be intuitive or rather intuitive in its use, whereas 1 (20%) felt that it was not intuitive. Overall, among the 5 parents, 2 (40%) were satisfied with the SensoGrip pen, 2 (40%) were neutral about it, and 1 (20%) did not respond. Of the 5 parents, 3 (60%) were in favor of continuing its use, 1 (20%) opted against it, and 1 (20%) did not respond to this specific question.

Participants' Design Evaluation

Participants evaluated the pen's design based on various features, as described in Table 2.

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Table 2. Opinions about the different design features of the SensoGrip pen. Occupational therapists (OTs) and children's opinions were obtained from the interviews, and parents' ratings were obtained using the questionnaire.

Design feature	Opinions		
	Children	Parents	OTs
Overall appearance and design	• "Good" (12/13, 92%) • "Medium" (C14; aged 6 y)	• Very suitable: 2/5, 40% • Suitable: 3/5, 60%	__[a]

Size and weight	• "Good" (C3; aged 6 y)
	• "Heavier than a conventional pen but great" (C15; aged 8 y)
	• "Should be a little bit thinner" (C1; aged 6 y)
		• Size
		  • Very suitable: 1/5, 20%
		  • Suitable: 2/5, 40%
		  • Indifferent: 1/5, 20%
		  • Not suitable: 1/5, 20%
		  • Comments—Too thick (2/5, 40%)
		• Weight
		  • Suitable: 3/5, 60%
		  • Mediocre: 2/5, 40%
		• Shape
		  • Suitable: 3/5, 60%
		  • Indifferent: 2/5, 40%
			• "Okay, but could be smaller, thinner, and lighter for better fit for children. Pen's tip could be a little bit shorter."

Material and haptics	• "Pleasant" (C3; aged 6 y) • "It can be held well" (C1; aged 6 y)	• Very suitable: 2/5, 40% • Suitable: 3/5, 60%	• "Anti-slip surface was good. Grip moulds could help some children to ensure ergonomic grip."
Finger sensor position	—	—	• "For some children hard to position fingers on the sensor, to ensure correct pressure measurements. Sensor should be placed nearer towards the pen's tip."
LED position	—	• LED should be positioned on the proximal end of the pen (1/5, 20%)	• "LED should be positioned on the proximal end of the pen for younger children (ensures better sight of the LED) and on the distal end for older children (ensures simultaneous sight of LED and written text)."
LED	• "Funny when it lights up" (C15; aged 8 y) • "Not bright enough" (C3; aged 6 y)	• Colored LED motivated children (3/5, 60%), but also distracted one child (1/5, 20%) • Wish for acoustic feedback (2/5, 40%)	• "Should be brighter. Some wished additional acoustic and/or vibration feedback."
Pen's tip and refill	• "Well slipping pen tip" (C3; aged 6 y)	• Tip runs smoothly on the paper (3/5, 60%) • Ink not erasable (2/5, 40%) • Pencil lead would be better (3/5, 60%)	• "Pencil lead would be better for younger children, colored pencil lead even better. Roller pen ink should be erasable."
Battery	—	• Runs down too fast (2/5, 40%) • Battery display missing (1/5, 20%) • "Poor" battery (1/5, 20%)	—

[a]Not available.

Technical Performance

Overall, the SensoGrip pen and app were found to be technically well functioning. The reported malfunctioning included the following: quick battery depletion and a long time to connect the pen to the app in some cases. Of the 16 SensoGrip pens, 2 (13%) broke. In one case, it fell on the floor, and in another case, a child was applying extremely high pressure on the pen. In one instance, the lead of the pen slipped inside the pen when a child was pressing it with very high pressure on the table. Crashing of the tablet app was reported only once over the test duration.

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Discussion

Usefulness, Satisfaction, and Perceived Impact of the System

OTs viewed the SensoGrip system as a valuable addition to their therapeutic toolkit. It met or exceeded the expectations for most, with 7 out of 8 (88%) OTs rating it highly on the USE questionnaire for its usefulness. The system's graphical display of writing pressure was particularly noted for its effectiveness in analyzing and guiding children's handwriting interventions. In addition, some children reported improvements in their handwriting, attributing this to the heightened pressure awareness provided by the biofeedback. This tool seems to provide information about sensory-motor processes during writing, which are not inherently perceptible to them [22].

Overall, the OTs were pleased with the system's performance, finding it enjoyable and effective—a sentiment that remained consistent throughout several weeks of therapy. This consistent satisfaction is indicative of the system's potential for long-term acceptance, avoiding the pitfall of waning interest over time [23].

Children's satisfaction was also noteworthy, with almost all (12/15, 80%) expressing the highest level of enjoyment. The interactive feature of the pen lighting up was a favorite. However, caution was advised for children with intellectual impairments, as a child's difficulty in comprehending the feedback suggested the need for tailored use assessments by OTs, especially given the possible correlation between intellectual and graphomotor challenges.

In summary, the SensoGrip system was recognized for its dual impact: enhancing awareness of handwriting pressure and increasing children's motivation to engage in writing tasks during therapy sessions.

Usability and Technical Performance

The SensoGrip system earned high scores for user-friendliness from OTs, with a median score of 6 out of 7 on the Likert scale. The ease with which users could learn the system was also rated highly, with scores ranging between 5 and 7. Feedback about future refinements included a preference for a thinner, lighter pen—a sentiment echoed by some children and parents. However, current design limitations prevent the reduction of the pen's thickness. In addition, the OTs suggested shortening the pen's tip to allow the child's hand to be closer to the paper while still keeping the fingers on the pressure-sensing zone on the grip area.

The OTs reported that most children easily adapted to writing with the SensoGrip pen. There was a consideration to reposition the LED to the pen's proximal end for better visibility for the OT, but the need for children to see the light during writing mandated its placement near the tip. A preference for pencil lead over ballpoint refills was noted, particularly for young children accustomed to pencils. The prototype's design accommodated a fixed-length ballpoint refill to avoid the complexities associated with a retracting pencil lead and pressure measurement.

Technical performance evaluations throughout the trial revealed that the system functioned at a high level. Most recorded technical issues during the trial were generally minor and typical for technical products, such as battery depletion and slow app response. The only significant technical issue occurred when 2 pens broke owing to falling on the ground and excessive pressure, which was attributed to the limitations of the manufacturing process in which the pen shafts were 3D printed. Despite these incidents, overall technical performance was not deemed to significantly influence user satisfaction or the system's usability.

Limitations

This study has certain limitations. The selection of OTs was based on their readiness to integrate a technical device into their practice, which may not reflect the perspectives of those with low technical proficiency. Consequently, the findings may predominantly represent the views of OTs who are already inclined toward technology, suggesting a potential bias toward perceiving the system as having considerable potential. This limits the broad applicability of the results across the entire OT population. Children's overwhelmingly positive feedback about the pen must be considered in light of possible bias, as responses might have been influenced by the desire to provide socially acceptable answers to adults. In addition, the study was conducted within the same institution responsible for developing the SensoGrip system. However, the study's integrity was maintained by ensuring that the research team was different from the development team. Given the primarily qualitative and explorative nature of the study and the absence of a control group, the findings reflect the subjective experiences of the participants. As such, the reported impacts should be interpreted with an understanding that they do not provide an empirical measure of the system's effectiveness.

Conclusions

This multimethods study evaluating the SensoGrip pressure-sensitive pen system offers insightful contributions to the field of pediatric occupational therapy. Through the involvement of 8 OTs with varying levels of experience (mean 13.5, SD 7 y); 16 children aged between 5 and 10 years, exhibiting handwriting difficulties; and their parents, the study describes the system's utility and potential. The participants engaged with the SensoGrip system within a natural, private practice therapy setting in Austria.

Our findings reveal that the SensoGrip system is met with strong acceptance and satisfaction, both from children who enjoyed the interactive feedback and from OTs who recognized its potential as a therapeutic tool. The system was instrumental in enhancing the children's awareness of handwriting pressure, thus showing the potential to promote more controlled and deliberate movements. OTs reported observing tangible improvement in the children's pressure modulation over the course of the intervention, which included 3 to 7 therapy sessions. However, the SensoGrip system's suitability varied among participants, with a subset of children not experiencing the anticipated benefits. These variances highlight the need for personalized approaches in the application of assistive technologies within pediatric occupational therapy.

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The study underscores the importance of such assistive technologies in reinforcing the development of fine motor skills. In particular, the real-time feedback component of the SensoGrip system was highlighted as a significant motivator for children, fostering both engagement and enjoyment in the handwriting process.

Although the SensoGrip system has shown promising results in this preliminary exploration, future studies involving controlled quantitative trials are essential to validate and quantify its impact. This study will ideally expand to consider the effects of age, developmental stage, and presence of comorbid conditions on the efficacy of the SensoGrip system.

The feedback from both the children and OTs underscore the potential of integrating technology-based interventions in therapeutic settings. Such interventions contribute not only to skill development but also to the intrinsic motivation of children, which is crucial for sustained engagement and therapeutic success.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Eligibility checklist for children, assessed by their occupational therapist.
[PDF File (Adobe PDF File), 78 KB - rehab_v11i1e51116_app1.pdf]

Multimedia Appendix 2
Usefulness, Satisfaction, and Ease of Use and Ease of Learning questionnaire, German translation.
[PDF File (Adobe PDF File), 214 KB - rehab_v11i1e51116_app2.pdf]

Multimedia Appendix 3
Focus group and interview guidelines.
[PDF File (Adobe PDF File), 103 KB - rehab_v11i1e51116_app3.pdf]

Multimedia Appendix 4
The participating therapists' acceptance of technology.
[PNG File , 183 KB - rehab_v11i1e51116_app4.png]

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Abbreviations

OT: occupational therapist
USE: Usefulness, Satisfaction, and Ease of Use and Ease of Learning

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Original Paper

Caregivers' Role in In-Home Video Telehealth: National Survey of Occupational Therapy Practitioners

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Abstract

Background: Older adults face barriers to specialty care, such as occupational therapy (OT), and these challenges are worse for rural older adults. While in-home video telehealth may increase access to OT, older adults' health- and technology-related challenges may necessitate caregiver assistance.

Objective: This study examines caregiver assistance with in-home OT video telehealth visits from the perspectives of OT practitioners at Veterans Health Administration (VHA).

Methods: A web-based national survey of VHA OT practitioners about caregivers' role in video telehealth was conducted between January and February 2022. Survey items were developed with input from subject matter experts in geriatrics and OT and identified patient factors that necessitate caregiver participation; the extent to which caregivers assist with different types of tasks (technological and clinical tasks); and the perceived facilitators of, benefits of, and barriers to caregiver involvement.

Results: Of approximately 1787 eligible VHA OT practitioners, 286 (16% response rate) participated. Not all survey items required completion, resulting in different denominators. Most respondents were female (183/226, 81%), White (163/225, 72.4%), and occupational therapists (275/286, 96.2%). Respondents were from 87 VHA medical centers, the catchment areas of which served a patient population that was 34% rural, on average (SD 0.22). Most participants (162/232, 69.8%) had >10 years of OT experience serving a patient cohort mostly aged ≥65 years (189/232, 81.5%) in primarily outpatient rehabilitation (132/232, 56.9%). The top patient factors necessitating caregiver involvement were lack of technical skills, cognitive impairment, and advanced patient age, with health-related impairments (eg, hearing or vision loss) less frequent. Technological tasks that caregivers most frequently assisted with were holding, angling, moving, repositioning, or operating the camera (136/250, 54.4%) and enabling and operating the microphone and setting the volume (126/248, 50.8%). Clinical tasks that caregivers most frequently assisted with were providing patient history (143/239, 59.8%) and assisting with patient communication (124/240, 51.7%). The top facilitator of caregiver participation was clinician-delivered caregiver education about what to expect from video telehealth (152/275, 55.3%), whereas the top barrier was poor connectivity (80/235, 34%). Increased access to video telehealth (212/235, 90.2%) was the top-rated benefit of caregiver participation. Most respondents (164/232, 70.7%) indicated that caregivers were at least sometimes unavailable or unable to assist with video telehealth, in which case the appointment often shifted to phone.

Conclusions: Caregivers routinely assist VHA patients with in-home OT video visits, which is invaluable to patients who are older and have complex medical needs. Barriers to caregiver involvement include caregivers' challenges with video telehealth or inability to assist, or lack of available caregivers. By elucidating the caregiver support role in video visits, this study provides clinicians with strategies to effectively partner with caregivers to enhance older patients' access to video visits.

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KEYWORDS

telemedicine; caregivers; occupational therapy; caregiver; care worker; telehealth; older adults; older adult; geriatric; rural; remote; OT practitioner; web-based; national survey; role; home care; clinical support; mobile phone

Introduction

Background

Providing care to 9 million veterans across 1321 facilities, Veterans Health Administration (VHA) is the largest integrated health care system in the United States [1]. A large portion of veterans served are classified as living in rural areas [2], with more than half of VHA enrollees traveling >25 miles to access care [3]. Patients living in the rural United States face difficulties accessing health care that are distinct from their urban counterparts. This is partly due to geography, as physician practices, hospitals, and other health care delivery resources are primarily situated in urban areas. For example, one-sixth of rural residents live 35% further away from an intensive care hospital than urban residents [4]. These disparities are even more striking when factoring in socioeconomic status. As public transit options in rural areas are often limited or nonexistent, patients who do not own reliable means of transportation face additional travel barriers. When comparing low-income rural and urban individuals, low-income rural individuals face worse health outcomes [5].

Disparities are further compounded by other sociodemographic factors. Rural Black people experience poorer health outcomes than their White counterparts [6,7], potentially because of social and environmental factors [8]. Patient age is also a factor when considering the impact of rurality on health, as the proportion of adults aged >65 years living in rural areas (17.5%) is larger than that living in urban areas (13.8%), with the divide expected to increase as the population ages [9]. Geriatric care is difficult to access for rural individuals, as 90% of geriatric physicians practice in urban areas [10]. Furthermore, older adults are more likely to have complex medical needs (eg, multiple chronic conditions and increased rates of dementia or disability), which can lead to an increased risk for institutionalization and the necessity for specialty care services.

One such specialty service is occupational therapy (OT), which assists older adults to age in place by supporting them to participate in meaningful activities ranging from activities of daily living, such as dressing or bathing [11,12], to leisure and work activities [13]. OT has been demonstrated to reduce older adult fall risk and increase older adult safety through home modifications [14], strength training, and educational interventions [15]. OT practitioners work with older adults with complex challenges, such as low vision and Alzheimer disease and related dementias, and frequently work with caregivers [16-19]. Similar to geriatrics and other specialty health care services, there are fewer OT practitioners in rural areas (2 per 10,000) versus urban areas (3 per 10,000) [20]. Ironically, the complex medical needs that necessitate OT services often make traveling to appointments with OT practitioners difficult.

Video telehealth is one of the ways to increase access to specialty services, such as OT; however, older adults may face barriers to video telehealth. Video telehealth expansion during the COVID-19 pandemic allowed clinicians, such as OT practitioners, to deliver rehabilitation services into patients' homes [21-23], thus increasing access by those for whom distance was a barrier [24]. However, although in-home video telehealth is ideal for OT, which focuses care delivery on the intersection between the person and the environment [25], there may be unique considerations for in-home OT video telehealth with older adults. For example, many older adults face challenges with technology due to age, health-related impairments, or low technical literacy [26]. OT practitioners may also want to see the home environment, and ambulating through the home while holding a video-enabled device may be challenging for older adults with mobility challenges. Furthermore, communication via video sessions may be more challenging for older adults with hearing or cognitive impairment. Caregivers may bridge the divide between older adults and in-home video telehealth. However, our recent scoping review of caregiver involvement in OT in-home video telehealth found little research examining caregivers' support role [27]. Given the breadth of OT services, which may involve hands-on provision of care and an emphasis on visualizing the patient and the environment, understanding the caregiver support role in OT video visits has potential applicability to myriad medical services delivered via video sessions by a range of clinician disciplines.

Objectives

To address this knowledge gap, this study examined the caregiver's role in supporting patient engagement in in-home video telehealth visits for OT services from the perspectives of VHA OT practitioners. Specifically, we sought to identify patient factors that necessitate caregiver participation in in-home OT video telehealth encounters; the extent to which caregivers assist with different types of tasks (technological and clinical tasks); and the perceived facilitators of, benefits of, and barriers to caregiver involvement.

Methods

Participants

A national survey was conducted with a volunteer sample of VHA OT practitioners (occupational therapists and OT assistants [OTAs]). From approximately 1787 OT practitioners employed across (at the time of survey administration) 1284 health care facilities (171 Veterans Affairs [VA] medical centers and 1113 outpatient sites) during the recruitment period, 333 (18.63%) consented to participate, and 286 (16% response rate) met the eligibility requirements and were included in the study (refer to Figure 1 for the survey flow). The criteria for participation included (1) being an occupational therapist or OTA and (2) having completed at least 10 in-home video telehealth encounters using VA Video Connect (VVC), VHA's proprietary videoconferencing software, involving a caregiver in the 24 months preceding the survey launch. No other eligibility criteria were applied.

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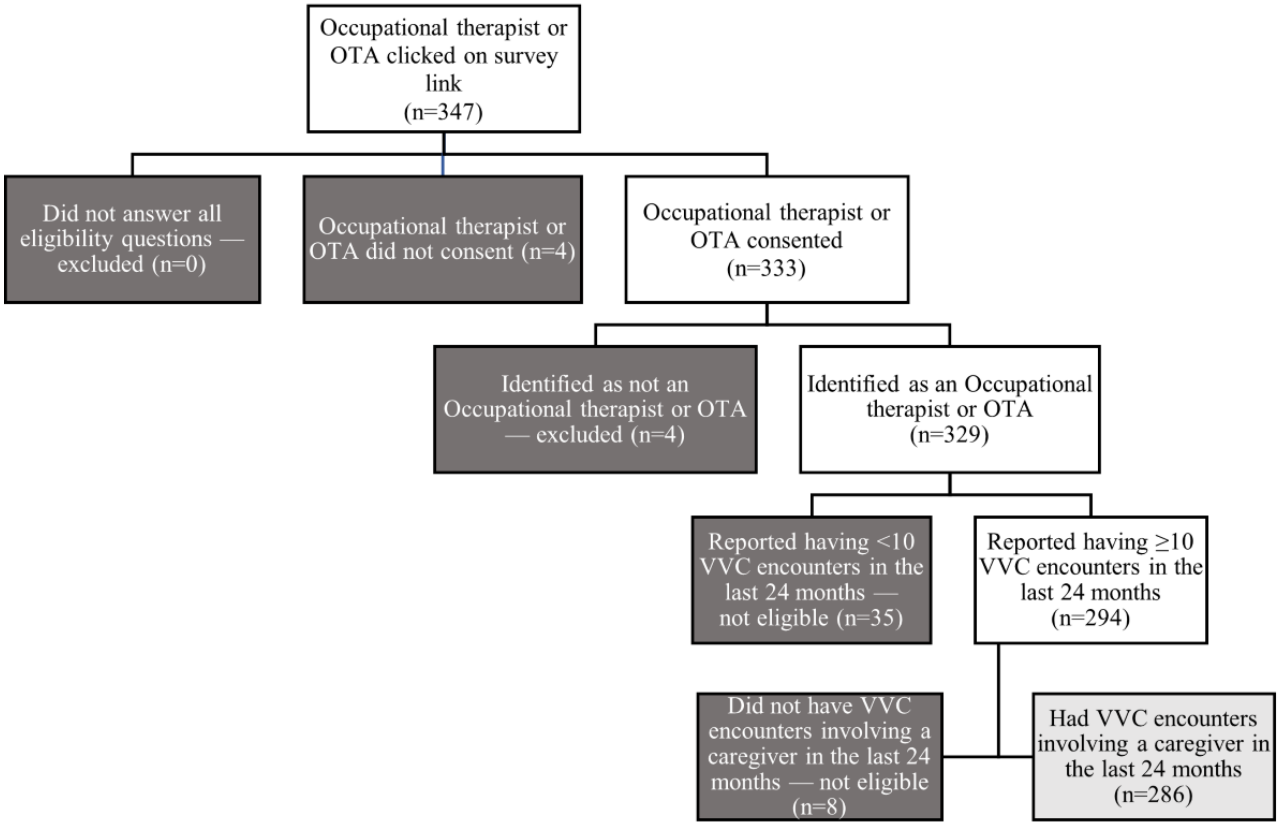
Figure 1. Participant flow diagram. OTA: occupational therapy assistant; VVC: VA Video Connect.



Survey Development

Here, we outline the survey details guided by the Checklist for Reporting Results in Internet E-Surveys [28]. Survey items gathered information about OT practitioners' demographics, including practice settings and populations served; patient factors that necessitated caregiver participation in in-home video telehealth; facilitators of caregiver participation; caregiver assistance with both technological and nontechnological tasks; the benefits of and barriers to caregiver involvement; and caregiver availability and relationship to the patient.

Initial survey items were developed in consultation with 7 subject matter experts (SMEs) in geriatrics, OT, caregiver concerns, and survey methodology. In addition to this collective experience, the development of survey items was informed by 2 sources. First, we drew on data regarding caregiver involvement in video telehealth gathered from interviews conducted between January and April 2021 with OT practitioners who were frequent users of in-home video telehealth. The interviews broadly discussed OT practitioners' use of video telehealth and included questions about caregivers' support role. Analysis of interview data related to caregiver involvement in video telehealth [29] informed the development of survey items. Specifically, the interview results that informed survey items were those about (1) patients for whom caregivers tended to be involved in video appointments, which informed the survey item about patient factors contributing to caregiver involvement; (2) what caregivers did during video telehealth visits, which informed survey items about the technological and clinical tasks with which caregivers assisted; and (3) how caregiver involvement enhanced the video sessions, which informed the survey item about the perceived benefits of caregiver participation. Second, we conducted a scoping review concerning caregivers' support role in OT video telehealth [27]. The scoping review results that informed survey items related to caregiver roles and the types of tasks caregivers assist with during video telehealth visits.

Survey items were then evaluated for clarity and content using cognitive interviewing, an evidence-based qualitative method used to examine whether survey questions serve their intended purpose [30]. Interviews were conducted by the first author with 4 OT SMEs, in addition to the SMEs previously described, in which the first author presented the survey draft to the SMEs and asked predetermined verbal probes that focused on the clarity of items, the overall survey purpose, and whether additional items should be added. The survey was revised based on our analysis of cognitive interview data, in which the first author collated interview notes about survey items to identify those that were unclear or required further explanation. The resulting survey items were then pretested with 6 VHA OT practitioners (5 of whom were different from those who participated in cognitive interviews) to gain insights into survey functionality and time to administer, using a web-based survey link. The average survey completion time was 11 (SD 2.82) minutes.

Survey Items

The final survey included 36 items (Multimedia Appendix 1). A total of 4 items addressed the inclusion criteria, including consent to participate, role (eg, occupational therapist or OTA), the number of completed in-home OT video encounters within the past 24 months, and the number of video encounters that

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involved a caregiver within the same timeframe. One of the items addressed patient factors contributing to caregiver participation in video telehealth, with a list of 12 potential factors among which respondents chose the top 5 factors. The factors included advanced age, cognitive impairments, and risk of falls. Facilitators of caregiver participation were explored through 2 items. First, participants were asked how often they used 7 facilitators of caregiver participation in video telehealth visits (including support tools; eg, national VA handouts, videos, or guides, and contacting technical support) on a 5-point Likert scale ranging from never to always. The participants were then asked to rate the effectiveness of the selected facilitators using a 5-point Likert scale that ranged from not effective to extremely effective. Adaptive questioning ensured that perceived effectiveness was collected for used facilitators. A complete list of all survey items is provided in Multimedia Appendix 1.

Data regarding caregiver assistance during video sessions were collected through 2 items in which participants were asked to rate the frequency of caregiver assistance before, during, or after video sessions for 12 technology-related tasks (eg, helping patients create or access email) and 8 clinical or nontechnological tasks (eg, offering input on patient function or details of the home and assisting with communication during sessions) on a 5-point scale ranging from never to always. The next item gathered the frequency of 9 barriers to caregiver participation in video telehealth using a 5-point scale ranging from never to always. Barriers included caregivers' anxiety, stress, or frustration; caregivers not wanting to participate in video telehealth; and caregivers' lack of technical skills or technical literacy. The perceived benefits of caregiver participation (eg, increased access to video telehealth) were collected through a 9-item checklist from which respondents selected all that applied.

Caregivers' availability to assist with video telehealth was gathered via 2 items. One item addressed the frequency of instances in which video telehealth would have benefited from caregiver involvement, but caregivers were not available, using a 5-item frequency scale ranging from never to always. This was followed by a checklist item of what tended to happen if no caregiver was available to assist (eg, appointment shifted to phone). Caregivers' relationship to patients (eg, spouse or adult child) was gathered through 1 checklist item that asked respondents to select the 3 most common relationships of caregivers who supported patient participation in video telehealth. If the participant selected paid care staff, such as home health aides, they were then prompted to provide a short description of paid care staff. Finally, participants were provided with a free-text item for any additional comments. Respondents also completed 10 practitioner demographic questions, including those on the primary VA medical center, number of years of practice, age, and practice setting. For most questions, options to select unsure or other were provided, with corresponding optional free-text boxes.

Ethical Considerations

In accordance with institutional procedures, this project was reviewed by VA Bedford's Institutional Review Board, which deemed the activity to be not research but quality improvement of an existing VA clinical service. Though deemed not research, the project was conducted in adherence with VA ethical and privacy protections and in accordance with the ethical standards of the relevant institutional or national bodies and consistent with the revised Helsinki Declaration [31].

Survey Approval

Before launch, the survey was reviewed by VHA's Organizational Assessment Sub-Committee (OASC) and Office of Labor-Management Relations (LMR) as part of standard procedures for employee surveys.

Survey Administration

The survey was conducted between January and February 2022. VHA OT practitioners were invited to participate through an email to the VHA OT listserv, with an initial email followed by 4 follow-up reminder emails over a period of 28 days. Participants accessed the survey through a secure, anonymous link only accessible while logged into an active VA network account. As survey links were not individualized, respondents could potentially complete the survey more than once. The invitation email and survey specified that participation was voluntary, anonymous, and confidential. Respondents were able to review their answers using the back button. Study data were collected and managed using REDCap (Research Electronic Data Capture) tools hosted at VHA [32]. REDCap is a secure, web-based application designed to support data capture for research studies, providing (1) an intuitive interface for validated data entry, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for importing data from external sources [32].

Data Analysis

Survey data were exported from REDCap to Excel (Microsoft Corp) and summarized using frequencies and percentages. All surveys with completed eligibility questions were included in analysis; however, as item completion was not required, response numbers varied and are reported by question. Some Likert scales were collapsed (eg, combining often with always and rarely with never) for ease of presenting results. Short free-text responses were analyzed using conventional content analysis [33]. The first author (with experience in OT, telehealth, and qualitative analysis) repeatedly read responses to determine whether free-text responses differed from predetermined survey options. Concepts identified as different from predetermined survey options were then grouped into categories, which were reviewed by DEW and EEM. Rurality geocoding developed by VHA's Office of Rural Health was used to estimate the percentage of rurality of the catchment areas associated with respondents' primary medical center.

Results

Participant Characteristics

Table 1 displays the respondents' demographics. Most respondents were female (183/226, 81%) and occupational therapists (275/286, 96.2%). Regarding ethnicity, of the 223 respondents, 18 (8.1%) identified as Hispanic or Latino, 179

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(80.3%) identified as not Hispanic or Latino, and 26 (11.7%) declined to respond. Regarding race, of the 225 respondents, 4 (1.8%) identified as American Indian, Alaska Native, Native Hawaiian, or other Pacific Islander; 15 (6.7%) identified as Asian; 14 (6.2%) identified as Black or African American; 163 (72.4%) identified as White; 6 (2.7%) identified as other; and 28 (12.4%) preferred not to answer. Participants' age, race, and gender (the data points available for VHA clinicians) aligned with those of VHA OT practitioners, according to internal VHA data. Participant demographics also closely aligned with those of OT practitioners in the United States, according to data published by the American Occupational Therapy Association (AOTA) [34]. Of note, respondents could select >1 category for race, gender, and practice setting.

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Table 1. Respondents' characteristics (N=286).

Demographic variables	Responses, n (%)
Role	
Occupational therapist	275 (96.2)
OT[a] assistant	11 (3.8)
Age (years; n=227[b])	
25-34	45 (19.8)
35-44	64 (28.2)
45-54	64 (28.2)
55-64	48 (21.1)
65-74	6 (2.6)
Race[c] (n=225)	
American Indian or Alaska Native	3 (1.3)
Asian	15 (6.7)
Black or African American	14 (6.2)
Native Hawaiian or other Pacific Islander	1 (0.4)
White	163 (72.4)
Declined to answer	28 (12.4)
Other	6 (2.7)
Ethnicity (n=223)	
Hispanic or Latino	18 (8.1)
Not Hispanic or Latino	179 (80.3)
Preferred not to answer	26 (11.7)
Gender[c] (n=226)	
Female	183 (81)
Male	28 (12.4)
Transgender or nonbinary	2 (0.9)
Preferred not to answer	13 (5.8)
Years of OT practice (n=232)	
≤5	25 (10.8)
6-10	45 (19.4)
11-20	56 (24.1)
21-30	72 (31)
>30	34 (14.7)
Years of OT practice at VHA[d] (n=232)	
≤5	85 (36.6)
6-10	67 (28.9)
11-20	57 (24)
21-30	22 (9.5)
>30	1 (0.4)
Number of OT in-home video encounters in the last 24 months	
10-24	50 (17.5)
25-99	129 (45.1)

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Demographic variables	Responses, n (%)
100+	107 (37.4)
Frequency of OT in-home video encounters involving a caregiver in the last 24 months	
Rarely	41 (14.3)
Sometimes	83 (29)
Often	138 (48.3)
Always	24 (8.4)
Proportion of patients aged >65 years treated by respondent (n=232)	
None	0 (0)
1%-25%	7 (3)
26%-50%	36 (15.5)
51%-75%	107 (46.1)
76%-100%	82 (35.3)
Specialty areas[c] (n=232)	
Inpatient rehabilitation	51 (22)
Outpatient rehabilitation	132 (56.9)
Home-based primary care	43 (18.5)
Inpatient mental health	14 (6)
Outpatient mental health	22 (9.5)
Skilled nursing or CLC[e]	24 (10.3)
Homeless or HUD-VASH[f]	10 (4.3)
Whole Health	17 (7.3)
TREWI[g]	8 (3.4)
Specialty	57 (24.6)
Other	34 (14.7)

[a]OT: occupational therapy.

[b]Not all questions were required to be answered, creating variations in the sample size for each question.

[c]The respondents could select >1 answer for the questions related to race, gender, and specialty areas; therefore, the total does not add up to 100%.

[d]VHA: Veterans Health Administration.

[e]CLC: Community Living Center.

[f]HUD-VASH: Housing and Urban Development–Veterans Affairs Supported Housing.

[g]TREWI: Physical Medicine and Rehabilitation Telerehabilitation Enterprise-Wide Initiative.

Most participants (162/232, 69.8%) had >10 years of OT experience in primarily outpatient rehabilitation (132/232, 56.9%). Free-text entries for practice setting revealed that 9.1% (21/232) of the participants worked in VA's Caregiver Support Program, a national program offering services to caregivers of eligible veterans [35]. The respondents were from 87 different VA medical centers, the catchment areas of which served a patient population that was 34% rural, on average (ranging from 0% to 98% rural).

Most respondents (189/232, 81.5%) indicated that more than half of the patients they treated were aged ≥65 years, with only 7 (3%) respondents indicating serving 1% to 25% of patients aged >65 years. None of the respondents reported not serving patients aged ≥65 years. Most respondents (179/286, 62.6%) had completed <100 in-home video encounters in the last 24 months.

Caregiver Characteristics and Availability

Regarding the frequency of caregiver involvement in video telehealth, 56.6% (162/286) of the respondents indicated caregivers often or always participated, whereas 29% (83/286) reported caregivers sometimes participated. Regarding how often patients would have benefited from caregiver assistance with in-home video telehealth but either no caregiver was available or caregivers were not willing or able to assist, 21.6% (50/232) of the respondents reported this often or always occurred. Just under half (49.1%, 114/232) of the respondents indicated that this sometimes occurred, and 23.7% (55/232) indicated that this rarely occurred. When caregivers were not

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available, most indicated that the appointment was shifted to phone (157/218, 72%) or rescheduled (106/218, 48.6%).

Regarding caregivers' role, the respondents selected the top 3 most common relationships to the patients of caregivers who participated in telehealth. Spouse was the most frequent relationship (222/235, 94.5%), followed by adult child (204/235, 86.8%) and paid care staff (90/235, 38.3%). Free-text entries describing paid care staff indicated that they were most often home health aides, with fewer reported roles for clinical staff (eg, home health nurses or home-based primary care OT practitioners). Less frequently reported relationships of caregivers who participated in video telehealth included grandchild (62/232, 26.7%); friend (24/232, 10.3%); sibling (18/232, 7.8%); and other (7/232, 3%), which, according to free-text entries, included patients' parent, niece, or neighbor (4/232, 1.7%).

Patient Factors Contributing to Caregiver Participation in In-Home Video Telehealth

OT practitioners were asked to identify the top 5 patient factors contributing to caregiver participation in video telehealth (Table 2). The most reported factors were patients' lack of technical skills or technical literacy (217/285, 76.1%); cognitive impairments (eg, memory loss, executive function; 206/285, 72.3%); advanced age (173/285, 60.7%); the lack of an email address, a device (eg, laptop or smartphone), or other technological requirements (169/285, 59.3%); and hearing impairment (107/285, 37.5%). Of 285 respondents, 17 (6%) selected other, with open text entries elaborating on the given categories (eg, suicidal ideation, which is an example of a psychological factor) or indicating caregiver reasons for participation (eg, caregiver is actively involved in patient care). The lowest reported factors (other than none of the above or other) were sensory impairments (eg, sensation loss, neuropathies), which was selected by 1.4% (4/285) of the respondents, and the risk of falls, which was reported by 13.7% (39/285) of the respondents.

Table 2. Patient factors that contribute to caregiver participation in in-home video telehealth (n=285). Survey items were shortened for presentation; for full details, see Multimedia Appendix 1.

Patient factors that contribute to caregiver participation in video telehealth	Respondents, n (%)
Lack of technical skills or technical literacy	217 (76.1)
Cognitive impairments	206 (72.3)
Advanced age	173 (60.7)
Lack of email, device, or other technology	169 (59.3)
Hearing impairment	107 (37.5)
Motor impairments	97 (34)
Vision impairment	79 (27.7)
Communication difficulties	69 (24.2)
Psychological factors	59 (20.7)
Risk of falls	39 (13.7)
Other	17 (6)
Sensory impairments	4 (1.4)
None of the above	2 (0.7)

Caregiver Assistance With Technological Tasks During In-Home Video Telehealth Visits

Respondents rated the frequency with which caregivers assisted with a list of technological tasks (Figure 2). The technological tasks with which caregivers most frequently (often or always) assisted included the following (listed in the order of frequency): holding, angling, moving, repositioning, or operating (eg, switching from front to back facing) the camera (136/250, 54.4%); enabling and operating the microphone and setting the volume (126/248, 50.8%); and enabling the camera (115/248, 46.4%). Caregivers often or always assisted with troubleshooting technology for the *initiation* of video (105/247, 42.5%) and *during* video sessions (100/248, 40.3%). Caregivers also often or always assisted with downloading or accessing the video software or link (97/249, 38.9%), entering the patient's personal details (eg, name and home address) to log into the video session (94/250, 37.6%), helping the patient create or access email (85/250, 34%), and loaning or providing a video-capable device (72/249, 28.9%). The technological tasks with which caregivers least frequently assisted (ie, technological tasks with the highest rarely or never ratings) were participating in a test call or dry run (73/249, 29.3%) and calling the VHA's national help desk for assistance (122/247, 49.4%).

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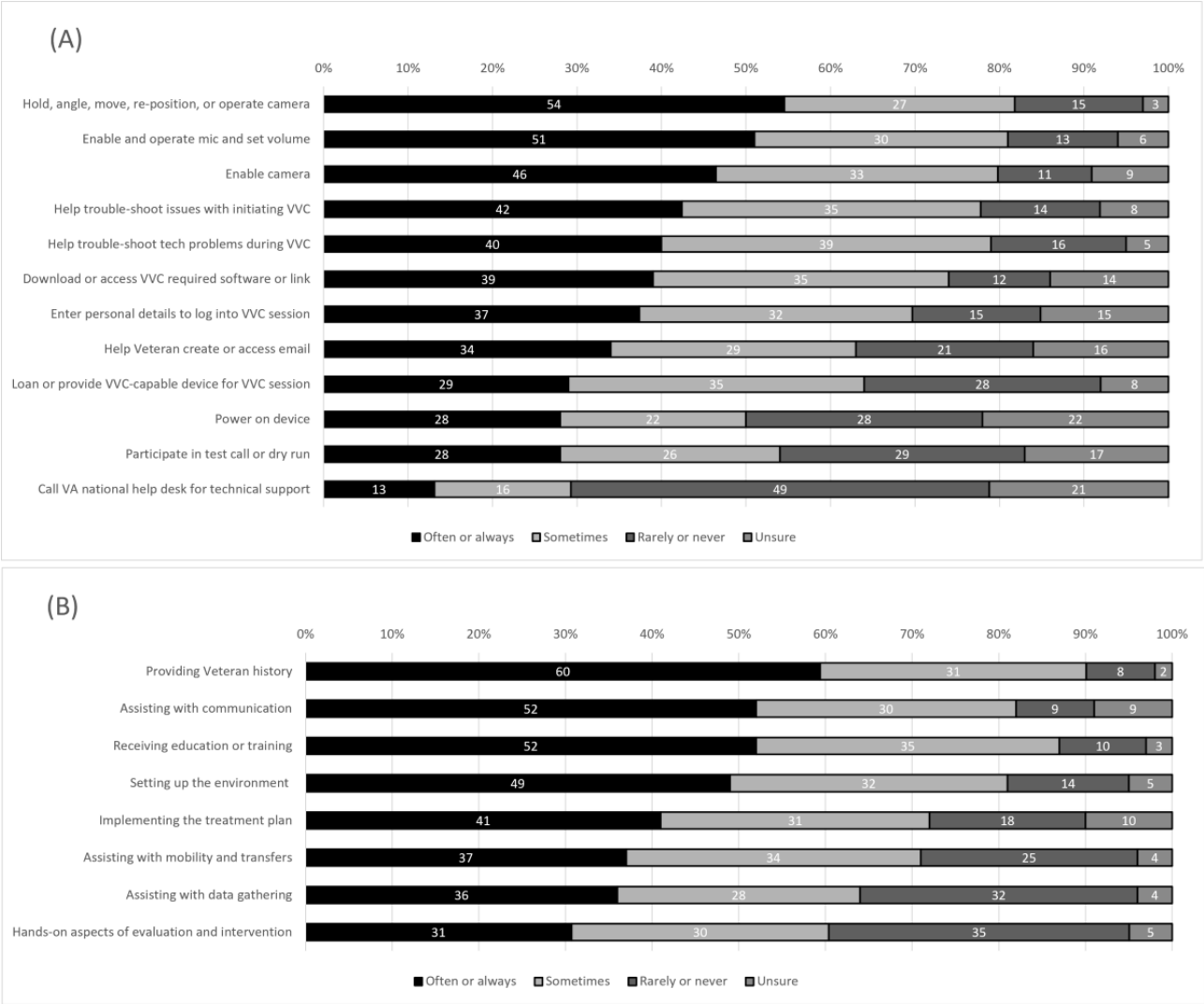
Figure 2. Frequency of caregivers' assistance with technological (A) and clinical (B) tasks during video telehealth visits. In these graphs of the frequency of technological and clinical tasks with which caregivers assisted during video telehealth visits, the tasks are ordered based on the number of often or always responses. Note: Survey items were shortened for presentation; for full details, see Multimedia Appendix 1. VA: Veterans Affairs; VVC: VA Video Connect.



Caregiver Assistance With Clinical Tasks During In-Home Video Telehealth Visits

Respondents were then asked to rate the frequency of caregivers' assistance with various clinical, nontechnological tasks (Figure 2). The tasks with the highest often or always ratings were providing history (eg, offering input on patient function or details of the patient's home; 143/239, 59.8%), assisting with communication (eg, reminding patients of appointments or prompting, cuing, or repeating questions or instructions during sessions; 124/240, 51.7%), and receiving education and training to support patient care (124/239, 51.9%). The least frequent clinical tasks (ie, clinical tasks with the highest rarely or never ratings) were assisting with hands-on aspects of evaluation and intervention (eg, assisting with range of motion or therapeutic exercise; 83/240, 34.6%), assisting with mobility and transfers (eg, supervising or providing contact guard; 60/239, 25.1%), and data gathering (eg, taking measurements; 77/239, 32.2%).

Facilitators of Caregiver Participation in In-Home Video Telehealth

Figure 3 displays the reported facilitators of caregiver participation in video telehealth, including the frequency of occurrence and perceived effectiveness. The facilitators with the highest often or always ratings for the frequency of occurrence were education that OT practitioners provided to caregivers about what to expect from video telehealth (152/275, 55.3%) and the OT practitioner's own troubleshooting of technology during video telehealth visits (121/276, 43.8%). Other facilitators, such as video support tools and the use of test calls with either the OT practitioner or telehealth staff, were reported less frequently, with two-thirds (185/273, 67.8%) of respondents indicating that they rarely or never contacted technical support during video sessions. Of note, the most frequent facilitators were not always perceived as the most effective; although 43.8% (121/276) of respondents indicated often or always troubleshooting technology themselves during video telehealth visits, only 21.7% (51/235) reported their own troubleshooting as very or extremely effective. Unsure ratings for the perceived effectiveness of facilitators ranged from 6.4%

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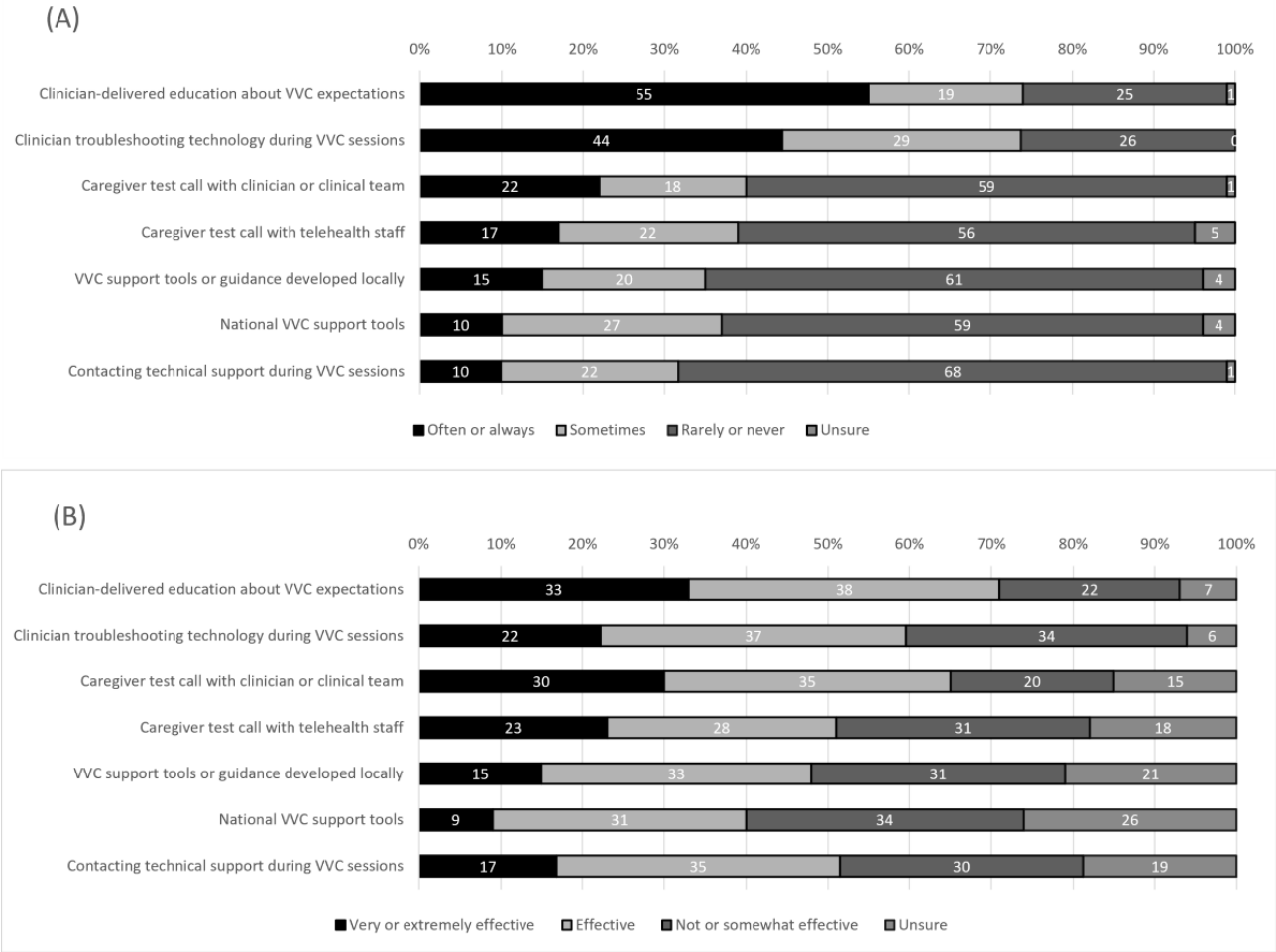
to 25.6%, with the facilitators that respondents were most unsure of being video support tools (eg, national VA handouts, videos, or guides; 46/180, 25.6%) and support tools or guides that the OT practitioner or the clinical team developed locally (29/140, 20.7%). As a reminder, branching logic was such that only the respondents who used a particular facilitator (ie, selected rarely, sometimes, often, or always to the frequency item) rated its effectiveness.

Figure 3. Facilitators of caregiver participation in video telehealth, including the frequency of occurrence and perceived effectiveness. Note: Survey items were shortened for presentation; for full details, see Multimedia Appendix 1. VVC: VA Video Connect.



Barriers to Caregiver Participation in In-Home Video Telehealth

Figure 4 displays a list of reported barriers that free-text entries from the survey's final question helped elaborate. The barriers with the highest often or always ratings were poor connectivity (80/235, 34%); caregivers' age or health-related impairments (eg, hearing or vision loss, cognitive impairment, or mobility challenges; 64/234, 27.4%); and caregivers' anxiety, stress, or frustration (52/235, 22.1%). Most respondents indicated that caregivers' lack of technical skills or literacy was a barrier, with 17% (40/235) indicating that it was a barrier often or always and 50.2% (118/235) indicating that it was a barrier sometimes. Most respondents indicated rarely or never encountering barriers such as caregivers' presence reducing patient privacy, caregivers not wanting to participate in video telehealth, or issues with scheduling.

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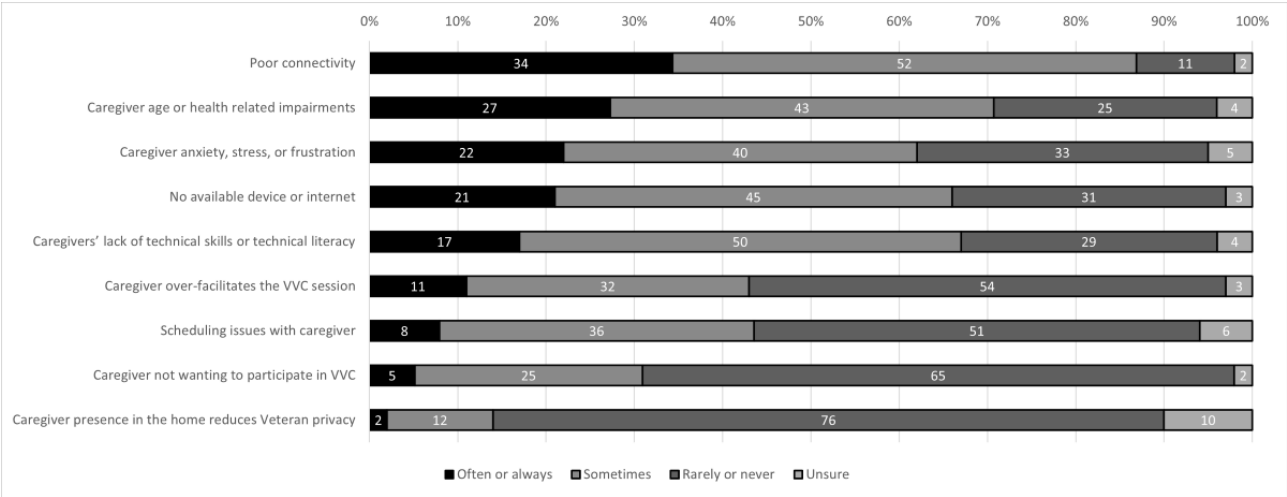
Figure 4. Barriers to caregiver participation in video telehealth. Note: Survey items were shortened for presentation; for full details, see Multimedia Appendix 1. VVC: VA Video Connect.



Free-text entries underscored the impact of technological challenges for rural patients in particular, with one of the respondents noting the following: "My coverage areas are very rural. Connectivity is a problem." Free-text entries also indicated features of the video platform as barriers, with one of the participants noting, "removing the requirement for veterans to enter their contact information into the initial screen would greatly increase veteran participation." Free-text responses also highlighted a need for system-level supports, such as Spanish-speaking technical support, or technical support and training tailored to individual needs.

Benefits of Caregiver Participation in In-Home Video Telehealth

Table 3 displays a list of the reported benefits of caregiver participation, with free-text entries providing further details. Benefits were gathered through a checklist item in which respondents selected all options that applied. The total number of benefits ranged from 0 to 10, with an average of 4.9 benefits per survey participant. The most frequently reported benefits were increased access to video telehealth (212/235, 90.2%) and increased collaboration with family (205/235, 87.2%). Other benefits related to the impact on care delivery, including additional information about or the verification of patient status (155/235, 66%) and increased ability to evaluate and intervene in the natural context (154/235, 65.5%). Free-text entries elaborated on the added value of caregiver involvement in video telehealth, with one of the respondents noting, "I do not think I would be able to get as much or accurate information [without caregiver assistance]."

Table 3. Benefits of caregiver participation in in-home video telehealth (n=235).

Benefits	Responses, n (%)
Increased access to VVC[a] for veterans	212 (90.2)
Increased collaboration with family	205 (87.2)
Additional information about or the verification of veteran status	155 (66)
Increased ability to evaluate and intervene in the natural context	154 (65.5)
Improved engagement by veterans during visits	146 (62.1)
Decreased veteran stress	141 (60)
Improved veteran outcomes	130 (55.3)
Reduced need for formal technical support	129 (54.9)
Increased veteran compliance with the treatment plan	128 (54.5)
None of the above	1 (0.4)
Other	3 (1.3)

[a]VVC: VA Video Connect, Veteran Affairs' videoconferencing platform.

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Discussion

Principal Findings

Most OT practitioner respondents reported that caregivers were often or always involved in in-home OT video telehealth sessions. This, coupled with the finding that over two-thirds of the respondents served cohorts primarily aged ≥65 years, aligns with evidence endorsing caregiver assistance as facilitative to older adults' access to video telehealth services [36,37]. Caregivers assisting with video telehealth were mostly spouses, which reflects a veteran patient population that is predominantly male and reliant on female spousal caregivers for support [38]. Adult children also frequently assisted. The finding that paid care staff (primarily home health aides) and patients' friends also occasionally assisted patients with video telehealth underscores the need for potentially innovative solutions (eg, community-based health workers [39]) to help patients who lack familial assistance to connect with video telehealth calls.

Patient Factors Contributing to Caregiver Participation in In-Home Video Telehealth

Regarding patient factors necessitating caregiver involvement, the primary factor was patients' lack of technical skills or knowledge, a common barrier to older adults accessing video telehealth [39-41], followed by cognitive impairment and advanced age. The increased technical complexity of video telehealth (which exceeds plain old telephone service [POTS]) is a barrier for older adults, who lag behind younger groups in the use of the internet and videoconferencing even after the pandemic [42]. Perceived difficulties for these groups may relate to the complexity of video telehealth, which involves multiple steps such as opening a software program and enabling a camera and microphone. There are also log-in steps unique to VHA's proprietary videoconferencing software, VVC, such as entering a phone number, address, and an emergency contact, which are meant to enhance patient safety. These additional steps may make accessing video telehealth via VVC more challenging than accessing it via commercial products such as FaceTime (Apple Inc) or Zoom (Zoom Video Communications). Evidence suggests a decreased learning curve when older adults use familiar technology [43].

Technical challenges with video telehealth may be exacerbated for those with cognitive impairment and those of a certain age. In our prior work, we interviewed patients with cognitive impairment via videoconferencing, and none of the participants were able to access videoconferencing independently [44]. Related to patient age, our finding that *advanced age* was a common factor contributing to caregiver involvement was difficult to interpret because we did not define *advanced age*. However, this finding raises concerns about the potential for ageist bias to influence clinicians' approach to telehealth with older adults. Ageist beliefs, such as the stereotype that older adults are technophobic, can influence clinicians' approach to telehealth, that is, to whom video telehealth is offered, and may exacerbate the digital divide [45,46]. Although age alone may be less informative than technological literacy as a contributor to the need for caregiver involvement in video telehealth, our own work and other studies suggest increased difficulty for those aged >75 years [47,48]. Age-related challenges, such as hearing and vision loss, were less frequent contributing factors, suggesting either that these challenges were less present or that they may be overcome by strategies such as increasing the volume, using headphones, or reducing visual clutter.

Caregiver Assistance With Technological Tasks During In-Home Video Visits

Regarding technical support tasks in video telehealth, our findings reveal that caregivers assist with an array of tasks that may reflect the nature of remote delivery of OT. According to our findings, caregivers most frequently assisted with camera operation, such as holding and angling the camera. This suggests that caregivers are central to enabling clinicians to visualize the patient and the home, a key benefit of video telehealth versus other types of telehealth that lack a visual component [49]. Caregivers' ability to assist the OT practitioner in obtaining views of the home may be particularly important for telehealth with older adults or individuals with disabilities who, because of mobility challenges or other impairments (eg, pain, fatigue, or sensory loss), may have difficulty simultaneously operating a camera and participating in clinical evaluation or intervention. Although we gathered information regarding caregiver involvement in a range of technological tasks, it should be noted that some of the lower-reported technological tasks, such as providing a device to the patient, downloading the software, and powering on the device, may have occurred before the session and therefore were not observed by the clinician. This highlights the need for a more comprehensive understanding of what caregivers do before the video session to enable patient participation. For example, clinicians could ask caregivers what steps they had to take to initiate the session and their relative ease preparing for or setting up the video session. Understanding the entire process of accessing video telehealth, including previsit steps, may help identify caregivers' support needs.

In a related vein, the need for both clinician and caregiver technology troubleshooting during the session suggests that a test call or other preparatory sessions may go far toward reducing in-session technical challenges. However, our finding that test calls were not facilitative to caregiver-involved video sessions suggests that test calls possibly are not occurring or that they are not helpful, which warrants further study. In fact, although nearly half of the OT practitioners often or always attempted to troubleshoot technology issues during video visits, less than one-quarter felt that their attempts were very or extremely effective. This endorses the notion that solutions beyond clinician troubleshooting, such as assistance from technical support teams and caregiver training before sessions, may be required. Regarding device procurement, a key benefit of telehealth services at VHA is the provision of video-enabled tablets to patients who lack the requisite technology [50,51]. While enabling VA patients to engage, this highlights lack of telehealth technology as possibly creating disparities for patients in other health care systems [52].

Caregiver Assistance With Clinical Tasks During In-Home Video Visits

Regarding clinical or nontechnological tasks, caregivers regularly assisted with a wide range of tasks, elaborating the

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potential for caregiver participation to facilitate video sessions for OT and other similarly complex clinical services. Tasks with the highest ratings related to verbal communication, such as providing patient history and reminding patients about appointments. This underscores caregivers' frequent role as care partners, especially for older adults [53]. It also suggests the importance of communication in telehealth, particularly for older adults and others encountering communication challenges [54]. Communication challenges in video telehealth that stem from technical glitches, such as lost audio and video, can result in patients feeling less engaged. Such challenges may be reduced through a preparatory session or coaching [55]. Other barriers may relate to the nature of interpersonal communication over videoconferencing, which, although better than phone for aspects such as establishing rapport [56], may create what one team of researchers referred to as (in the context of distance learning) *transactional distance* between patients and clinicians [57], whereby patients feel less connected to care [58]. This may be exacerbated for patients whose language is different from that of the clinician [59]. Caregiver engagement by rephrasing in the patients' language or repeating questions or information may lessen this distance.

The lowest reported clinical tasks caregivers assisted with related to hands-on aspects of evaluation and intervention, reflecting a gap in the literature about caregivers' role in OT video sessions and in dynamic assessment more broadly. Our recent scoping review of caregivers' support role in OT video sessions indicated that although caregivers are often mentioned as being involved in evaluation and intervention, information about the level of caregiver involvement (ie, whether they physically assisted patients or the types of assistance they provided) was generally lacking [27]. This points to a potential lost opportunity in that caregivers may be able to assist remote clinicians during video sessions by setting up the environment, operating the camera, or providing standby supervision. However, evidence for caregivers assuming such a therapist extender role during video sessions is lacking. In fact, clinical guidelines for the use of videoconferencing for performance-based assessment in general are lacking, particularly with populations contending with chronic conditions or disabilities [60,61]. A systematic review of video-delivered exercise interventions for older adults noted that although many studies cited caregiver involvement, studies did not describe what caregivers did during the video sessions [62].

More research is needed to explicate how caregivers might assist during video telehealth without increasing caregiver burden. For example, in our prior work delivering an in-home video telehealth home safety assessment to patients with dementia, which required caregivers to ambulate throughout the home while holding a portable computing device, the operation of the technology was fatiguing for some caregivers [63]. This highlights the potential negative impact of assisting during video telehealth on caregivers. Our finding that caregivers' own health conditions or anxiety are potential barriers to their assistance during video telehealth suggests the need for guidelines regarding how to effectively partner with caregivers, particularly for tasks that might be more demanding or complex, such as assisting with mobility assessments. Caregivers' psychosocial factors should be factored in when determining the level of assistance asked of caregivers during video telehealth, especially as some caregivers experience anxiety and social loneliness [64] or have high rates of burden [65]. This, coupled with the finding that most respondents indicated that caregivers' lack of technical skill sometimes affected video sessions, highlights the need for caregiver-facing technical support or coaching and for an improved understanding of caregiver barriers and perspectives in general.

Benefits of and Barriers to Caregiver Involvement

In addition to enhancing clinical care delivery, findings revealed that caregiver involvement in in-home video visits increased access to care for patients and allowed for increased collaboration with family members, especially for older patients. This aligns with evidence in which caregivers report that being involved in patients' video visits helps them get their own questions answered [36]. It also underscores the potential for caregiver contribution in video telehealth to enhance decision-making around care transitions, an important facet of older adult care [66,67]. Findings also reveal potential challenges to caregiver involvement in video sessions, particularly among rural populations. The most frequent barrier was poor connectivity, which aligns with evidence of difficulty with Wi-Fi and internet access in rural areas [68,69]. In addition, it is important to note that challenges integrating caregivers into patient care present in brick-and-mortar settings, such as caregivers' difficulty assisting patients with implementing care plans [70,71] or lack of knowledge about patient health conditions [72], may also be present in video visits.

Regarding the availability of assistance with video sessions, this work suggests that lack of caregiver assistance may further widen the digital divide for certain patients. The finding that it was relatively common for caregivers to not be available to assist aligns with evidence that the absence of a caregiver is a barrier to older adults' access of video telehealth [73]. Furthermore, our finding that when caregivers were unavailable, the appointment shifted to the phone underscores the potential for patients to not receive the same quality of care if a caregiver is not available to assist. The limitations of phone to ascertaining visual information will inhibit evaluation by clinicians, such as OT practitioners, who rely on visual observation of the patient and home environment. The fact that video appointments with older patients and those from lower socioeconomic backgrounds or racial and ethnic minority groups are more likely to convert to phone [74] indicates that an unequal distribution of video telehealth may exacerbate existing health care access challenges for patients from historically marginalized populations [75].

Limitations

This study has several limitations. VHA's fully developed telehealth infrastructure and resources (eg, proprietary video telehealth software, national technical support hotline, dedicated technical support staff, and a tablet loaner program) may limit generalizability to health care settings that lack such resources. Nonrespondent bias may also constrain generalizability, as practitioners may have felt pressured to participate, or those with a strong interest may have been more likely to participate in the survey. Furthermore, we did not gather patient

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demographics or caregivers' perspectives of video visits, knowledge that is necessary to gain a complete understanding of disparities operating within video appointments and the full extent of caregiver involvement. A more comprehensive understanding of the myriad factors involved in the video delivery of more complex services, such as OT, would enhance our ability to address digital divide issues.

Conclusions

Although the use of video telehealth has rapidly expanded since the pandemic, digital divide issues highlight that not all individuals have equal access to the service. Patients of VHA frequently rely on caregivers to engage in video visits, particularly those who are older; who are from a rural area; or who have complex medical needs, such as dementia. Caregiver participation can enable patients to access video telehealth by providing both technical and clinical support. Such assistance is invaluable to clinical services like OT, which relies on the visualization of the home and of the patient. However, caregivers themselves may face challenges or need support in facilitating video telehealth. Furthermore, suitable assistance may need to be provided to patients who lack caregivers. By elucidating the role of caregiver support in video telehealth, including the types of tasks caregivers assist with and the benefits of caregiver participation, this study provides clinicians with considerations for how to effectively partner with caregivers to enhance older patients' access to video telehealth.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey items.
[DOCX File , 20 KB - rehab_v11i1e52049_app1.docx]

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Abbreviations

AOTA: American Occupational Therapy Association
LMR: Office of Labor-Management Relations
OASC: Organizational Assessment Sub-Committee

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OT: occupational therapy
OTA: occupational therapy assistant
POTS: plain old telephone service
REDCap: Research Electronic Data Capture
SME: subject matter expert
VA: Veterans Affairs
VHA: Veterans Health Administration
VVC: VA Video Connect

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Original Paper

Validity and Reliability of a Telehealth Physical Fitness and Functional Assessment Battery for Ambulatory Youth With and Without Mobility Disabilities: Observational Measurement Study

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Abstract

Background: Youth (age 15-24 years) with and without disability are not adequately represented enough in exercise research due to a lack of time and transportation. These barriers can be overcome by including accessible web-based assessments that eliminate the need for on-site visitations. There is no simple, low-cost, and psychometrically sound compilation of measures for physical fitness and function that can be applied to youth with and without mobility disabilities.

Objective: The first purpose was to determine the statistical level of agreement of 4 web-modified clinical assessments with how they are typically conducted in person at a laboratory (convergent validity). The second purpose was to determine the level of agreement between a novice and an expert rater (interrater reliability). The third purpose was to explore the feasibility of implementing the assessments via 2 metrics: safety and duration.

Methods: The study enrolled 19 ambulatory youth: 9 (47%) with cerebral palsy with various mobility disabilities from a children's hospital and 10 (53%) without disabilities from a university student population. Participants performed a battery of tests via videoconferencing and in person. The test condition (teleassessment and in person) order was randomized. The battery consisted of the hand grip strength test with a dynamometer, the five times sit-to-stand test (FTST), the timed up-and-go (TUG) test, and the 6-minute walk test (6MWT) either around a standard circular track (in person) or around a smaller home-modified track (teleassessment version, home-modified 6-minute walk test [HM6MWT]). Statistical analyses included descriptive data, intraclass correlation coefficients (ICCs), and Bland-Altman plots.

Results: The mean time to complete the in-person assessment was 16.9 (SD 4.8) minutes and the teleassessment was 21.1 (SD 5.9) minutes. No falls, injuries, or adverse events occurred. Excellent convergent validity was shown for telemeasured hand grip strength (right ICC=0.96, left ICC=0.98, $P<.001$) and the TUG test (ICC=0.92, $P=.01$). The FTST demonstrated good agreement (ICC=0.95, 95% CI 0.79-0.98; $P=.01$). The HM6MWT demonstrated poor absolute agreement with the 6MWT. However, further exploratory analysis revealed a strong positive correlation between the tests (r=0.83, $P<.001$). The interrater reliability was excellent for all tests (all ICCs>0.9, $P<.05$).

Conclusions: This study suggests that videoconference assessments are convenient and useful measures of fitness and function among youth with and without disabilities. This paper presents operationalized teleassessment procedures that can be replicated by health professionals to produce valid and reliable measurements. This study is a first step toward developing teleassessments

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that can bypass the need for on-site data collection visitations for this age group. Further research is needed to identify psychometrically sound teleassessment procedures, particularly for measures of cardiorespiratory endurance or walking ability.

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KEYWORDS

cerebral palsy; telehealth; young adults; telemonitoring; exercise; therapy; therapeutic exercise; assessment; teleassessment; reliability; usability; disability; youth; physical fitness; videoconference

Introduction

In clinical trials of exercise, conventional measures of physical fitness and function (2 determinants of successful interventions) require participants to be physically present at a laboratory to undergo measurement procedures with specialized equipment. This requirement is burdensome and time-consuming, which negatively affects enrollment rates. In fact, 2 of the most common reasons for nonparticipation in exercise interventions are a lack of time and transportation [1,2]. To overcome these challenges, exercise trials have begun to use web-based videoconferencing to implement intervention protocols and, more recently, collect study outcome data (ie, teleassessments). The obvious benefit of teleassessments is that they negate the need for participants to travel to an on-site research facility. This benefit is critical for advancing scientific knowledge in exercise research.

Clinical exercise interventions are limited by their ability to reach a representative sample size, and this limits the generalizability of study findings. Systematic reviews of exercise research among young adults have reported that clinical trials lacked representativeness. One review reported that only 77% of studies achieved their recruitment targets [3]. Another review reported that 86% of adults who participated in exercise research were Caucasian (mean age 51 years) [4]. Representativeness was worse among clinical populations. Considering people with physical disabilities, reviews have found that the average sample size for randomized controlled trials of exercise is 30 people: 15 per treatment and 15 per control group [1,5,6]. Moreover, a review found that 58.9% of adults with physical disabilities who were contacted to participate in exercise trials were lost before study enrollment and an even smaller percentage of people completed the exercise trial or returned for their follow-up data collection [1]. There is a genuine need for accessible and inclusive ways to increase participation in exercise trials, given that 1 in 4 adults in general and 1 in 2 adults with physical disabilities in the United States do not meet the national guidelines for exercise [7-10]. Achieving the national guidelines for exercise is important for preventing and managing all-cause morbidity and mortality [5,7,11,12].

There are existing studies on telehealth assessments, particularly among middle-aged and older adults [13-20]. Relevant prior works included a study that investigated mobility-focused physical outcome measures, which included the hand grip strength test, the five times sit-to-stand test (FTST), and the timed up-and-go (TUG) test [19]; multiple studies have investigated a remotely delivered version of a 6-minute walk test (6MWT) [21-23]; and a pilot investigated balance and gait assessments [24]. The 6MWT has also been found to be a valid indicator of cardiorespiratory fitness [25-27]. There were similar teleassessment investigations with the movement assessment battery for children (5-11 years old) [28], as well as the TUG test in children and teenagers (6-18 years old) with autism spectrum disorder [29]. Notably, a systematic review found that teleassessments had strong psychometric properties among adults [20], but there are far less investigations among younger age groups, particularly younger age groups with difficulties in gross motor function.

The youth demographic, defined as persons aged from 15 to 24 years according to the United Nations and the World Health Organization (WHO), is important because this is the age range where people adopt sedentary lifestyles that last throughout adulthood. There are 3 reasons why exercise promotion is important among youth: (1) data demonstrate that exercise participation levels are alarmingly low and continue to decline throughout the youth age range [30-33], particularly among youth with disabilities [34-36]; (2) adoption of exercise behavior during youth may increase the likelihood that people are regular exercisers in adulthood [37,38]; and (3) exercise during youth may prevent obesity and cardiometabolic disease in adulthood [39,40]. Moreover, the youth age range is where clinical populations tend to experience functional decline [41]. One study found that people with cerebral palsy (CP) with mobility disabilities experience clinically significant declines in physical function as they age from adolescence to adulthood [42]. Another study on youth with CP found that the probability of walking is highest at age 9 years (68%) and lower at age 18 years (approx. 50%) [43]. Two other studies have revealed the same pattern of functional loss and called for a more comprehensive therapeutic approach beyond the traditional focus on childhood [44,45].

Making an impact on exercise participation will require telehealth-driven exercise trials, with teleassessments that are inclusive of youth with and without disabilities. Inclusive trials are important not only for health promotion but also for disability equity, as fundamentally described in the *First Global Physical Activity and Sedentary Behavior Guidelines for People Living with Disability*, released by WHO: "Creating opportunities for inclusion in physical activity for people living with disability can help eliminate such barriers by changing perceptions, emphasizing strengths and abilities, promoting personal resilience, and having an onward impact on inclusion in society" [46,47].

Teleassessments that support large-scale exercise trials should include safe, valid, and reliable methods with affordable equipment. Nevertheless, there are few established methods among the youth age range. Additionally, there has not been a psychometric evaluation of a standardized compilation of

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teleassessments (ie, teleassessment battery) that is inclusive of youth with and without disabilities. Thus, this study investigated the validity and reliability of an inclusive teleassessment battery. The battery included physical tests for indicators of physical fitness and function that could be performed at home through videoconferencing.

Specifically, our study had the following 3 purposes:

- Primary purpose: to determine the level of convergent validity between tele- and in-person assessments of exercise among youth with and without disabilities by comparing the agreement between test results using the intraclass correlation coefficient (ICC) for validity (ICC-v). We hypothesized that the teleassessment tests would at least demonstrate good agreement with conventional in-person assessments.
- Secondary purpose: to determine the level of interrater reliability for the teleassessment tests between 2 independent raters using the intraclass correlation coefficient for reliability (ICC-r), specifically among youth with disabilities. We hypothesized that 2 raters would achieve at least good agreement on each rater-dependent test included in the battery.
- Tertiary purpose: to describe the feasibility of the teleassessments through several metrics, such as assessment duration, technical usability issues, perceived barriers and facilitators with the setup and main procedure, and potential home implementation.

Methods

Design and Overview

This was an observational measurement study evaluating the validity and reliability of a teleassessment battery. The study compared modified teleassessment procedures to the gold standard: in-person evaluations among youth with CP and without disabilities. Data were collected from August 2022 to February 2023. The study aimed to recruit 19 youth, 9 (47%) with CP and 10 (53%) without disabilities. Participants performed 4 physical tests under the following 2 conditions: in person with supervision and videoconference assessments in a simulated home environment. The order in which the assessments were completed was randomized. Both assessments were completed in a single visit to the laboratory.

Recruitment Criteria and Process

The general eligibility criteria were as follows: (1) age 15-24 years and (2) the ability to understand instructions and communicate in English. Additional eligibility criteria for people with disabilities included (1) self-reported mobility disability and (2) ability to walk 20 feet with or without assistance from a caregiver or mobility device. The presence of any orthopedic, vascular, cardiac, or other health-related issue that could make the study procedures unsafe was considered an exclusionary criterion.

People with disabilities were recruited from the medical and billing record databases of the Children's Hospital from the Division of Pediatric Rehabilitation Medicine, which works with a diverse group of children and youth with disabilities. People without disabilities were recruited from the student population of Auburn University and were age- and sex-matched to participants with disabilities. Recruitment strategies included referrals, study flyers, mailouts, and word of mouth.

Power Analysis and Sample Size Justification

This study aimed to enroll a sample size of 19 individuals to satisfy an ICC power calculation with the following components for the primary study purpose: statistical power $(1 - \beta)=0.8$; $\alpha=.05$; 2 observations; $H_0=0.7$, $H_1=0.9$ [48].

Measures

A total of 4 tests were included to assess physical fitness and motor function. Tests that require complex coordination or precise timing were not considered due to feasibility concerns. The tests were chosen based on their feasibility and safety to be performed in an average home setting [49], their broad use in research and clinical settings, and their well-researched psychometric properties in the adult population with and without disabilities [50-59]. The teleassessment protocols were modified to better suit the home environment. Picture demonstrations and instructions are included in Multimedia Appendix 1.

The tests were conducted in the following order: the hand grip strength test with a dynamometer, the FTST, the TUG test, and the 6MWT.

Hand Grip Strength Test (Physical Fitness)

The participants were instructed to sit in a stationary chair using a Camry digital hand dynamometer. The procedure included 3 trials with each hand, with the elbow flexed at 90°, with a 30-second rest in between trials. For videoconference assessments, the field of view included the participant's upper body. The participants were instructed to position the laptop camera to include their elbow, the device, and their face to ensure the posture was correct. Several studies have supported the validity and reliability of this test among a variety of populations [51-55].

Five Times Sit-to-Stand Test (Physical Fitness)

The equipment included a chair, 24 inches in height, without arm rests. The participants were instructed to sit in the chair and then stand up and sit down 5 times as fast as they could. The time it took to complete the task was recorded in seconds. For the videoconference assessment, each participant was instructed to rotate the chair 90° so that the recording included a profile view of the participant's entire body (at least the shoulders, hips, and knees); see Figure 1. A repetition was counted as complete only when the participant's rear contacted the chair. Several studies have supported the validity and reliability of the FTST [60-63].

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Figure 1. Laptop camera view of the FTST. FTST: five times sit-to-stand test.

Timed Up-and-Go Test (Lower Extremity Function)

The participants were instructed sit in a chair and then to stand up, walk straight to a cone that was placed 118 inches (3 m) away from the chair, turn around, and walk back to sit down in the chair. The time it took to complete the task was recorded in seconds. For the videoconference assessment, the participants were instructed to rotate the chair 90°. They were then instructed to place down the measuring tape starting from the chair. The tape needed to be straight, without wrinkles or folds. The participants were instructed to adjust the camera angle to include their entire body throughout the test, the floor, the chair, and the entire 3 m walkway (Figure 2). The task was considered complete only when the participant's rear contacted the chair. The reliability and validity of the TUG test have been demonstrated in a variety of populations [56].

Figure 2. Laptop camera view of the TUG test: TUG: timed up-and-go.

Six-Minute Walk Test (Lower Extremity Function and Cardiorespiratory Fitness)

For the in-person 6MWT, participants were instructed to walk as much as possible in 6 minutes around a circular track that was marked by cones. The distance walked was measured with a distance-measuring wheel, which was held by a research staff member, who followed the participant around the track during the test. The 6MWT has a variety of studies supporting its psychometric properties for measuring lower extremity function or walking ability and cardiorespiratory fitness among a variety of populations [21-23,25-27,50,57].

The research team devised a shorter, home-modified version of the 6MWT to reflect the space constraints often found in a participant's home (Figure 3). The home-modified 6-minute walk test (HM6MWT) followed the TUG test. Thus, from the previous TUG teleassessment setup, participants were instructed to place an additional cone directly at their feet while sitting in the chair. The participants were then asked to move the chair

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out of the way of the 2-cone obstacle course. The camera was positioned to include the participant's entire body throughout the test, the floor, and the entire walkway. The equipment in total included 2 cones and a piece of measuring tape to measure out the 118-inch (3 m) walkway. The assessor counted the number of laps that were completed in 6 minutes. Assessors also estimated the length of the last incomplete lap as a fraction (eg, 0.25 laps) during the 6 minutes.

Figure 3. Laptop camera view of the 6MWT: 6MWT: 6-minute walk test.

Procedures

All participants completed the 2 types of assessments (tele- and in-person assessments) in a single visit. The order in which a participant completed the tele- and in-person assessments was randomized and counterbalanced. In-person assessments were conducted in a typical laboratory setting. Teleassessments were conducted in a different setting; the space for teleassessments was measured to be a minimum of 10 × 15 square feet to resemble a modest estimate of an average living room. The in-person assessments were performed under the supervision of a research staff member, while the videoconference assessments were conducted using Zoom videoconferencing. For the latter, participants set up each teleassessment with the verbal guidance of the research staff member on Zoom. A caregiver was allowed to assist their child in the teleassessment setup and in performing the tests in order to prevent falls that might occur.

The general procedure was as follows: participants were briefed and provided informed consent; they completed the study surveys (demographic information and videoconference literacy), underwent randomization via a coin flip, and completed the tests under both conditions; and then they completed a follow-up questionnaire on their experience with the teleassessments. Videoconference literacy was assessed via the Video Conference Literacy and Usability Questionnaire, which was modified from the Telehealth Usability Questionnaire [64]. The follow-up questionnaire included 3 open-ended questions: (1) likes about the assessments, (2) dislikes about the assessments, and (3) technical issues or problems they experienced during the assessments. Study staff were also instructed to record problems or issues they observed during the assessments on the data collection form.

Regarding the setting, participant groups (youth with and without disabilities) completed the testing at 2 different university laboratories. The protocols for conducting the assessments were matched between the research teams. To assist with the standardization, assessors were given scripts on how to guide participants in setting up the teleassessments and performing each test.

For study purpose 1, 1 research staff member scored all assessments for youth with disabilities (author BL, a disability exercise specialist with over 10 years of clinical experience). Graduate research assistants scored all assessments for youth without disabilities. For study purpose 2, the videoconference recordings of the functional tests part were scored independently by 2 raters (author LM, a senior disability exercise specialist, and a doctoral student in rehabilitation science), who were blinded to the randomization, assessment type, order, and participant and researcher conversations before and after the assessments. The raters were trained to score by the lead investigator (BL) using an operations manual included in Multimedia Appendix 1. Training included a preliminary assessment of interrater reliability for a sample of 3 participants, from which they had excellent agreement for all assessments (>99% absolute agreement for the hand grip strength test, the FTST, and the TUG test; 96% for the 6MWT). The plan was to retrain them if they achieved less than 95% agreement on the assessments. Study purpose 3, feasibility, included several descriptive metrics: the participant feedback survey; duration to complete the assessments in minutes; problems, issues, or nuances experienced during the testing; and observational feedback from the assessors (recorded on the data collection form).

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Equipment

Teleassessment rooms were equipped with a Chromebook brand laptop (Samsung Galaxy Chromebook Professional Laptop, 13.3 inches, with a built-in microphone and web camera). At the start of the teleassessment, the laptop was positioned on the table. Assessment equipment included a hand grip strength dynamometer (CAMRY digital hand grip dynamometer), disc cones, a distance-measuring wheel, and a soft measuring tape that was cut to a 118-inch (3 m) length.

Analysis

For study purpose 1, ICCs were used to examine the convergent validity (ICC-v) between the test conditions. ICC-v values were complemented with Bland-Altman plots to visualize differences in agreement [65]. For the HM6MWT, additional exploratory analyses were performed to identify the optimal multiplier for the laps that would best estimate the distance in meters obtained from an in-person 6MWT. Specifically, the number of laps was first multiplied by a value of 6 m (cones were laid out 3 m away from each other—hence a minimum track of 6 m) and tested, then multiplied by 7 m, 8 m, and so on until the multipliers for the highest ICC-v were identified. For only the 6MWT, Pearson correlation analysis was planned if agreement analyses were not identified through the ICC-v.

For study purpose 2, ICCs were used to examine the interrater reliability (ICC-r) between 2 assessors (a doctoral student in rehabilitation science and a senior exercise physiology researcher). The assessors scored recorded videos of the teleassessments from the 9 (47%) ambulatory youth with CP, since the study team anticipated higher variability of performance due to mobility disability.

ICCs and their 95% CIs were calculated using IBM SPSS version 24. For the ICC-v, a 2-way mixed-effects model with absolute agreement was used with single or average measures, as appropriate for each test. For the ICC-r, a 2-way random-effects model was used with absolute agreement and single measures. The ICC interpretation criteria were as follows: 0-0.5 was considered poor; 0.5-0.75, moderate; 0.75-0.9, good; and 0.9 or higher, excellent [66]. The ICC analyses were first calculated against ICC H_0=0.75 to derive the conclusion that the validity or reliability was at least good in terms of agreement, in accordance with the study hypotheses. Further comparison against excellent agreement (ICC H_0=0.9) was conducted if preliminary analysis identified good agreement.

For study purpose 3 (feasibility), data on the following items were collected: the duration of both types of assessments, technical usability issues, and problems or adverse events experienced by participants or assessors.

Ethical Considerations

Written informed consent was obtained from all participants prior to their engagement in the study. For completing the study, participants without disabilities were compensated with extra course credit, while participants with disabilities were compensated with a US $60 gift card. The study procedures were conducted separately at each university and approved by the Institutional Review Board of each university (University of Alabama at Birmingham: #300009041; Auburn University: #22-112 EP 2204), with the agreement that study results would be combined for analysis. Participation was kept confidential.

Results

Participant Information

Participant characteristics are shown in Table 1. All 9 (47%) youth with mobility disabilities were ambulatory with a primary diagnosis of CP with a Gross Motor Function Classification System Level of I-III; of them, 8 (89%) were described as hemiplegic in terms of motor disability. One required physical assistance from a caregiver while walking, and another wore a right-leg orthotic device during the tests. One person with CP had mild-to-moderate cognitive disability. There were no statistically significant differences between groups in age, height, weight, or other aspects. Participants generally reported high videoconference literacy and usability scores.

Table 1. Overall participant characteristics (N=19).

Characteristics	Youth with CP (n=9)	Youth without disabilities (n=10)
Demographics		
Age (years), mean (SD)	17.4 (1.9)	19.3 (1.2)
Sex (male/female), n (%)	5 (56) male, 4 (44) female	5 (50) male, 5 (50) female
Height (cm), mean (SD)	160.1 (15)	160 (35)
Weight (lb), mean (SD)	142.7 (38)	149.6 (29)
Videoconference literacy and usability questionnaire, mean (SD)		
Usefulness	13.2 (1.6)	12.1 (1.9)
Ease of use and learnability	12.7 (1.9)	13.1 (1.9)
Interface quality	17.2 (2.6)	15.3 (2)
Interaction quality	14.1 (2.9)	10.5 (6.8)
Reliability	10.6 (2.4)	8.8 (2.1)
Satisfaction and future use	18.6 (1.9)	16.1 (2.7)

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Convergent Validity (Purpose 1)

Table 2 displays the ICC-v analysis results between in-person assessments and teleassessments for the hand grip strength test, the FTST, and the TUG test. Hand grip strength $ICC_{(2,3)}$ analyses, with H_0=0.75 (test value calculation vs a null hypothesis of good agreement), demonstrated statistically significant agreement between test conditions for both right-hand (ICC=0.96, 95% CI 0.9-0.99; *P*<.001) and left-hand (ICC=0.98, 95% CI 0.95-0.99; *P*<.001) grip strength. FTST test $ICC_{(2,1)}$ analysis, with H_0=0.75, demonstrated statistically significant agreement between test conditions (ICC=0.95, 95% CI=0.79-0.98; *P*=.01). However, the agreement result for the FTST was not statistically significant when tested against excellent agreement (*P*=.17). TUG $ICC_{(2,3)}$ analysis, with H_0=0.75, demonstrated statistically significant agreement between test conditions (ICC=0.92, 95% CI 0.79-0.98; *P*=.01). Agreement results remained statistically significant when tested against excellent agreement (H_0=0.9). Bland-Altman plots (Figure 4) supported the ICC analyses and demonstrated strong agreement between conditions for hand grip strength, the FTST, and the TUG test.

Table 2. ICC-v[a] for the hand grip strength test, the FTST[b], and the TUG[c] test.

Test	In-person assessment, mean (SD)	Teleassessment, mean (SD)	ICC-v (95% CI)	*P* value
Right-hand grip strength (lb)	63 (29.8)	61.9 (26.9)	0.96 (0.90-0.99)	<.001
Left-hand grip strength (lb)	61.8 (25.9)	64.2 (28.8)	0.98 (0.95-0.99)	<.001
FTST (seconds)	13.0 (5.9)	15.1 (7.7)	0.95 (0.79-0.98)	.01
TUG test (seconds)	8.5 (3.2)	9.2 (4.0)	0.92 (0.79-0.97)	.01

[a]ICC-v: intraclass correlation coefficient for validity.

[b]FTST: five times sit-to-stand test.

[c]TUG: timed up-and-go.

Figure 4. Bland-Altman plots for agreement between in-person and telehealth assessments of the hand grip strength test, the FTST, and the TUG test. FTST: five times sit-to-stand test; TUG: timed up-and-go.

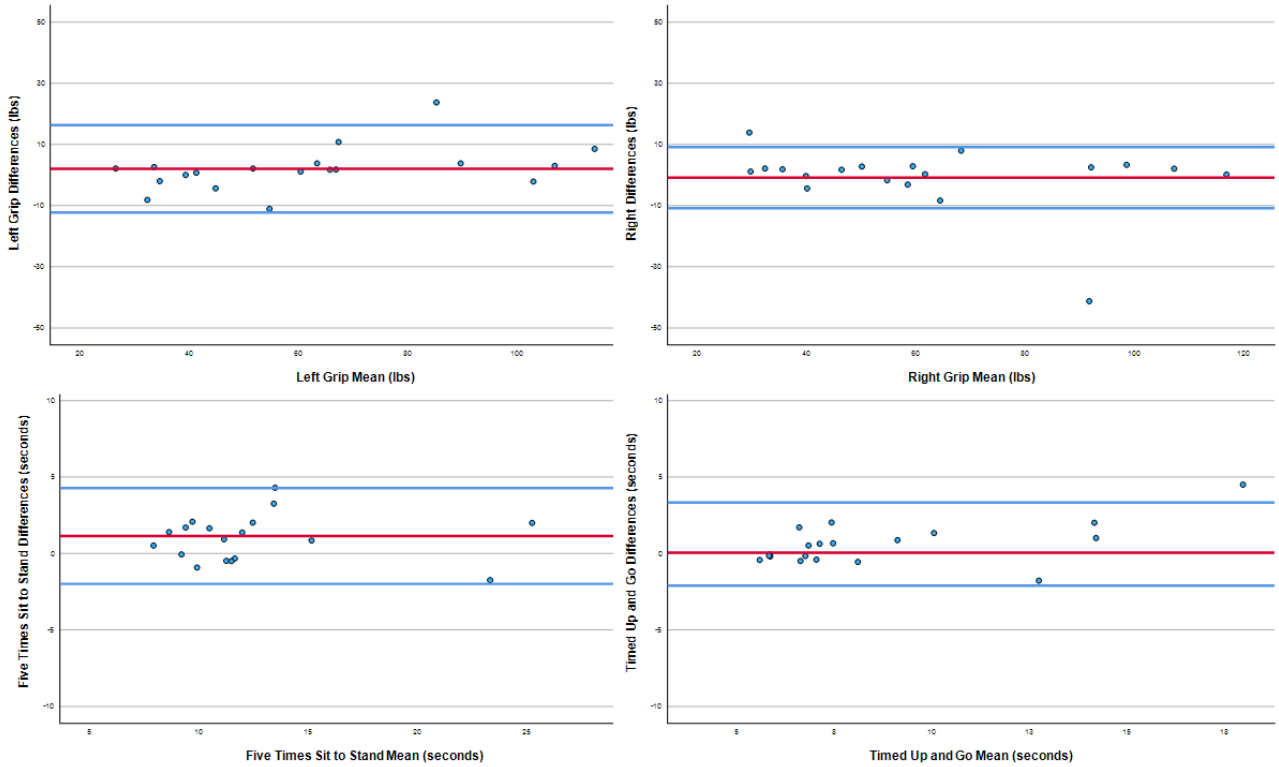

Table 3 displays the exploratory ICC-v analysis results between in-person assessments and teleassessments. Exploratory $ICC_{(2,1)}$ analyses demonstrated that the conversion factor (CF) of a 10.7 lap multiplier provided the highest ICC agreement value (Table 3). However, the HM6MWT 10.7 lap multiplier $ICC_{(2,1)}$, with H_0=0.75, did not demonstrate statistically significant agreement with on-site 6MWT distances (*P*=.18). Teleassessment 10.7 $ICC_{(2,1)}$ analysis, with H_0=0.5 (fair agreement), showed a statistically significant agreement (ICC=0.83, 95% CI 0.62-0.93; *P*=.01). The Bland-Altman plot showed seemingly poor agreement for the teleassessment to either underestimate or overestimate walking distances compared to those obtained in person (Figure 5). Follow-up Pearson correlation analysis

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resulted in a strong positive correlation between both teleassessment laps counted (r=0.83, *P*<.001; Figure 6) and teleassessment walking distance with a 10.7 CF (r=0.83, *P*<.001) compared to on-site walking distances.

Table 3. ICC-v[a] for the exploratory conversions of the HM6MWT[b] and the 6MWT[c].

Test	Converted distance (m), mean (SD)	6MWT distance (m), mean (SD)	ICC-v (95% CI)	*P* value
HM6MWT with x10.6 m/lap (m)	488 (128)	496 (119)	0.83 (0.62-0.93)	.18
HM6MWT with x10.7 m/lap (m)	493 (129)	496 (119)	0.83 (0.62-0.93)	.18
HM6MWT with x10.8 m/lap (m)	493 (131.8)	496 (119)	0.83 (0.61-0.93)	.18

[a]ICC-v: intraclass correlation coefficient for validity.

[b]HM6MWT: home-modified 6-minute walk test.

[c]6MWT: 6-minute walk test.

Figure 5. Bland-Altman plot for agreement in meters between the 6MWT and the converted HM6MWT with a 10.7 CF for laps to meters. 6MWT: 6-minute walk test; CF: conversion factor; HM6MWT: home-modified 6-minute walk test.

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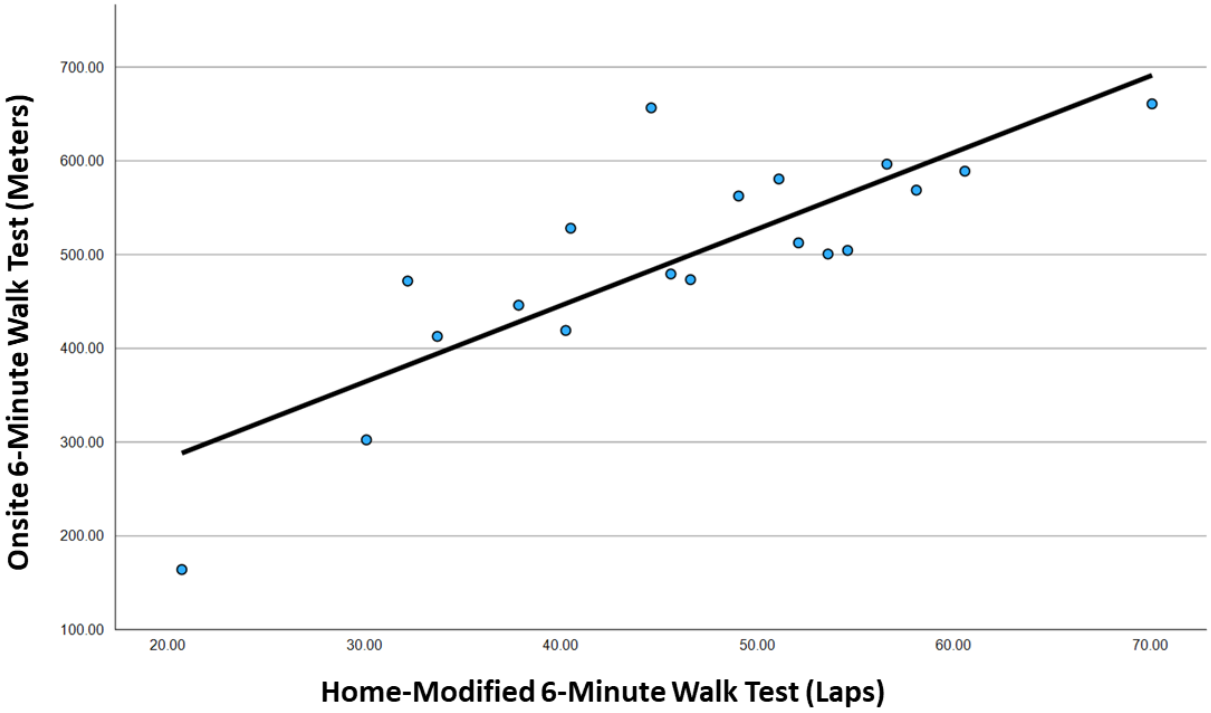
Figure 6. Linear regression analysis between the HM6MWT number of laps and the 6MWT in meters (r=0.825, 95% CI 0.593-0.930). The fitted line has a slope of 8.15 and a constant of 120.5. 6MWT: 6-minute walk test; HM6MWT: home-modified 6-minute walk test.



Teleassessment Interrater Reliability and Disability (Purpose 2)

Hand grip strength $ICC_{(2,3)}$ analyses, with H_0=0.75 (good agreement), demonstrated statistically significant agreement between raters for both right-hand (ICC=1.0, 95% CI 1.0-1.0; *P*<.001) and left-hand (ICC=0.998, 95% CI 0.998-1; *P*<.001) grip strength. These results were the same when tested against excellent agreement (H_0=0.9). For the rest of the teleassessment battery (FTST, TUG, and HM6MWT), the ICCs for reliability testing between the 2 raters (ICC-r) for the youth with CP are displayed in Table 4. The results demonstrated excellent agreement (tested against H_0=0.9) for all 3 rater-dependent tests.

Table 4. ICC-r[a] for the interrater reliability of the rater-dependent tests.

Test	Rater 1, mean (SD)	Rater 2, mean (SD)	ICC-r (95% CI)	*P* value
FTST[b] (seconds)	17.0 (7.73)	16.9 (7.75)	0.998 (0.992-1.000)	<.001
TUG[c] (seconds)	11.53 (4.57)	11.41 (4.65)	0.999 (0.997-1.000)	<.001
HM6MWT[d] (laps)	36.85 (14)	36.75 (13.86)	0.999 (0.999-1.000)	<.001

[a]ICC-r: intraclass correlation coefficient for reliability.

[b]FTST: five times sit-to-stand test.

[c]TUG: timed up-and-go.

[d]HM6MWT: home-modified 6-minute walk test.

Feasibility (Purpose 3)

For all participants, the time to complete the in-person battery (mean 16.9, SD 4.8 minutes) was on average 20% shorter (16.9/21.1 minutes) than the time to complete the teleassessment battery (mean 21.1, SD 5.9 minutes), and this difference was statistically significant (mean 4.16, SD 5.3 minutes; *P*=.003). Youth with CP took 45% longer (20.4/14.1 minutes) to complete the in-person assessments (mean 20.4, SD 2.4 minutes) than youth without disabilities (mean 14.1, SD 4.3 minutes), and this difference was statistically significant (mean difference 6.33, SD 3.8 minutes; *P*=.001). In addition, youth with CP took 33% longer (24.8/18.7 minutes) to complete the teleassessments (mean 24.8, SD 2.8 minutes) compared to youth without disabilities (mean 18.7, SD 5.7 minutes), with a mean difference of 6.11 (SD 5.4) minutes (*P*=.01). No adverse events, such as falls, occurred throughout the study.

Three participants with CP reported that the HM6MWT made them feel slightly dizzy and was more difficult because of the track's limited length and the frequent turns resulting from it. Three participants without disabilities reported that the HM6MWT was more difficult due to the space limitation. This idea was supported by all 3 assessors, who observed that participants seemingly had to put more conscious effort into making the turns around the cones, particularly when walking

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at a fast speed. The assessors also noted that cognitive disability seemed to cause variability in turns. The 1 (5%) participant with mild-to-moderate cognitive disability walked in different paths around the cones on each lap: some big paths around the cones and some small tight paths. Some participants adopted head-and-eye-focusing strategies to prevent feeling nauseated when turning. Participants generally reported that the tests were similar between the 2 settings, except for the HM6MWT.

Discussion

Principal Findings

This study investigated the feasibility, validity, and reliability of an inclusive telehealth battery of physical fitness and function among a cohort of youth with and without disabilities. A strength of the teleassessment battery was that it could be delivered with minimal, low-cost supplies. The battery included 4 web-modified tests, and the results of these tests were compared with how they were typically conducted on-site at a laboratory. All 4 web-based tests were modified so that they could be delivered through videoconferencing and within a small home environment. Most modifications were minor, except for the HM6MWT, which included the largest modification: a long-distance track that was converted to a small straight-path walkway. Overall, study findings suggested that the teleassessment battery had accessible feasibility, as indicated by safety and convenience. The mean time for completing the assessments was short, under 30 minutes. No falls, problems, or other adverse events occurred. Findings warrant a true examination of feasibility in a less controlled environment: the participants' homes. Of note, the study findings showed that a novice and an expert assessor can achieve similar results when conducting the web-based assessments (excellent interrater reliability), which has important practical implications for implementation. First, highly experienced personnel may not be necessary to conduct the teleassessments. Second, a participant who completes an intervention does not need to be scored by the same rater who scored their baseline assessments, thereby reducing scheduling constraints and the burden on research staff. Most importantly, findings largely demonstrated good-to-excellent convergent validity between the tele- and in-person assessments.

Comparison With Previous Work

Regarding validity, the web-modified versions for the hand grip strength test, the FTST, and the TUG test had excellent agreement with scores obtained from the in-person assessments. Researchers and health professionals may feel confident in performing these tests through videoconferencing, when the participant's environment conforms with the study procedures. As for the HM6MWT, the findings are less clear. The HM6MWT demonstrated only fair absolute agreement with in-person assessments, and this was when analyzed with the best-possible CF for transforming laps walked into walking distance in meters. Bland-Altman plots showed that the web-modified test overestimated or underestimated walking distances by greater than 100 m, which is substantially large, given that the mean walking distance for this age group is 496 m. This finding indicated that the HM6MWT distance in meters (converted from laps) should not be compared with the distance in meters obtained from an in-person 6MWT. Nevertheless, correlation analysis demonstrated strong agreement between the 2 types of test conditions, indicating that the web-modified 6MWT could still be considered a valid assessment. Consequently, the HM6MWT could still potentially be useful for measuring pre- and postintervention changes in walking performance. We would recommend that health professionals consider the number of laps counted as the outcome measure, as opposed to the walking distance obtained through a CF, to avoid confusion with interpretation of these results with in-person walking tests. Of course, further research is needed to support the validity of the HM6MWT. For example, given that the 6MWT is often used as an indirect indicator of cardiorespiratory endurance in clinical populations, there is a need to explore whether changes in HM6MWT laps over time are comparable with changes in cardiorespiratory fitness (criterion validity). There is a dire need for home-based assessments for cardiorespiratory fitness, given that there are (to the best of our knowledge) no scientifically sound assessments for measuring cardiorespiratory fitness remotely at home without specialized equipment and personnel.

Study findings are comparable with those among different age groups. One study reported that a videoconference assessment of the FTST is extremely reliable (ICC>0.9) and the TUG test is highly reliable (ICC>0.7) among older adults [13]. Another study among adults (mean age 37, SD 12.5 years) demonstrated excellent agreement for grip strength (ICC 0.99, 95% CI 0.99-0.99), good agreement for the FTST (ICC 0.84, 95% CI 0.75-0.9), and fair agreement for the TUG test (ICC 0.64, 95% CI 0.47-0.77). The study concluded that untimed measures, such as grip strength, have excellent reliability. For the timed outcome measures, comparison of in-person and telehealth outcomes was not recommended [19]. Likewise, study findings for interrater reliability are consistent with those reported by other investigations that included older adults without disabilities [17,18]. Regarding modifications to the conventional 6MWT, a previous study had children with CP perform the 6MWT over 15 and 30 m courses [67]. The authors concluded that a shorter and narrower walking course could result in more turning and less straight walking paths, both of which could negatively affect or add volatility to the walking distances [67]. This could explain the variable differences observed between the HM6MWT and 6MWT distance results in our study.

Future Considerations

It is important to note that not all youth will prefer teleassessments versus in-person assessments. We would recommend that future trials include both options for youth to complete the assessments. Moreover, our study included simple assessments with minimal verbal instructions. Many exercise assessments require specialized equipment and instructions and complex movements, which will make these assessments difficult to perform via videoconferencing. There is a need to identify innovative measurement methods or technology that can address logistical issues for more complex tasks.

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Limitations and Future Directions

This exploratory pilot study had inherent limitations. First, the sample size, although statistically powered for the primary analyses, was clearly not large enough to be a truly representative sample. One of the most notable limitations of our study is that the 9 youth with disabilities all had CP as their preexisting condition and were ambulatory. The result of only youth with CP was a coincidence. Although CP is an umbrella term with overlapping neuromuscular characteristics with traumatic brain injury, spinal cord injury, or other neuromuscular diseases, diversifying the study population would further promote the adoption of teleassessment as a modality of research and clinical assessment. Future research is also needed to identify home-based measures of physical fitness and function for people who are nonambulatory. People who are nonambulatory are underrepresented in exercise trials among people with disabilities and are often excluded from participation [1]. Of note, the study sample was also highly literate with videoconferencing, which will likely not be generalizable to the population.

Second, the study was not conducted in a real-world setting. The teleassessments were conducted in a controlled setting within a research laboratory where Wi-Fi and equipment were well maintained and set up by laboratory staff for use. The necessary space for the teleassessments (approx. 10 × 15 square feet) may also not be available without obstacles in a person's home. Thus, study findings for feasibility will likely not represent the technical challenges that people may encounter outside the research environment—for example, shipping the equipment to the participants' homes and calibrating equipment.

Third, this study focused only on convergent validity and interrater reliability. Other aspects of psychometric properties, such as responsiveness and the level of measurements, should be investigated, ideally with clinical populations with disabilities in their youth.

Finally, although the order of the test conditions was randomized, since all tests were performed in a single session, there is still the possibility that a learning effect influenced the results.

Conclusion

This study demonstrated that a teleassessment battery is feasible and certain components of it may be suitable for measuring fitness and function among ambulatory youth with CP and without disabilities. Convergent validity was excellent for the hand grip strength test and good for the FTST and the TUG test. The HM6WT requires further investigation or supportive measures prior to being used in a clinical trial. Standardized instructions for conducting the teleassessments are included in Multimedia Appendix 1. This study fills a gap in research on the youth age group, who are often neglected in research due to their presumed healthiness, not belonging to either children or adults in the narrow sense.

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Data Availability

The data sets generated and analyzed during this study are not publicly available due but are available from the corresponding author upon reasonable request.

Authors' Contributions

BL, DW, and JW contributed to the initial manuscript draft. BL, CSJ, KS, MM, DW, LAM, YK, and HL assisted with the data collection and statistical analysis. BL and HL were largely responsible for the manuscript revisions. All authors contributed to the final manuscript. No artificial intelligence software or program was used in the writing of this manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Manual of procedures.
[DOCX File , 360 KB - rehab_v11i1e50582_app1.docx]

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Abbreviations

6MWT: 6-minute walk test
CF: conversion factor
CP: cerebral palsy
FTST: five times sit-to-stand test
HM6MWT: home-modified 6-minute walk test
ICC: intraclass correlation coefficient
ICC-r: intraclass correlation coefficient for reliability
ICC-v: intraclass correlation coefficient for validity
TUG: timed up-and-go

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Original Paper

A Digital Intervention to Promote Self-Management Self-Efficacy Among Community-Dwelling Individuals With Stroke: Pilot Randomized Controlled Trial

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Abstract

Background: Digital interventions provided through smartphones or the internet that are guided by a coach have been proposed as promising solutions to support the self-management of chronic conditions. However, digital intervention for poststroke self-management is limited; we developed the interactive Self-Management Augmented by Rehabilitation Technologies (iSMART) intervention to address this gap.

Objective: This study aimed to examine the feasibility and initial effects of the iSMART intervention to improve self-management self-efficacy in people with stroke.

Methods: A parallel, 2-arm, nonblinded, randomized controlled trial of 12-week duration was conducted. A total of 24 participants with mild-to-moderate chronic stroke were randomized to receive either the iSMART intervention or a manual of stroke rehabilitation (attention control). iSMART was a coach-guided, technology-supported self-management intervention designed to support people managing chronic conditions and maintaining active participation in daily life after stroke. Feasibility measures included retention and engagement rates in the iSMART group. For both the iSMART intervention and active control groups, we used the Feasibility of Intervention Measure, Acceptability of Intervention Measure, and Intervention Appropriateness Measure to assess the feasibility, acceptability, and appropriateness, respectively. Health measures included the Participation Strategies Self-Efficacy Scale and the Patient-Reported Outcomes Measurement Information System's Self-Efficacy for Managing Chronic Conditions.

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Results: The retention rate was 82% (9/11), and the engagement (SMS text message response) rate was 78% for the iSMART group. Mean scores of the Feasibility of Intervention Measure, Acceptability of Intervention Measure, and Intervention Appropriateness Measure were 4.11 (SD 0.61), 4.44 (SD 0.73), and 4.36 (SD 0.70), respectively, which exceeded our benchmark (4 out of 5), suggesting high feasibility, acceptability, and appropriateness of iSMART. The iSMART group showed moderate-to-large effects in improving self-efficacy in managing emotions (r=0.494), symptoms (r=0.514), daily activities (r=0.593), and treatments and medications (r=0.870), but the control group showed negligible-to-small effects in decreasing self-efficacy in managing emotions (r=0.252), symptoms (r=0.262), daily activities (r=0.136), and treatments and medications (r=0.049). In addition, the iSMART group showed moderate-to-large effects of increasing the use of participation strategies for management in the home (r=0.554), work (r=0.633), community (r=0.673), and communication activities (r=0.476). In contrast, the control group showed small-to-large effects of decreasing the use of participation strategies for management in the home (r=0.567), work (r=0.342, community (r=0.215), and communication activities (r=0.379).

Conclusions: Our findings support the idea that iSMART was feasible to improve poststroke self-management self-efficacy. Our results also support using a low-cost solution, such as SMS text messaging, to supplement traditional therapeutic patient education interventions. Further evaluation with a larger sample of participants is still needed.

Trial Registration: ClinicalTrials.gov 202004137; https://clinicaltrials.gov/study/NCT04743037?id=202004137&rank=1

(JMIR Rehabil Assist Technol 2024;11:e50863) doi:10.2196/50863

KEYWORDS

digital intervention; feasibility; mobile health; participation; rehabilitation; self-efficacy; self-management; stroke; technology; telehealth; telemedicine; text messaging

Introduction

People receive limited inpatient rehabilitation services after a stroke, with an average rehabilitation stay of 18.6 days [1]. Those with no major motor impairments (eg, neurologically mild stroke) are often discharged from acute care without rehabilitation [2,3]. Stroke survivors are at risk for developing depression [4], experiencing reduced quality of life [5], and having an increased chance of stroke recurrence [6,7]. Moreover, restricted participation in home, community, work, and social activities following stroke is common [8,9] and can last over 6 months [10]. Stroke survivors often manifest chronic neuropsychiatric symptoms (eg, fatigue, depressed mood, and cognitive dysfunction), which can impact their stroke recovery and delay or prevent a return to prestroke social roles [11]. Thus, learning strategies to manage poststroke symptoms and cope with challenges after transitioning back to community living is essential in stroke rehabilitation [9]. Self-management programs, also known as therapeutic patient education interventions [12], could help stroke survivors improve health management and participation in home, work, and community activities [11,13]. Most stroke self-management programs use a self-efficacy–building approach to promote and maintain active participation in home and community activities poststroke [14]. Improving self-efficacy to manage symptoms and chronic conditions ultimately leads to enhanced participation [11,13]. A systematic review of 22 studies (N=1761) investigated the influence of interventions supporting self-management skills on poststroke outcomes. Given the heterogeneity of the findings, no meta-analysis was conducted. However, the results showed that self-management interventions based on self-efficacy principles could improve the quality of life, depression, daily activities, and physical functioning in stroke survivors [15]. Targeting self-efficacy in managing symptoms and behaviors becomes a critical behavioral approach to addressing the long-term consequences of stroke [15,16].

Self-management interventions are well suited to mobile health (mHealth) technologies [17,18] as mHealth delivery methods offer several advantages, including increased access for individuals who live in rural areas or have limited transportation options. Additionally, mHealth technologies provide the potential for real-time monitoring and feedback, the ability to tailor intervention components to individualized needs, and the ability to reduce administration costs [19,20]. A meta-analysis of 14 randomized controlled trials (N=1597) focused on examining what theories were applied to the development of technology-based self-management interventions and investigating their effectiveness in improving depression, anxiety, fatigue, and self-efficacy for people with neurological disorders. The results showed that cognitive-behavioral and social-cognitive theories are the 2 most common theories used to develop technology-based self-management interventions in individuals with neurological disorders. In addition, cognitive-behavioral theory–based interventions were effective in enhancing self-efficacy and reducing depression, anxiety, and fatigue. In contrast, social-cognitive theory–based interventions were effective in reducing depression only [21]. In particular, this review found large effects in enhancing self-efficacy and reducing anxiety and moderate effects in reducing depression and fatigue. Although this meta-analysis showed promising results for neurological disorders, the study populations in these 16 studies did not include people after a stroke. Thus, research is needed to verify that this evidence applies to people after a stroke. To harness the benefits of the mHealth delivery, we developed a technology-supported self-management intervention, the interactive Self-Management Augmented Rehabilitation Technologies (iSMART) intervention, adapted from the face-to-face, stroke-focused psychoeducation program Improving Participation after Stroke Self-Management (IPASS) [11,13]. iSMART simplified the original IPASS psychoeducation sessions and added text messaging and behavioral coaching components [22]. We integrated SMS text messaging into iSMART because it is easily

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customized to individual needs and accessible to anyone with a cell phone [23,24]. Live health coaches, based on behavioral activation [25], supplement psychoeducation sessions to support intervention uptake and promote effective collaboration, negotiation, and motivation while encouraging individuals to take responsibility for their recovery and wellness by fostering healthy behaviors [26].

To test this novel intervention's feasibility and potential benefits, this study aimed to (1) evaluate the acceptability, appropriateness, and feasibility of iSMART in individuals with stroke and (2) establish the preliminary effect size of iSMART in improving self-management self-efficacy in individuals after stroke. We hypothesized that (1) iSMART would be feasible to deliver and be acceptable to people with stroke and (2) iSMART would result in a moderate effect for improving poststroke self-management self-efficacy.

Methods

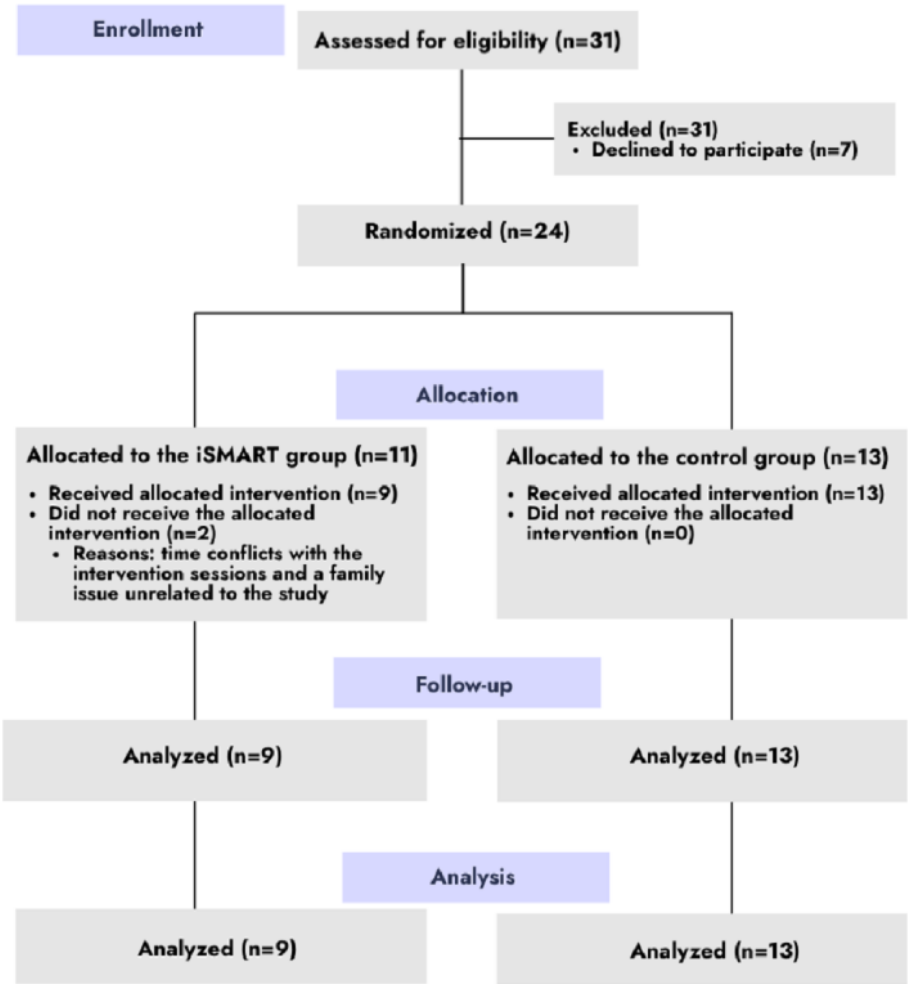
Design and Recruitment

We conducted a parallel, 2-arm, nonblinded, randomized controlled trial of 12-week duration. Participants were recruited from a stroke registry at a university-affiliated acute care hospital between January and March 2021. Using a random number generator guided by a biostatistician, participants were randomized to receive either the iSMART intervention or a manual of stroke rehabilitation (attention control). All participants in both groups continued receiving standard-of-care rehabilitation services their treating physicians recommended.

Participants and Randomization

Potential participants (N=31) were recruited between January 2021 and March 2021 based on the following inclusion and exclusion criteria. Inclusion criteria were (1) mild-to-moderate stroke (National Institutes of Health Stroke Scale scores ≤13) [27], (2) ischemic or hemorrhagic stroke, (3) aged 18 years or older, (4) English-speaking, (5) ≥3 months after stroke, (6) self-identified as having ≥1 chronic condition, and (7) mobile phone ownership. Exclusion criteria were (1) preexisting neurologic or psychiatric disorder (eg, dementia or schizophrenia), (2) severe poststroke cognitive impairment (Short Blessed Test score ≥9), (3) history of functional problems (Premorbid Modified Ranking Scale score ≥2) before the stroke, (4) severe aphasia (Boston Naming Test <10) [28], and (5) visual problems that make reading words on the device difficult. Of the screened individuals who had a stroke, 24 were randomized (CONSORT [Consolidated Standards of Reporting Trials] diagram; Figure 1).

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram showing participant recruitment and completion. iSMART: interactive Self-Management Augmented by Rehabilitation Technologies.



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Procedures

Overview

This study was a remote clinical trial, that is, a clinical trial performed remotely, including the interaction between the experimenter and participant and the assessment of outcomes [29]. Study staff contacted potential participants from a stroke research registry at a university-affiliated hospital in the Midwestern United States to explore their interest in the study. After that, study staff sent participants a secure link through email or SMS through the REDCap (Research Electronic Data Capture; Vanderbilt University) [30] and scheduled video or phone sessions to assist participants in completing the consent form and screening test for eligibility. Eligible participants were randomly allocated to the iSMART or control groups using a random sequence computer-generated program to ensure allocation concealment. Neither study staff nor participants were masked for randomization assignments. Following consent, participants underwent a remote enrollment, at which iSMART participants were oriented to technologies used in the study (ie, the videoconferencing platform and SMS) by study staff. Study staff also obtained the phone's operating system (Android or iOS) and linked the phone number to the web-based iSMART platform used to send and receive text messages from participants. Participants in both groups started their allocated interventions after all participants completed baseline testing. The intervention lasted for 3 months. After completing their allocated interventions, all participants completed a postintervention assessment. Participants in both groups continued to receive health services as prescribed by their clinicians. Participants in the iSMART group were compensated US $300 for completing the allocated intervention and outcome measures and data plan coverage. Participants in the control group were compensated US $120 for completing the allocated intervention and outcome measures. No messages were sent to participants in the control arm, so they were not compensated for data usage. The trial ended in June 2021.

The iSMART Intervention

The iSMART was a 12-week, technology-supported, coach-guided, self-management intervention comprising 3 components: psychoeducation, behavioral coaching, and text messaging. A licensed occupational therapist served as the coach in this study. The psychoeducation component was built upon the Social Cognitive Theory [31] and the person-environment-occupation-performance model [32] and implemented through weekly, 2.5-hour sessions in a group videoconferencing format. These sessions focused on teaching participants self-management strategies, including problem-solving, decision-making, positive thinking, communication, and accommodation, for managing symptoms and supporting participation in home, work, community, and social activities.

The coaching component was built on behavioral activation theory and modified from the *Revised Treatment Manual of the Brief Behavioral Activation Treatment for Depression* [25]. It was implemented weekly in 0.5-hour sessions in a one-to-one videoconferencing format. Individual coaching sessions engaged participants in collaborative goal setting with the coach to identify values and select personal activity goals from 25 predefined goals. The coach then entered the selected goals into the web-based iSMART platform so participants could receive messages customized to their chosen goals. These goals target improving participation in different life areas, including daily responsibilities, relationships, interests and recreation, education and career, and mind, body, and spirituality derived from the behavioral activation manual [25].

The text messaging component was adapted from previous studies, with effectiveness demonstrated in hospital workers [33,34] and adults with severe mental illness [35]. We adapted and pretested text messages with the planning group members, intending to increase the uptake by individuals with stroke (details in the next paragraph). Text messages were sent following the predefined schedules, including goal reminders (delivered on Mondays), goal monitoring (Tuesdays), mood monitoring (daily), self-management tips (Thursdays to Saturdays), ecological needs assessment (Saturdays), and motivational messages (Sundays). Figure 2 provides snapshots of these messages.

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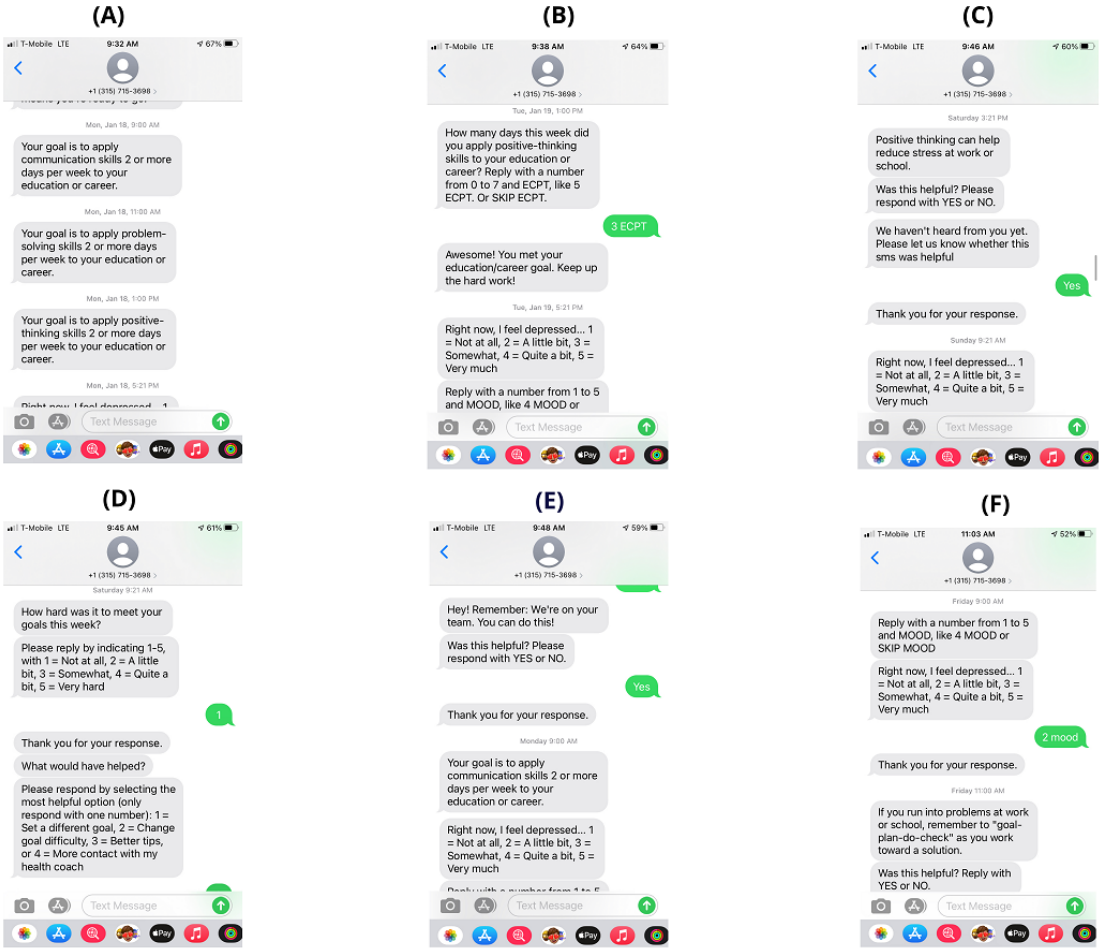
Figure 2. Screenshots of different types of messages. (A) goal reminder, (B) goal monitoring, (C) self-management tip, (D) ecological needs assessment, (E) general motivation, and (F) mood monitoring.



We formed a planning group, including 2 stroke rehabilitation clinicians, a stroke survivor, a technologist, and a self-management expert, to guide the intervention adaptation using a systematic intervention-mapping process [22,36]. During this adaptation process, we applied the behavior change wheel [37] and behavioral change technique taxonomy [38] to specify strategies that help individuals change self-management behaviors. Specifically, we identified 7 behavioral determinants most likely to affect the intervention goal and outcomes, including knowledge, behavioral regulation, skills, self-efficacy, motivation, negative and positive affect, and social and environmental support. We also identified the mechanisms of action (eg, beliefs about capabilities, values, knowledge, and motivation) most likely to affect the selected behavioral determinants. We then used the linkage table published by Carey et al [39] to match the behavioral change techniques (eg, information about health consequences, information about social and environmental consequences, instructions on how to perform the behavior, and feedback on behavior) to each of the mechanisms of action. Finally, to ensure iSMART should be applied to the selected behavioral change techniques, we developed a set of empirically supported strategies and integrated these strategies into different parts of the 3 treatment components. Details of the intervention development of iSMART, including the theoretical framework, mechanisms of action, behavioral change techniques, and the set of empirically supported strategies, are described elsewhere [22].

Control Intervention

Participants in the control group received a study-specific manual comprising stroke-specific information based on resources from the American Stroke Association and the Canadian Stroke Association. Manual content includes stroke overview, stroke prevention, rehabilitation, fatigue, weight management, fitness, medication, sleep, balance, healthy eating, emotional changes, social support, home modifications, and return to work or school. This study staff made telephone calls once a week to ask if participants had any problems while reading the manual and encouraged participants to read through the manual. The study staff did not deliver any iSMART content.

Outcome Measures

Feasibility Measures

Rates of retention and engagement were automatically recorded through the web-based iSMART platform. We defined retention as the rate at which participants completed or remained in the study and engagement as the rate at which participants responded to text messages. We defined retention and engagement rates as ≥80%, based on a previous technology intervention that showed participants who achieved these criteria demonstrated better outcomes [35]. The project found that

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participants who met the criteria would demonstrate better target health outcomes. Participants also completed three 4-item implementation measures postintervention: the Feasibility of Intervention Measure (FIM), the Acceptability of Intervention Measure (AIM), and the Intervention Appropriateness Measure (IAM) [40]. Weiner et al [40] found that these measures had strong structural validity with .89 for FIM, .85 for AIM, and 0.91 for IAM and test-retest reliability with .88 for FIM, .83 for AIM, and .87 for IAM. However, no discriminant validity of these measures was studied [40]. We defined the benchmark for high feasibility, acceptability, and appropriateness as the mean score of 4 (out of 5) on the FIM, AIM, and IAM.

Self-Efficacy Measures

Participants completed the Participation Strategies Self-Efficacy Scale (PS-SES) and the Patient-Reported Outcomes Measurement Information System's Self-Efficacy (PROMIS-SE) for managing chronic conditions at baseline and postintervention. PS-SES is a 35-item measure to assess self-efficacy in using participation strategies to manage home, work, community, and communication [41]. Lee et al [41] found that the Cronbach α coefficients of internal consistency of PE-SES were high (α=.884 to .926).

PROMIS-SE consists of five 4-item short forms to assess self-efficacy for managing daily activities, medications, treatment, symptoms, emotions, and social interactions [42]. Confirmatory factor analyses confirmed the multidimensional structure of the PROMIS-SE.

Data Analysis

Participants who completed the intervention were selected for data analyses, as we did not compute any missing values of outcomes for those who did not complete the study. Demographic characteristics between the 2 groups were evaluated using Fisher exact tests or Wilcoxon rank sum tests. Considering the small sample size of this study, we computed nonparametric analyses with median scores of FIM, AIM, and IAM and self-efficacy measures. We reported both mean and median scores for resolution purposes.

We compared retention and engagement rates and the FIM, AIM, and IAM scores of the iSMART intervention with the predefined benchmarks. We conducted Wilcoxon rank sum tests to evaluate any differences between the groups on FIM, AIM, and IAM scores. To establish the effect sizes for change in self-efficacy, we computed change scores from baseline to postintervention. We then compared the change scores between the 2 groups using Wilcoxon rank sum tests. Due to the small size, any demographic differences between groups at baseline may have artificially inflated the group difference in study outcomes. Thus, we also examined any significant changes for each group using Wilcoxon signed rank tests. We used effect sizes to interpret the intervention effect instead of statistical significance (ie, $P \leq .05$) [43]. We defined small effects if $0.1 \leq r < 0.3$, moderate effects if $0.3 \leq r < 0.5$, and large effects if $r \geq 0.5$ [44]. We reported effect sizes as they were independent of sample size so that we could express the size of an intervention effect regardless of the size of the study [45].

Ethical Considerations

All participants provided informed consent. The ethics committees of Washington University (202004137) and Northwestern University (STU00215743) reviewed and approved this study. We registered the study at ClinicalTrials.gov (202004137). We reported this study adhering to the CONSORT statement [46,47].

Results

Participants

Participant flow is presented in Figure 1. A total of 31 participants were screened, 24 were randomized, and 22 (iSMART: n=13 and control: n=9) completed the study. Table 1 shows the baseline characteristics of the participants.

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Table 1. Clinical and demographic information of the participants.

Variables	Overall (n=24)	Control (n=13)	iSMART[a] (n=11)	*P* value[b]
Age (years), mean (SD)	59 (12)	57 (12)	62 (11)	.35
Sex, n (%)				>.99
Male	14 (58)	8 (62)	6 (55)	
Female	10 (42)	5 (38)	5 (45)	
Marital status, n (%)				>.99
Married or cohabitating	13 (54)	7 (54)	6 (55)	
Separated, divorced, or widowed	7 (29)	4 (31)	3 (27)	
Single	4 (17)	2 (15)	2 (18)	
Total household income (US $), n (%)				.18
0 to 14,999	3 (12)	0 (0)	3 (27)	
15,000 to 34,999	5 (21)	2 (15)	3 (27)	
35,000 to 54,999	4 (17)	4 (31)	0 (0)	
55,000 to 74,999	3 (12)	2 (15)	1 (9.1)	
75,000 or more	7 (29)	4 (31)	3 (27)	
Do not wish to answer	2 (8.3)	1 (7.7)	1 (9.1)	
Premorbid disability (Modified Rankin Scale), n (%)				.77
No symptoms	20 (83)	11 (85)	9 (82)	
No significant disability	3 (12)	2 (15)	1 (9.1)	
Slight disability	1 (4.2)	0 (0)	1 (9.1)	
Stroke severity (NIH[c] Stroke Scale), mean (SD)	3.5 (4.2)	1.8 (3.1)	5.5 (4.7)	.06
Residential status, n (%)				.21
Alone	8 (33)	6 (46)	2 (18)	
With others	16 (67)	7 (54)	9 (82)	
Financial responsibilities, n (%)				.46
Dependent	23 (96)	13 (100)	10 (91)	
Primary or partial responsibility	1 (4.2)	0 (0)	1 (9.1)	
Race, n (%)				.68
Black	9 (38)	4 (31)	5 (45)	
White	15 (62)	9 (69)	6 (55)	
Stroke diagnosis, n (%)				>.99
Hemorrhagic	4 (17)	2 (15)	2 (18)	
Ischemic	20 (83)	11 (85)	9 (82)	
Stroke side, n (%)				.75
Bilateral	1 (4.2)	0 (0)	1 (9.1)	
Left	7 (29)	3 (23)	4 (36)	
Right	9 (38)	6 (46)	3 (27)	
Unknown	7 (29)	4 (31)	3 (27)	
Time since stroke (days), mean (SD)	1245 (1079)	957 (1059)	1585 (1048)	.09
Education (years), mean (SD)	15 (3)	14 (3)	15 (3)	.55
Number of the previous stroke, mean (SD)	2 (4)	2 (2)	3 (5)	.18

[a]iSMART: interactive Self-Management Augmented by Rehabilitation Technologies

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[b]Wilcoxon rank sum test; Fisher exact test.

[c]NIH: National Institutes of Health.

Feasibility Measures

Retention and Engagement

A total of 2 participants in the iSMART group withdrew from the study, resulting in a retention rate of 82% (9/11) that exceeded the predefined benchmark. Reasons for withdrawal included (1) time conflicts with the group sessions and (2) a family issue unrelated to the intervention. The engagement (SMS text message response) rate across all participants was 76%, ranging from 22% to 96%. Although the overall engagement rate was slightly below the predefined benchmark, only 2 out of 9 participants had response rates less than 80% (ie, 22% and 49%).

Feasibility, Acceptability, and Appropriateness

The mean scores of FIM, AIM, and IAM for the iSMART participants were 4.11 (SD 0.61), 4.44 (SD 0.73), and 4.36 (SD 0.70), respectively, which met our benchmarks, suggesting high feasibility, acceptability, and appropriateness of the iSMART intervention (Table 2). Participants in the iSMART group rated higher FIM, AIM, and IAM scores than those in the control group, with a moderate effect for feasibility (r=0.449; P=.04) and large effects for acceptability (r=0.505; P=.02) and appropriateness (r=0.540; P=.01).

Table 2. Feasibility, acceptability, and appropriateness measures between the interactive Self-Management Augmented by Rehabilitation Technologies (iSMART) and control groups.

Measures	Control (n=13)		iSMART (n=9)		Wilcoxon statistic	Effect size
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		
FIM[a]	3.48 (0.65)	3 (3, 4)	4.11 (0.61)	4 (4, 4.25)	28.5	0.449
AIM[b]	3.60 (0.66)	3.5 (3, 4)	4.44 (0.73)	5 (4, 5)	24.5	0.505
IAM[c]	3.54 (0.63)	3.5 (3, 4)	4.36 (0.70)	4.25 (4, 5)	22	0.540

[a]FIM: Feasibility of Intervention Measure.

[b]AIM: Acceptability of Intervention Measure.

[c]IAM: Intervention Appropriateness Measure.

Self-Efficacy Measures

Figures 3 and 4 show the PS-SES and PROMIS-SE change scores, illustrating significantly greater improvements in the iSMART group than in the control group. Table 3 shows the between-group effect sizes. All between-group effects were favorable to the iSMART group. PS-SES home management (r=0.571; P=.008), PS-SES community management (r=0.500; P=.02), and PROMIS-SE medications and treatments (r=0.506; P=.02) showed large effects. PS-SES work (r=0.464; P=.03), PS-SES communication management (r=0.478; P=.03), and PROMIS-SE emotions (r=0.313; P=.15) showed moderate effects.

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Figure 3. Changes in Participation Strategies Self-Efficacy Scale (PS-SES) scores after intervention. iSMART: interactive Self-Management Augmented by Rehabilitation Technologies.

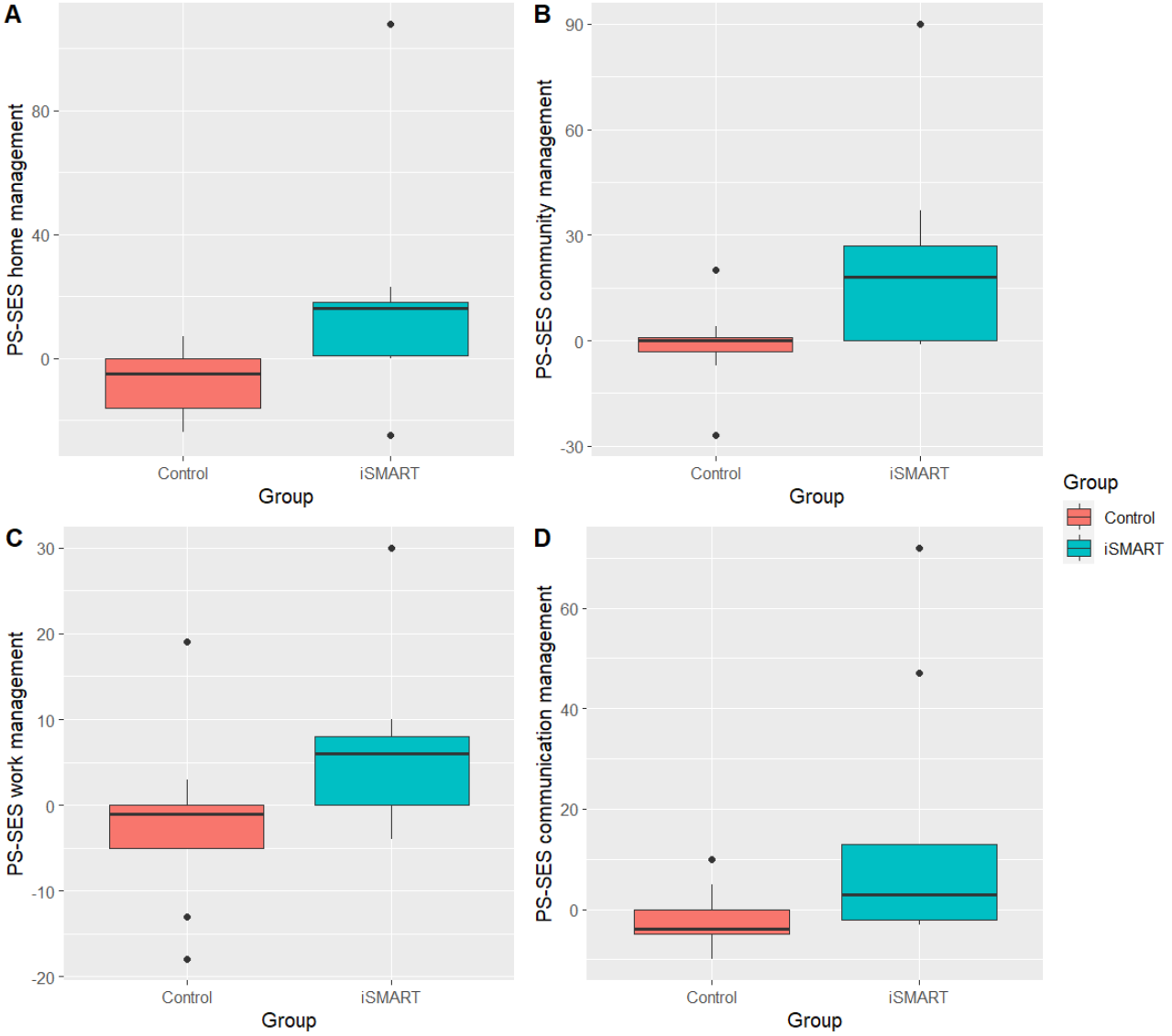

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Figure 4. Changes in Patient-Reported Outcomes Measurement Information System's Self-Efficacy (PROMIS-SE) scores after intervention. iSMART: interactive Self-Management Augmented by Rehabilitation Technologies.

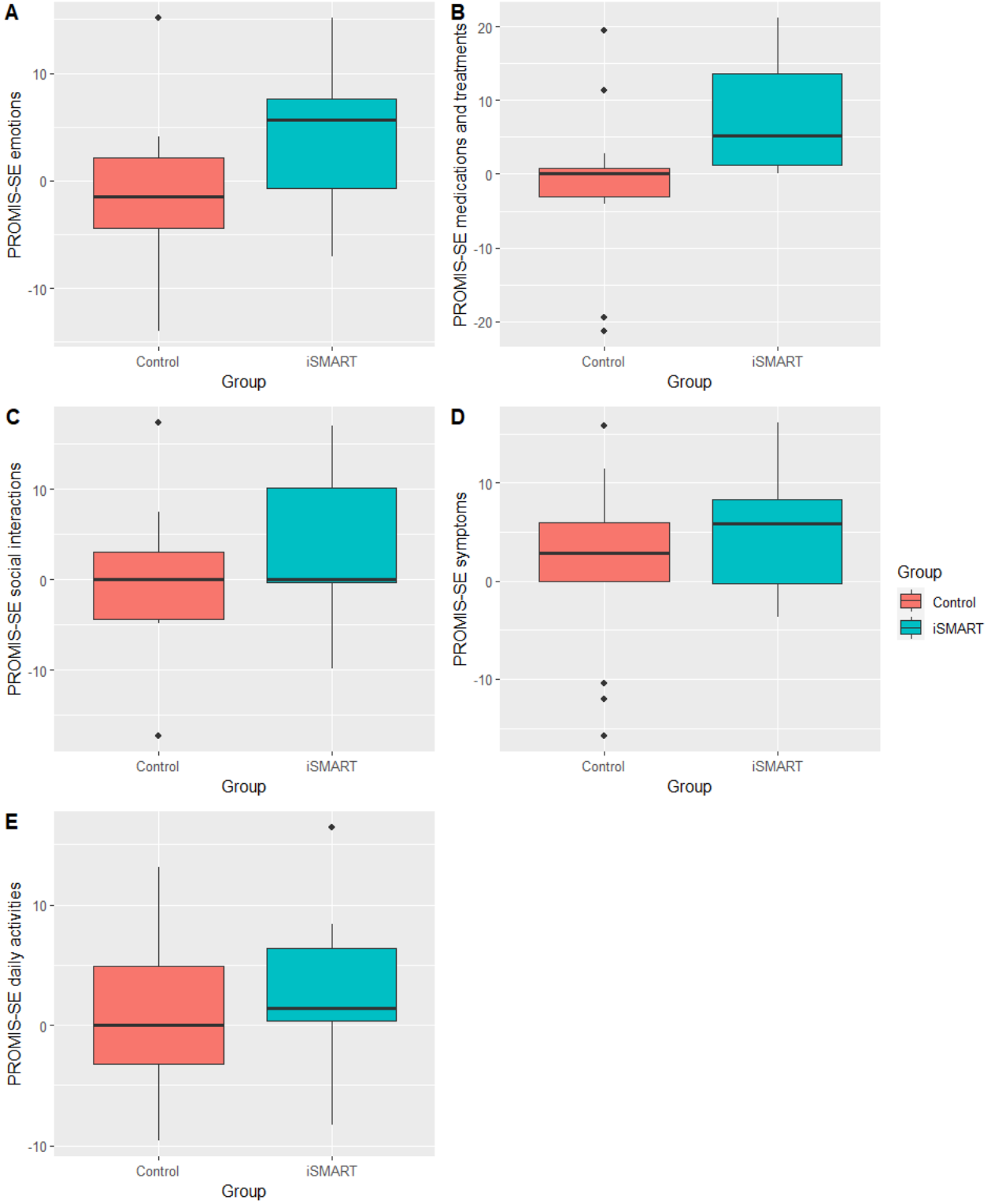

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Table 3. Pre- and postintervention self-efficacy scores between the control and interactive Self-Management Augmented by Rehabilitation Technologies (iSMART) groups.

Outcome measures	Control (n=13)						iSMART (n=9)						Between-group	
	Pre, mean (SD)	Post, mean (SD)	Pre, median (IQR)	Post, median (IQR)	*W*	*r*	Pre, mean (SD)	Post, mean (SD)	Pre, median (IQR)	Post, median (IQR)	*W*	*r*	*W*	*r*
PS-SES[a]														
Home management	105 (12.6)	97.5 (16.3)	106 (96, 113)	92 (82, 113)	47.5	.567	83.6 (38.5)	102 (21.5)	102 (57, 114)	115 (86, 120)	7	.554	18.5	.571
Community management	82.8 (16.5)	81.3 (17.8)	82 (77, 100)	80 (72, 95)	35.5	.215	60.7 (36)	82.8 (20.8)	43 (35, 99)	98 (70, 100)	3	.673	23.5	.500
Work management	60.6 (10.8)	58.8 (9.5)	65 (56, 68)	62 (51, 68)	39	.342	46.8 (19.1)	53.2 (18.3)	47 (36, 63)	56 (38, 70)	4	.633	26	.464
Communication management	67.4 (15)	65.5 (14.6)	72 (66, 79)	71 (56, 76)	55.5	.379	52.9 (26.7)	67.9 (15.3)	62 (30, 77)	74 (60, 80)	7	.476	25	.478
PROMIS-SE[b]														
Emotions	47.1 (9.1)	46.1 (8.6)	49.6 (38.8, 53.2)	46.1 (38.5, 51.6)	58.5	.252	49.1 (7.8)	53.1 (7.6)	49.6 (41.0, 53.9)	51.5 (48.2, 55.3)	10	.494	36.5	.313
Medications and treatments	46.1 (8.7)	45.1 (9.1)	43.5 (40.4, 50.4)	41.1 (38.8, 50.4)	42.5	.049	43.2 (9.9)	51.5 (10)	41.1 (37.1, 47.3)	55.5 (44.0, 60.6)	0	.870	23	.506
Social interactions	44 (8.5)	44.3 (9.4)	42.5 (37.3, 48.4)	42.5 (38.8, 53.0)	36.5	.049	49.9 (10.1)	52.8 (7.5)	49.7 (42.5, 59.8)	52.9 (48.7, 59. 8)	6	.182	48.5	.143
Symptoms	49.4 (8.8)	51.1 (8.1)	49 (44.8, 52.8)	47.7 (45.3, 57.2)	28.5	.262	49.7 (7.5)	55.1 (6.9)	48.8 (46.9, 53.7)	54.6 (50.0, 63.5)	6	.514	50	.121
Daily activities	47.7 (8.2)	49 (6.7)	47.7 (42.7, 51.2)	46 (43.4, 54.8)	32	.136	46.7 (9.7)	49.9 (8.9)	44.4 (37.8, 53.3)	52.5 (42.1, 55.7)	6	.593	44.5	.199

[a]PS-SES: Participation Strategies Self-Efficacy Scale.

[b]PROMIS-SE: Patient-Reported Outcome Measurement Information System's Self-Efficacy.

Table 3 further shows the within-group effect sizes. The iSMART showed moderate-to-large effects of increasing the use of participation strategies for management in the home (r=0.554; P=.14 [large]), work (r=0.633; P=.06 [large]), community (r=0.673; P=.04 [large]), and communication activities (r=0.476; P=.14 [moderate]). In contrast, the control group showed small-to-large effects of decreasing the use of participation strategies for management in the home (r=0.567; P=.05 [large]), work (r=0.342; P=.26 [moderate]), community (r=0.215; P=.44 [small]), and communication activities (r=0.379; P=.21 [moderate]).

In addition, the iSMART showed moderate-to-large effects of increasing self-efficacy in managing emotions (r=0.494; P=.16 [moderate]), symptoms (r=0.514; P=.11 [large]), daily activities (r=0.593; P=.11 [large]), and treatments and medications (r=0.870; P=.01 [large]), except a small effect of increasing self-efficacy in managing social interactions (r=0.182; P=.40). In contrast, the control group showed small effects of decreasing self-efficacy in managing emotions (r=0.252; P=.38), symptoms (r=0.262; P=.43), daily activities (r=0.136; P=.61), and treatments and medications (r=0.049; P=.81), except no change in self-efficacy in managing social interactions (r=0.049; P=.88).

Discussion

Principal Findings

This study evaluated the feasibility and established preliminary effect sizes of iSMART, an mHealth intervention for improving self-efficacy for chronic stroke management, in a group of community-dwelling stroke survivors. Our results showed that iSMART is feasible and acceptable for mild-to-moderate chronic stroke survivors. Participants also showed moderate improvements in most self-efficacy measures after completing the iSMART.

Previous Works and Study Implications

We observed sufficient retention (82%) and engagement (SMS text message response) rates (76%) in the iSMART group. In addition, the iSMART group showed greater ratings than the control group on all 3 implementation measures, suggesting that iSMART is a feasible self-management program for stroke

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survivors. The iSMART had a similar retention rate to those reported in mHealth interventions for pediatric weight management (78%) [48], antiretroviral therapy (85%) [49], and tuberculosis treatment (87%) [49]. The text message response rate was similar to other mHealth interventions targeting behavior changes in neuropsychiatric conditions. Suffoletto et al [50] reported 74% to 97% messaging response rates in an education and behavioral support intervention using text messages to assess daily symptoms and provide support to adults with mild traumatic brain injury. Although we found that a larger portion of the iSMART participants met the engagement criteria (>80%), 2 out of 9 participants had response rates less than 80% (ie, 22% and 49%). The wide range of engagement was commonly found in other technology-based interventions for stroke survivors. For example, Guidetti et al [51] developed a technology-supported intervention for stroke survivors in Sweden and Uganda and stated that participants responded to 44% to 100% (mean 78%) of the text messages they received. A recent study of mHealth weight management intervention in adults with mental illness from which the iSMART was derived found that participants who met the criteria (>80% of text responses) in the first month of intervention had greater weight loss than those who did not [35]. These results suggest that future technology-based interventions may enhance intervention responses and effectiveness by increasing participants' engagement up to the criteria that may maximize health and rehabilitation outcomes. Future studies are needed to formally test the engagement criteria and examine their relationships with treatment responses and outcomes for iSMART in stroke survivors.

Our findings indicated that iSMART yielded moderate-to-large effects in improving self-efficacy in using participation strategies for home, work, community, and communication management. Future interventions in improving participation outcomes following a stroke should make it a key behavioral target, given its beneficial mediatory effect on mobility and participation [52]. Participants who completed the iSMART intervention showed moderate-to-large effects of increasing self-efficacy in managing emotions, symptoms, daily activities, and treatments and medications. In contrast, the control intervention only yielded small effects. The beneficial effects of the iSMART intervention are consistent with other technology-supported self-management interventions that were effective in increasing self-efficacy and perceived participation in everyday life among stroke survivors [51,53]. This study also observed that mHealth delivery might amplify treatment effects. Compared to a nontechnology-based self-management intervention (ie, IPASS) that the iSMART was derived from, the SMART showed superior effects than the IPASS [11]. Nevertheless, because this study had a small sample (N=22), interpretations of these results should be very cautious. A future study using a larger sample size and using the face-to-face self-management program as a control is warranted to test the additional benefit of mHealth delivery of self-management interventions.

Limitations and Future Directions

This study had several limitations. We did not conduct the intent-to-treat analysis in this pilot study. The intent-to-treat analysis has been considered the standard approach to randomized controlled trial analyses [54]. A future, definitive trial will complete this analysis to avoid biased estimates. In addition to the constraints associated with a small sample size, participants were recruited from a single institution, restraining the generalizability of the findings. We found a trend toward statistical significance for greater stroke severity and longer time since stroke in the iSMART group at baseline than the control group, which may have artificially inflated the difference between groups on study outcomes. For this feasibility study, we examined the intervention score changes using within-group models to avoid this potential bias and found results favoring the iSMART group. Nevertheless, future, and larger-scale studies are needed to examine if these factors were potential covariates affecting the treatment outcomes. We used 3 implementation measures to examine the treatment's acceptability, appropriateness, and feasibility. Notably, these measures were fairly correlated, and their discriminant validity was not thoroughly tested. Thus, future research would benefit from further exploration of the discriminant validity of these constructs. This study did not collect information on how social support, built environment, technology access, and other environmental barriers impact intervention engagement in individuals with neuropsychiatric conditions, including stroke [55,56]. Future studies should examine whether these barriers mediate or modulate the impact of iSMART on poststroke outcomes.

Future research should consider the co-design approach when designing or adapting digital interventions to increase participant retention and engagement. Co-design is a process in which targeted end users and other relevant stakeholders' partner with the research team to work together in all aspects of intervention development, testing, and dissemination [57]. Co-designed digital interventions are more effective than traditional approaches, where researchers and clinicians primarily design interventions [58]. This approach is particularly beneficial when collaborating with underrepresented and minority communities because the co-design allows for conceptual or tool redevelopments and refinements based on the social, linguistic, and cultural needs of partnership groups [59]. Future studies of iSMART will need to engage more stroke survivors and caregiver stakeholders in user-centered design activities, especially those from underserved communities, to identify which characteristics of the intervention, individual users, and the care environment best facilitate iSMART implementation and effectiveness [60].

This study only examined the effect of iSMART on self-efficacy over 12 weeks. Future studies are warranted to examine the long-term impact on self-efficacy and other disability outcomes, such as the reintegration of everyday living, quality of life, and perceived recovery in stroke survivors. iSMART included three intervention components. While considering all components together as a complex intervention, we found this intervention to have adequate feasibility and positive initial effects. A specific approach, the multiphase optimization strategy framework [61], has been used to test the performance of individual intervention components in the development of technology-supported interventions such as weight loss [62], palliative care [63], and physical activity promotion [64]. A

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future study is needed to identify the iSMART components (main effects or interactions) that contribute meaningfully to improvement in intervention engagement and health outcomes in people after stroke. Future research may test the multiphase optimization strategy approach to identify if all or some intervention components are needed to optimize the iSMART intervention.

Conclusions

This study provides preliminary evidence to support the feasibility of delivering iSMART, a technology-supported self-management intervention to help stroke survivors increase self-efficacy for managing chronic conditions and supporting home, work, and community participation. Our findings support using a low-cost solution, such as text messaging, to supplement traditional therapeutic patient education interventions. More research is needed to provide more robust efficacy data to support the benefits of the iSMART intervention.

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Data Availability

The data generated and analyzed during this study cannot be sufficiently deidentified and, therefore, cannot be made publicly available due to ethical considerations. Deidentified data can be made available for further research from the corresponding author on reasonable request.

Authors' Contributions

AWKW, GEN, and DCM contributed to the study's conception and design. OD and AWKW contributed to the preparation of the materials. QB contributed to data management and analysis. ZL, YL, and AWKW wrote the first draft of the manuscript. All the authors commented on previous versions and read and approved the final manuscript.

Conflicts of Interest

GEN has received research support from the National Institutes of Health (NIH), the Health Resources and Services Administration, the Barnes Jewish Hospital Foundation, the Washington University McDonnell Center for Systems Neuroscience, the Mallinckrodt Institute of Radiology, and the Usona Institute (drug only) and has served as a consultant for Alkermes, Inc, CarelonRx, Otsuka, and Sunovion. DCM reported research support from the NIH. He has served as a consultant for Otsuka Pharmaceuticals, Optum Behavioral Health, the Centerstone Research Institute, and the OneMind Foundation. He receives royalties from Oxford Press and has an ownership interest in Adaptive Health. SIL reported on research support from the NIH. MWMF has served as an independent contractor for Isaac Ray Forensic Group and Michigan Avenue Neuropsychologists. CLM has an ownership interest in Infinite Arms. He reported on subcontracts from the NIH and VA Headache Centers of Excellence. AWKW reported on research support from the NIH, the National Institute on Disability, Independence, and Rehabilitation Research, and the Craig H Neilsen Foundation. No other disclosures were reported.

Multimedia Appendix 1
CONSORT-eHEALTH (V 1.6.1).
[PDF File (Adobe PDF File), 1174 KB - rehab_v11i1e50863_app1.pdf]

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Abbreviations

AIM: Acceptability of Intervention Measure
CONSORT: Consolidated Standards of Reporting Trials
FIM: Feasibility of Intervention Measure
IAM: Intervention Appropriateness Measure
IPASS: Improving Participation after Stroke Self-Management
iSMART: interactive Self-Management Augmented by Rehabilitation Technologies
mHealth: mobile health
NIH: National Institutes of Health
PROMIS-SE: Patient-Reported Outcomes Measurement Information System's Self-Efficacy

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PS-SES: Participation Strategies Self-Efficacy Scale
REDCap: Research Electronic Data Capture

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Corrigenda and Addenda

Correction: Validating the Safe and Effective Use of a Neurorehabilitation System (InTandem) to Improve Walking in the Chronic Stroke Population: Usability Study

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Related Article:

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In "Validating the Safe and Effective Use of a Neurorehabilitation System (InTandem) to Improve Walking in the Chronic Stroke Population: Usability Study" (JMIR Rehabil Assist Technol 2023;10:e50438) the authors made three linguistic improvements, added one missing acknowledgment, and changed the corresponding author:

In the first sentence of the Discussion, the original text reads as:

> *The goal of this study was to validate that participants representative of InTandem's intended use population can safely and effectively use InTandem, through the completion of critical tasks, and demonstrate knowledge and comprehension of materials*

The word "demonstrate" should be "demonstration of" to align to the phrasing of "completion of critical tasks" and will now read as:

> *The goal of this study was to validate that participants representative of InTandem's intended use population can safely and effectively use InTandem, through the completion of critical tasks, and demonstration of knowledge and comprehension of materials.*

In the first paragraph of the "Strengths and Limitations" section, the original text reads as:

> *The accumulated evidence for InTandem includes a feasibility study that resulted in a clinically relevant improvements in speed…*

The authors removed the "a" between "in" and "clinically relevant" and the text now reads as:

> *The accumulated evidence for InTandem includes a feasibility study that resulted in clinically relevant improvements in speed...*

In the "Background on Formative Testing" section, the original text reads as:

> *...(2) the identification of which interactions with the product users needed the most education and were less immediately intuitive out of the box.*

The text should include "on" after "education" and will now read as:

> *…(2) the identification of which interactions with the product users needed the most education on and were less immediately intuitive out of the box.*

The authors neglected to acknowledge a colleague in the Acknowledgments section which originally read as:

> *This work acknowledges the intellectual contributions made by the broader team at EVERSANA and MedRhythms. We thank Chrissy Stack, Jennifer Lavanture, Holly Roberts, Barbara Heikens, and*

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Lauren Steidl for their contributions to and coordination of this paper, and Eric Richardson for study support during both formative and validation research activities. This work was supported by MedRhythms.

And will now read as:

This work acknowledges the intellectual contributions made by the broader team at EVERSANA and MedRhythms. We thank Chrissy Stack, Jennifer Lavanture, Holly Roberts, Barbara Heikens, and Lauren Steidl for their contributions to and coordination of this paper, Ashley Levesque for her manuscript preparation support, and Eric Richardson for study support during both formative and validation research activities. This work was supported by MedRhythms.

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In addition, we have updated the author metadata to indicate that authors KES and SHC (first two authors) contributed equally.

The correction will appear in the online version of the paper on the JMIR Publications website on February 21, 2024, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Original Paper

Results of Gensingen Bracing in Patients With Adolescent Idiopathic Scoliosis: Retrospective Cross-Sectional Feasibility Study

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Abstract

Background: Bracing is an essential part of scoliosis treatment. The standard of brace treatment for patients with scoliosis today is still very variable in terms of brace quality and outcome. The Gensingen brace is a further developed Chêneau brace derivative with individual design, which can be adapted through computer-aided design.

Objective: This study aims to generate a template to obtain a database for prospective multicenter studies study to analyze the results of high-corrective asymmetric Gensingen brace treatment for patients with adolescent idiopathic scoliosis (AIS).

Methods: A template for the database was created, which contains the patients' basic data (age, menarcheal status, Risser Sign, curve pattern, and daily brace wearing time), the Cobb angles of curvature, and the cosmetically relevant angles of trunk rotation (ATR). A retrospective review of medical records of patients with AIS, who met the Scoliosis Research Society's inclusion criteria for brace studies, was performed to test the feasibility of the template. Template items were filled in by the researchers.

Results: Out of 115 patients between 2014 and 2018, the complete data of 33 patients followed up at least 3 months after complete Gensingen brace weaning could be analyzed. The mean age was 12 years, the mean Cobb angle was 33.6°, and the mean Risser value was 0.7 at the beginning of the treatment. The mean improvement in the Cobb angle on in-brace x-ray imaging was –26.1 (80% of in-brace correction). The Cobb angle of the major curvature changed as follows: curve stabilization was achieved in 7 (21.2%) cases, and curve improvement was achieved in 26 (78.8%) cases. None of the patients showed a curve progression. The Cobb angle was significantly reduced in the brace at the end of treatment and at follow-up evaluation ($P<.001$). ATR improved significantly for thoracic ($P<.001$) and lumbar curves ($P<.001$).

Conclusions: The database proved to be informative in the assessment of radiological and clinical outcome parameters. The example data set we have generated can be a helpful tool for professionals who work in clinics but do not store regular patient data. Especially with regard to different patient collectives worldwide, different results may be achieved with the same standards of care. In addition, the results of this study suggest that above-average correction effects with a full-time brace application lead to significant improvements in the Cobb angle after brace treatment has been completed.

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KEYWORDS

scoliosis; brace treatment; feasibility study; outcome; skeletal; spine; back; musculoskeletal; curvature; spinal; database; template; design; brace; orthopedics; injury; rehabilitation; Gensingen brace; conservative brace treatment; Idiopathic Scoliosis; orthopedic; injuries; data science; data management

Introduction

3D spinal deformities, called scoliosis, can have different causes. What most forms of scoliosis have in common is that they tend to progress in curvature during periods of increased growth. In most cases (between 80% and 90%), scoliosis affects otherwise healthy individuals and first appears during the pubertal growth spurt [1-4].

Treatment of adolescent idiopathic scoliosis (AIS) consists of corrective exercise treatments, the application of various braces, and surgical treatment [5]. High-quality studies support the use of physical therapy measures [6-8] and brace application [9-13].

Scoliosis can progress rapidly, especially in adolescence—a period of rapid growth. Therefore, it is very important to apply evidence-based treatment approaches promptly. When patients are meaningfully "observed" rather than braced, a curve progression of 6° within a period of 6 months is between 20% and 40% more likely in growing children and adolescents [1]. Hence, it is crucial that patients with AIS receive conservative management treatments as soon as possible after their diagnosis, especially if they are premenarchal and still have significant growth potential [14].

Despite the existing evidence for treatment with braces, there is a significant variation in the success rates of different brace applications and even within individual brace families. Meanwhile, it is crystallizing that highly corrective asymmetric braces are superior to a more symmetrically compressive thoracolumbosacral orthosis. However, even with asymmetric brace applications, the quality of treatment is highly variable [15]. Therefore, to ensure patient safety, only computer-aided design (CAD) brace series should be used, which are subject to a quality management program and that use standardized adjustment algorithms corresponding to the curvature pattern [15-17].

One of these brace series is the Gensingen Brace (GBW) [18,19], used in our centers and other centers worldwide. Based on our clinical experience, we hypothesize that the progression of curvature in children with AIS treated with GBW can be stopped and that there would be improvements in curvature in a certain proportion of the cohort [19,20].

Although GBW efficacy has been demonstrated in previous studies published in the literature, follow-up studies after completion of treatment are limited [19,20].

The purpose of this study is to test the feasibility of a prospective multicenter study by generating a database, including radiological and clinical outcome parameters. For this purpose, the database has been tested with a retrospective review of medical records of patients from 1 center.

Methods

Ethical Considerations

This retrospective cross-sectional study was conducted in accordance with the tenets of the Declaration of Helsinki. Ethics approval for the study was obtained from the Ethics Committee of Bandırma University (2022/195). The parents of each child were informed of the study procedures, and written consent of the caregivers and participants was obtained which in accordance with the ethics committee's guidelines. The data set did not contain any identifiable information.

Study Design

This paper reports the results of treatment with a GBW for AIS in a retrospective nonrandomized feasibility study.

Recruitment

Patients who were admitted to Nan Xiaofeng's Spinal Orthopedic Workshop and Schroth Health Technology centers between 2014 and 2018 and were treated with a GBW and followed up at least 3 months after complete brace weaning were included in this study.

A template for the database to be tested was created, which contains the basic data of the patients and their Cobb curvature angles and the cosmetically relevant angles of trunk rotation (ATR). A retrospective review of medical records of patients with AIS, who met the Scoliosis Research Society's (SRS's) inclusion criteria for brace studies [20], was performed, and the investigators then filled in the template. These criteria were as follows: female patients with prescribed brace treatment for AIS, aged between 10 and 14 years, with a Cobb angle between 25° and 40° for at least 1 structural curve, during growth with a Risser stage between 0 and 2, premenarcheal or less than 1 year after menarche, and without previous treatment [21].

Patients with nonidiopathic scoliosis; other orthopedic, neuromuscular, or rheumatic diseases; mental or psychiatric problems; iliac crest ossification of Risser stage 3-5, or continuing treatment were excluded.

According to the current guidelines, it is recommended that patients with Risser stage 0-3 and a scoliosis progression risk of more than 60% according to the Lonstein and Carlson [22] formula should start bracing treatment. In this study, risk of progression was calculated and brace treatment was recommended to the patients. For brace treatment to be effective, full-time use was recommended [23].

All children in this study used the GBW (Figures 1-3).

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Figure 1. A 12-year-old minor patient with a single lumbar curve of 32° treated with a short Gensingen brace (GBW) with full in-brace correction (middle picture). Final outcome 12 months after brace weaning with a curvature of 22° with a nicely recompensated clinical appearance (right).

Figure 2. A 12-year-old minor patient with a single thoracic curve of 48° treated with a functional 3-curve balanced with a minor and shorter lumbar countercurve and Gensingen brace (GBW) with full in-brace correction (middle picture). Final outcome 9 months after brace weaning with a curvature of 28° with a nicely recompensated clinical appearance (right).

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Figure 3. A 12-year-old minor patient with a Lenke 6 combined curve of 45° (thoracic) and 40° (lumbar) treated with a functional 4-curve, double curvature and Lenke Gensingen brace (GBW) with good in-brace correction (middle picture). Final outcome 15 months after brace weaning and a curvature of 37° (thoracic) and 32° (lumbar) with a nicely recompensated clinical appearance (right). In particular, a Lenke 6 pattern is not as easy to correct with a brace like other curve patterns.

The GBW is a further developed Chêneau brace derivative with individual design, which can be adapted through CAD. Customization, accuracy, and quality control of scoliosis braces are significantly aided by CAD. By using this technology, braces can be generated specifically for each patient's particular spinal curve pattern, resulting in more effective and comfortable treatment. The individual production steps have already been described in the literature [18]. First, the patient is scanned, and patient data are collected and entered into the database together with the x-ray image. Based on these data, the basic model corresponding to the curvature pattern is first selected from the brace library.

The patient’s scan is cropped and scaled. Then, the selected brace is inserted into the scene and adjusted in accordance with the individual’s body shape. Then, the correction algorithms specified for the particular pattern and curvature strength (Cobb angle) are applied accordingly. The result is a brace model that reflects the respective curvature pattern and the individual entities of the patient [24].

The following brace weaning process was applied. For curves with an initial curve grade of ≤35, the brace wearing time was decreased by wearing the brace for 16 hours per day for 3 months, 12 hours per day for 3 months, and at night for 6 months. For curves above the initial grade of 35, brace treatment was terminated by wearing a brace for 16 hours per day for 12 months, 12 hours per day for 12 months, and 6 months at night.

Database Template

The template for the database contained the following: the patient's age (in years) before starting treatment and the menarcheal status (in months) were recorded. Risser's sign and curvature pattern, according to the Augmented Lehnert-Schroth (ALS) classification, were evaluated on pretreatment x-ray imaging. The Cobb angle and ATR were evaluated as primary outcome measures. The progression factor was calculated with the Cobb angle, patient's age, and Risser's finding. Daily brace-wearing time was recorded by asking parents and patients.

Risser's sign determines bone maturity, growth rate, and progression risk of a patient with scoliosis. It has been reported to be reliable and sensitive in determining bone maturity. Risser grading was assessed on the anteroposterior radiograph. The epiphyseal plate starts becoming visible from the lateral edge of the anterior superior iliac spine, progresses medially, and finally fuses at the posterior superior iliac spine. Degree of completion was indicated as a percentage: grade 1: ≤25%; grade 2: between 26% and 50%; grade 3: between 51% and 75%; and grade 4: between 75% and 100%. When the epiphyseal plate is fully fused to the ilium, it is defined as being grade 5 [25].

Curve classification was performed in accordance with the ALS classification that was developed as an expansion of the Lehnert-Schroth classification and included eight different curvature types: (1) 3CH: functional 3-curve, with hip prominence; (2) 3CTL: functional 3-curve, thoracolumbar, which implies a functional 3-curve with hip prominence and a thoracolumbar apex at thoracic vertebra 12; (3) 3C: functional

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3-curve balanced with a minor and shorter lumbar countercurve; (4) 3CL: functional 3-curve lumbar with a long lumbar countercurve; (5) 4C: functional 4-curve, double curvature; (7) 4CL: functional 4-curve with major lumbar curvature; and (8) 4CTL: functional 4-curve with major thoracolumbar curvature (and an apex at lumbar vertebra 1) [26].

The Cobb method was used to measure the degree of curvature: vertical lines were drawn on the superior and inferior vertebral endplate lines of the neutral vertebrae on the anteroposterior x-ray image of the whole spine [27], and the angle of the 2 vertical lines was recorded. X-ray images were taken at four stages: (1) before treatment (baseline), (2) at 4 to 6 weeks after the brace was fitted (in-brace), (3) at the end of treatment, and (4) at follow-up assessment after brace weaning. All braceless x-ray images were taken at least 24 hours after removal to eliminate the brace effect. All x-ray measurements were taken independently by the same experienced orthopedist. The difference between the Cobb angle at follow-up and that before treatment were calculated. Based on this difference, 3 possible outcomes are distinguished in accordance with the International Society On Scoliosis Orthopaedic and Rehabilitation Treatment's guidelines: curve correction (≤–5° Cobb angle), curve stabilization (>–5° and <5° Cobb angle), and curve progression (≥5° Cobb angle) [23].

The ATR is the most commonly used method for clinical and cosmetic assessment of scoliosis. ATR of 86% repeatability is supposed to be a reliable measurement. A change of 2° in interobserver measurements is considered significant [28]. ATR are measured using a special inclinometer called a scoliometer (according to Bunnel [28]). The patient was asked to bend forward with relaxed arms (Adam's forward bend test). The scoliometer is placed on the back of the patients, and the maximum degree of each curve was recorded [28]. ATR measurements obtained before treatment and at follow-up assessment were analyzed.

The risk for progression of the Cobb angle was calculated using the progression factor formula in accordance with Lonstein and Carlson [22]:

Risk for Cobb angle progression = Cobb angle – (3 × Risser stage) / chronological age (in years) (1)

The International Society On Scoliosis Orthopaedic and Rehabilitation Treatment's guidelines and the validated Schroth Best Practice Academy Guidelines suggest using this formula to decide treatment indications and avoid over- and undertreatment [29,30].

According to this formula, observation is recommended for cases with a risk factor of 1.4 and below (<40% incidence of progression), physiotherapy is recommended for cases with a risk factor of 1.4-1.6 (between 40% and 60% incidence of progression), and brace treatment is recommended for cases with a risk factor of 1.6 and above (>60% incidence of progression) [31].

Statistical Analysis

Data analysis was performed using SPSS (version 16; IBM Corp). The Shapiro-Wilk test was used to test the normality of each variable. *P* values less than .05 were considered statistically significant for a 2-tailed test. Mean (SD) values and minimum and maximum values were determined using descriptive statistics.

Repeated-measures ANOVA was used to compare Cobb angle values at baseline, in-brace, end of treatment, and follow-up, and a paired samples *t* test was used to compare ATR values at baseline and follow-up.

Results

Out of 115 patients from 2014 to 2018, complete data of 33 patients who could be followed up at least 3 months after complete brace weaning have been analyzed. The mean age was 12 years, the mean Cobb angle was 33.6°, and the mean Risser value was 0.7 at the beginning of the treatment (Table 1). Based on the ALS classification, most cases (45.5%) had a 3C scoliosis pattern (major thoracic curve). A total of 18 of the patients were premenarcheal, and menarche had started in 15 patients (mean 5.7 months).

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Table 1. Baseline demographic and clinical characteristics of patients.

Variables	Value
Age (years), mean (SD; range)	12 (1.06; 10-14)
Risser value, mean (SD; range)	0.7 (0.8; 0-2)
Main Cobb angle (°),mean (SD; range)	33.6 (8.1; 22-50)
Angle of trunk rotation (°; thoracic), mean (SD; range)	9.4 (5.1; 2-21)
Angle of trunk rotation (°; lumbar), mean (SD; range)	5.5 (4.05; 0-15)
Main curve location, n (%)	
Thoracic	26 (78.8)
Lumbar	7 (21.2)
Augmented Lehnert-Schroth curve classification, n (%)	
3CH[a]	5 (15.2)
3CL[b]	15 (45.5)
3CN[c]	5 (15.2)
4C[d]	6 (18.2)
4CTL[e]	2 (6.1)

[a]3CH: functional 3-curve, with hip prominence.
[b]3CL: functional 3-curve lumbar with a long lumbar countercurve.
[c]3CN: functional 3-curve, compensated.
[d]4C: functional 4-curve, double curvature.
[e]4CTL: functional 4-curve with major thoracolumbar curvature.

The mean treatment period with the brace was 33.6 (SD 10.1, range 15-51) months, and the mean follow-up duration was 12 (SD 6.1, range 3-35) months. Daily brace wearing time in the first year of the brace treatment was 21.3 (SD 1.2, range 16-22) hours. All patients reported wearing the brace for at least 20 hours each day, with the exception of 1 who only wore it for 16 hours.

The mean improvement in Cobb angle on x-ray imaging performed in the brace was –26.1° (SD 6.8°, range –43° to –12°; Figure 4), which implies a correction effect in the brace of 80%. The difference in Cobb angle at baseline and follow-up was –11.7° (SD 6.8°, range –24° to 0°; a 35% improvement from the initial value). The change in ATR at baseline and follow-up was –4.5° (SD 4.5°, range –13° to –6°; a 49% improvement from the initial value), and the change in lumbar ATR was –3.2° (SD 4.2°, range –12° to –7°; a 62% improvement from the initial value). Changes in the Cobb angle and thoracic and lumbar ATR values at the end of treatment were significant (Table 2).

Figure 4. Changes in the main Cobb angle over time.

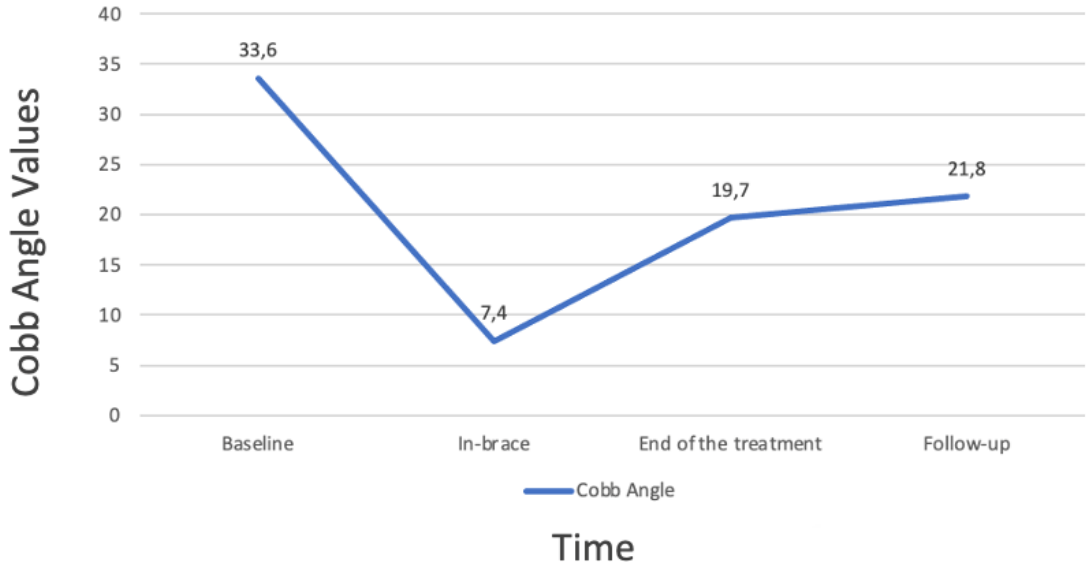

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Table 2. Changes in the Cobb angle and angles of trunk rotation (ATR).

Outcome measurements	Value, mean (SD; range)	*P* value
Main Cobb angle (°)		
Baseline	33.6 (8.1; 22 to 50)	<.001[a]
In-brace	7.4 (7.9; –11 to 25)	<.001[b]
End of treatment	19.7 (9.3; 2 to 42)	<.001[b]
Follow-up	21.8 (9.2; 3 to 42)	<.001[b]
Thoracic ATR (°)		<.001
Baseline	9.4 (5.1; 2 to 21)	
Follow-up	4.4 (2.6; –2 to 12)	
Lumbar ATR (°)		<.001
Baseline	5.5 (4.05; 0 to 15)	
Follow-up	2.3 (2.3; –3 to 8)	

[a]Repeated-measures ANOVA.

[b]Paired samples *t* test.

The mean progression risk factor was 2.6 (SD 0.7, range 1.43-4.55), which, in the case of untreated scoliosis, would correspond to a probability of progression of far more than 95% reported by Lonstein and Carlson [22]. According to the SRS's criteria, curve stabilization was achieved in 7 (21.2%) cases, and curve improvement was achieved in 26 (78.8%) cases. None of the patients had a curve progression in this sample with a probability of progression of far more than 95% reported by Lonstein and Carlson [22].

The improvement in the Cobb angle achieved in the brace was negatively moderately correlated with the pretreatment Cobb angle (P=.008, r=–0.452). There was a positive moderate correlation between the amount of change in Cobb angle obtained at the end of treatment and the amount of improvement obtained in the brace (P<.001, r=0.593).

Discussion

Principal Findings

Our study shows that the template generated can be used for future prospective multicenter studies. On analyzing the data we saved in the template, the results showed that the GBW, which provides a 3D correction, is effective in stopping curvature progression and reducing the angle of curvature in adolescents with idiopathic scoliosis who continue to experience vertebral growth and are at high risk of progression.

Brace treatment and scoliosis-specific exercise methods are the most widely used, accepted, and effective treatment methods for patients with AIS [6-11,31,32]. Extensive evidence in the literature shows the effectiveness of brace treatment [15,33,34]. Previous studies have reported that brace treatment stops progression, corrects moderate curves, and reduces the rate of surgical indication [33-35]. Our results show that besides stopping curvature progression with high-correction full-time bracing also potentially improves the Cobb angle and ATR.

After the onset of the initial deformity, it is generally accepted that AIS progresses with asymmetric vertebral growth that occurs during the growth spurt. Adolescence is one of the periods of rapid growth. It has been reported that children with a high risk for progression during the rapid growth period experience progression in their curvature when left untreated [31].

In this study, the risk of progression was >95%, according to the formula developed by Lonstein and Carlson [22]. However, when growth was complete and in subsequent evaluations, it was found that there was no progression at all. The Cobb angle did not increase by ≥5° in any patient.

The patient population included in this study does not differ significantly from the cohorts of previously published studies in terms of age, maturity, menarcheal status, Cobb angle, and curvature pattern distribution [18,19].

Weiss et al [19] assessed 28 patients with AIS with a mean age of 12.7 years and Cobb angle of 30.5° using the GBW. However, they carried out their final evaluation an average of 24 months after brace treatment was initiated. They reported that the in-brace correction in their sample was from 33.9° to 15.9°, indicating an average correction of 52.7%.

In another study, Weiss et al [18] observed 167 patients with AIS who were treated with a GBW over a period of at least 18 months. The authors reported a 47%-52% rate of correction of the Cobb angle of the main curve in the brace [18]. When we calculated the success rate in accordance with the Cobb angle obtained in the brace, the treatment success rate was 80% in our cases.

In previous studies [18,19], the success rate at the end of treatment was between 86% and 92% in different subcohorts, but in our study, progression in curvature was stopped and no longer observed in all children. Therefore, GBW's success may be considered as 100% in this study. Since the brace design worldwide follows standardized CAD algorithms and the

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material (high-density polyethylene) does not differ from that used in other studies, the specifics of the studied collective might play a role. The cohort studied is from mainland China, and it is possible that the patients included in this study take brace treatment more seriously than may be the case in other countries. Another factor may be that brace treatment in China has to be financed by the patients or their parents themselves, which may also improve their motivation to wear the brace.

The main curvature Cobb angle at first diagnosis was >40° in 8 children included in this study. Considering that the Risser grade is low and the growth potential of these children is high, it is predicted that the curvatures will most likely progress. However, children with a curvature of >40° completed their treatment with an average of 16.7° (range 2°-34°). Based on these results, the use of GBWs significantly reduces the need for surgical treatment in children with AIS.

In this study, a template prepared by the investigators was filled with the help of a retrospective review of medical records. Our study shows that it would be appropriate to use this template in future prospective studies and the data intended to be recorded in this template can indicate treatment effectiveness for brace treatment. An international multicenter study considering the SRS's inclusion criteria for brace treatment studies seems feasible.

Our study supports the conclusions of other studies regarding the corrective effect of the brace [36,37] and confirms previous findings in this field, which show that above-average corrective effects with full-time brace application lead to significant improvements in the Cobb angle after completion of brace treatment [38,39].

Evaluation of the treatment outcomes with the Cobb angle, which is still accepted as the gold standard today, the establishment of the study sample group considering the SRS's brace study criteria, and continuation of the follow-up of the children after the end of treatment can be considered as the strengths of the study.

Limitations

The study's limitations include our inability to determine the changes specific to different curve patterns, the fact that the effectiveness of the brace was not evaluated at different daily wearing times, and the fact that daily brace wearing time was recorded in accordance with the participants' families statement. We suggest investigating the effectiveness of brace treatment in different curvature patterns and different wearing times with larger sample groups in future studies.

Conclusions

The results of this study suggest that above-average correction effects with full-time brace application lead to significant improvements of the Cobb angle upon completion of brace treatment. The example data set we have generated can be a helpful tool for professionals who work in clinics but do not store regular patient data. Furthermore, prospective multicentral studies with large samples can be conducted by collecting the same data at different centers.

Data Availability

The data that support the findings of this study are available upon request from the authors.

Authors' Contributions

XN, HX, and LZ conceptualized the study. XN, TKC, and BA designed the study. TKC, BA, and MB supervised the study. XN, HX, LZ, and MB collected the data. TKC and BA carried out the analysis. HX, LZ, and MB conducted the literature review. XN, TKC, BA, HX, LZ, and MB drafted the manuscript. XN, TKC, and BA critically reviewed the manuscript. The manuscript has been read and approved by all named authors.

Conflicts of Interest

None declared.

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Abbreviations

3C: functional 3-curve balanced with a minor and shorter lumbar countercurve
3CH: functional 3-curve, with hip prominence
3CL: functional 3-curve lumbar with a long lumbar countercurve
3CTL: functional 3-curve, thoracolumbar
4C: functional 4-curve, double curvature
4CL: functional 4-curve with major lumbar curvature
4CTL: functional 4-curve with major thoracolumbar curvature
AIS: adolescent idiopathic scoliosis
ALS: Augmented Lehnert-Schroth
ATR: angles of trunk rotation
CAD: computer-aided design
GBW: Gensingen Brace
SRS: Scoliosis Research Society

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Original Paper

Quality of Life in Children With Achondroplasia Undergoing Paired Limb Lengthening With an External Fixator and Modified Distraction Control: Observational Nonrandomized Study

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Abstract

Background: Transosseous distraction osteosynthesis is prioritized in orthopedic care for children with achondroplasia. However, difficulties encountered during treatment and rehabilitation directly impact patients' quality of life. Using rod external fixators within a semicircular frame for osteosynthesis is less traumatic compared to spoke circular devices. Their straightforward assembly and mounting on the limb segment can help significantly reduce treatment duration, thereby improving children's quality of life during treatment and rehabilitation.

Objective: This study aimed to conduct a comparative analysis of the quality of life (measured by postoperative pain syndrome, physical activity, and emotional state) among children with achondroplasia undergoing paired limb lengthening using either an external fixator with modified distraction control or a circular multiaxial system developed by the authors.

Methods: This was an observational, prospective, nonrandomized, and longitudinal study with historical control. The study group consisted of 14 patients ranging from 5 to 15 (mean 7.6, SD 2.3) years old with a genetically confirmed diagnosis of achondroplasia. All patients underwent paired limb lengthening with a rod external fixator and a modified distraction control developed by the authors. A total of 28 limb segments, among them 4 (14%) humeri, 8 (29%) femurs, and 16 (57%) tibias, were lengthened in 1 round. Unpublished data from the previous study served as the control group, comprising 9 patients (18 limb segments) of the same age group (mean age at surgery 8.6, SD 2.3 years), who underwent limb lengthening surgery using a circular multiaxial system—2 (11%) humeri, 6 (33%) femurs, and 10 (56%) tibias. The Wong-Baker Faces Rating Scale was used to measure pain symptoms, while the Russified Pediatric Quality of Life (PedsQL) v4.0 questionnaire assessed quality of life.

Results: During the latent phase (7 to 10 days after surgery), a more pronounced decrease in the indicators of physical activity and emotional state on the PedsQL v4.0 questionnaire was noted in the control group (mean 52.4, SD 4.8 versus mean 52.8, SD 5.5 points according to children's responses and their parents' responses, respectively) compared to the experimental group (mean 59.5, SD 6.8 points and mean 61.33, SD 6.5 points according to the children's responses and their parents' responses, respectively). The differences between the groups were statistically significant ($P<.05$ for children's responses and $P<.01$ for parents' responses). Importantly, 6 months after surgery, these quality-of-life indicators, as reported by children in the experimental group, averaged 70.25 (SS 4.8) points. Similarly, their parents reported a mean of 70.54 (SD 4.2) points. In the control group, the corresponding values were 69.64 (SD 5.6) and 69.35 (SD 6.2), respectively. There was no statistically significant difference between the groups.

Conclusions: The external fixator with modified distraction control developed by the authors provides a higher standard of living compared with the circular multiaxial system during the latency phase.

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KEYWORDS

achondroplasia; external fixator; quality of life; transosseous osteosynthesis; paired limb lengthening; bone growth disorder; dwarfism; limb lengthening; circular multiaxial system; hereditary disease; limb reconstruction; children; youth; pediatric; bone disorder; orthopedics; rehabilitation; bone; growth; disorder; genetic

Introduction

Achondroplasia is a hereditary disease characterized by a deceleration in bone and cartilage growth. The term "achondroplasia" was first used in 1878 by Jules Parrott, and in 1900, the neurologist Pierre Marie first described the main features of the disease in children and adults. According to the International Classification of Diseases (ICD-10), this pathology is classified in chapter XVII "Congenital malformations, deformations, and chromosomal abnormalities" (Q00-Q99), specifically in the section "Congenital malformations and deformations of the musculoskeletal system." More specifically, it falls under code Q77, which encompasses osteochondrodysplasia with defects of growth of tubular bones and spine. Within this category, Q77.4 is specifically designated for achondroplasia. This congenital skeletal disorder in children belongs to the group of systemic dysplasias [1] and is associated with a defect in the zone of cartilage proliferation [2].

At birth, children in this nosological group display a proximal shortening of the upper and lower extremities, a relatively short and narrow trunk, trident-shaped hands, and macrocephaly with hypoplasia of the middle third of the face and a protruding forehead. Growth parameters at birth are usually slightly less than normal, but with age, there is a progressive lag from the normal values (total shortening of the limbs is especially pronounced in the upper arms and thighs). Infants with achondroplasia are most characterized by decreased muscle tone, causing them to learn movement and walking skills later in life. Intellect and cognitive abilities are not affected by this malformation [3,4]. A review of the specialized literature showed that the incidence of achondroplasia varies widely from 1:15,000 to 1:30,000 newborns, regardless of gender or race [5]. The main cause of achondroplasia is a de novo mutation in fibroblast growth factor receptor-3 (FGFR3), which leads to a disruption of the endochondral ossification mechanism [6].

Despite a wide array of pathological symptoms, disproportional dwarfism remains central in defining the stereotypes and lifestyle of patients living with this condition. It is characterized by significant limb shortening and deformity. The combination of external and radiological manifestations in the musculoskeletal system, which are exacerbated in the process of growth, strongly influences the way these patients perceive themselves and lead their lives. This issue is particularly marked in childhood, where more attention is paid to a person's appearance [7,8].

Currently, transosseous distraction osteosynthesis is prioritized in orthopedic care [9,10]. This method is based on the general biological property of tissues to respond by regeneration to dosed stretching [11]. The conventional approach for uniform tubular bone lengthening typically involves 1 mm per day in 0.25 mm fractions across 4 sessions [12]. However, the period of osteosynthesis in this mode varies from 4 to 18 months, which correlates with the planned magnitude of lengthening [13,14]. Challenges encountered during treatment and rehabilitation significantly impact patients' quality of life [15]. Traditionally, the Ilizarov circular system has been utilized for limb lengthening in patients in this nosological group [9]. The features of this equipment, as well as the fundamental studies on reparative tissue regeneration processes and the proposed surgical intervention options, remain highly relevant to this day. [16]. However, the complexity of the design, its excessively bulky nature, and its many parts can lead to long assembly times and require an increased time under anesthesia. In turn, these factors contribute to challenges during rehabilitation, limiting the use of this type of external fixator in pediatric practice [17]. Nevertheless, external fixators are the most common in the treatment of patients with achondroplasia in many countries [18-20]. According to the available literature, osteosynthesis with rod external fixators based on a semicircular frame is less traumatic compared to spoke circular devices. Moreover, rod fixators lead to less disruption of venous and lymphatic outflow in the postoperative period [20]. Rod fixators are more compact in appearance and provide sufficient rigidity to aid in bone fragment stabilization. Their straightforward assembly and mounting on the limb segment can help significantly reduce surgery duration, which is important in paired limb lengthening [21]. The authors developed a bar external fixation device with a distraction control system that showed better results than the circular multiaxial system regarding fixation time, regenerative length, deformation angles, pain intensity indexes, and complication rates [11]. This study aims to compare the quality of life (focusing on postoperative pain syndrome, physical activity, and emotional state) of children with achondroplasia undergoing paired limb lengthening using 2 different methods: an external fixator with modified distraction control and a circular multiaxial system developed by the authors.

Methods

Study Design

This was an observational, prospective, nonrandomized, and longitudinal study with a historical control. The experimental group included 14 patients, including 8 (57%) males and 6 (43%) females, aged between 5 and 15 (mean 7.6, SD 2.3) years. All patients had a genetically confirmed diagnosis of achondroplasia and received treatment at the state municipal enterprise "Multiprofile City Children's Hospital No 2" in Astana, Kazakhstan, spanning from August 2018 to January 2020. All patients underwent paired limb lengthening using a rod external fixator with modified distraction control developed by the authors. A total of 28 limb segments, including 4 (14%) humeri, 8 (29%) femurs, and 16 (57%) tibias, were lengthened in 1 round. All operations were performed by the same team of surgeons. The patients were dynamically followed up for 18 months.

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Unpublished data from the previous study were used as the control group, which comprised 9 patients, including 3 (33%) males and 6 (67%) females, matching the same age group (mean age during surgery 8.6, SD 2.3 years). Patients in the control group also had a genetically confirmed diagnosis of achondroplasia and underwent limb lengthening surgery using a circular multiaxial system between January 2012 and July 2018. A total of 18 segments of tubular bone were lengthened in the control group—comprising 2 (11%) humeri, 6 (33%) femurs, and 10 (56%) tibias. All operations were performed by the same team of surgeons as in the experimental group. This study did not involve a clinical trial.

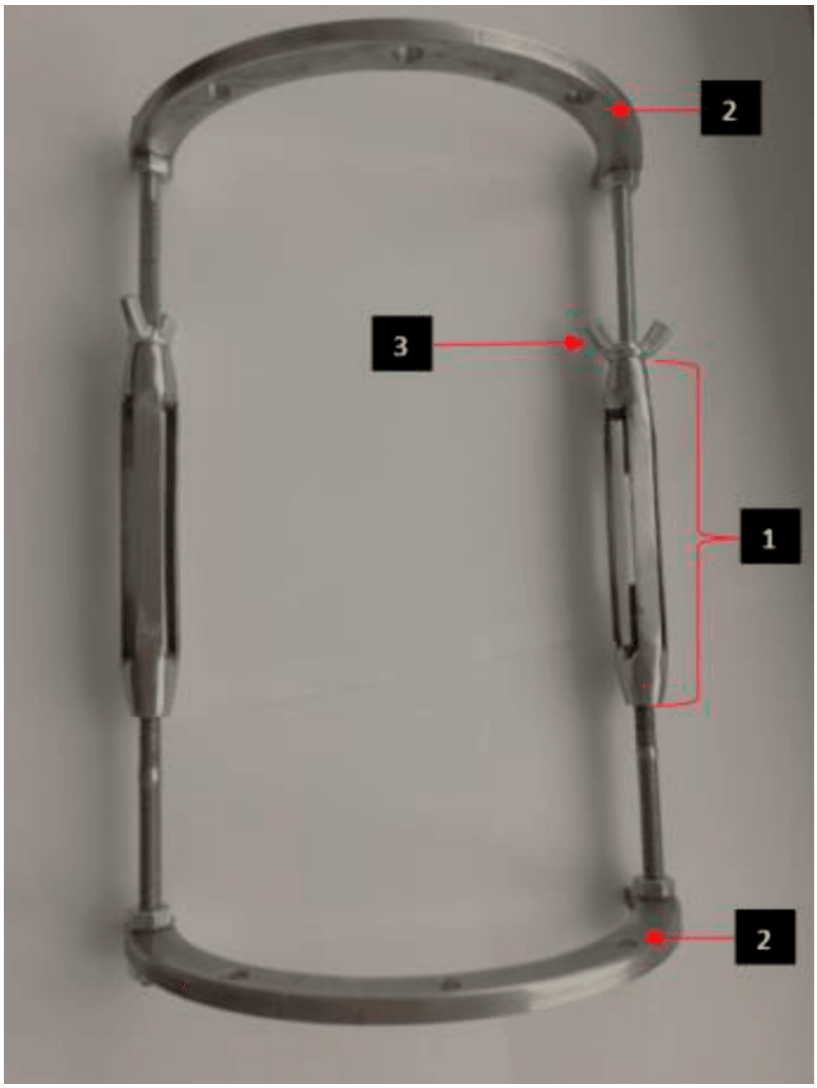
Clinical Examination

Patients underwent preliminary clinical and radiological assessments. The clinical evaluation included orthopedic and neurological status: assessment of ligamentous elasticity and mobility of the knee joint, presence of torsional deformities of the lower extremities, child growth, and proportionality of the skeletal structure. The radial diagnostic protocol included radiographs of both lower extremities in straight projection over the entire length in a bipedal standing position with the correct orientation of the patellas (facing forward). Angular changes in the extremities were analyzed based on the radiographs obtained. The patients were examined by various specialists, including a pediatrician, endocrinologist, neurologist, cardiologist, and otolaryngologist, during the preoperative phase to identify any concomitant pathologies and mitigate intra- and postoperative complications.

Operative Technique

Surgical treatment was performed under general endotracheal anesthesia. During the surgical procedure, a semicircular external rod fixator design with a distraction mechanism of the authors' modification was used (Figure 1). The operations were performed simultaneously on 2 identical segments, according to the tibia-tibia and femur-femur schema. To minimize the traumatic nature of the surgical intervention, a closed corticotomy of the middle third of the diaphysis was performed.

Figure 1. A semicircular external rod fixator design with the authors' modified distraction mechanism. (1) Mechanism of the fixator in the form of a 2-section sliding structure. External rod section with internal thread and 2 rods with an external millimeter thread. (2) Supporting bases on which the distraction system is fixed when installing an external fixation device on a limb segment. The 1-mm distraction step is performed by axial rotation according to the marks. (3) Nut stabilizing internally threaded rods on the proximal threaded rod.



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Postoperative Rehabilitation

Postoperative rehabilitation for patients with achondroplasia comprised 3 steps: a latency phase, a period of distraction and consolidation, and a period of functional adaptation of patients after device removal. The latency phase lasted 7 to 10 days, depending on the duration of postoperative edema recession and pain intensity. Lengthening was initiated at the end of the latent phase on the 7th to 10th day after surgery, with an average daily distraction rate of 0.75 mm. Restorative treatment was initiated on the second day after surgical intervention with constant parental involvement.

The amount of exercise depended on pain levels, distal limb swelling, and the patient's psychological state. To prevent contractures of adjacent joints, the focus was on passive-active exercises ranging from 5 to 10 minutes, up to 3 times a day. Under medical supervision, patients were gradually mobilized to stand upright using walkers for up to 5 minutes and were taught to walk within the room. During distraction, the time of passive and active joint development sessions increased to 40 minutes, occurring 5 to 6 times a day, while the walking duration extended to 15 minutes.

The hospital stay for patients typically ranged from 10 to 14 days, adhering to the Republic of Kazakhstan's Standard of Medical Care in Hospital Conditions. The hospital stay was determined based on the duration of the latency phase (period of postoperative edema recession and reduction of pain intensity). Subsequently, patients were discharged to outpatient treatment. Distraction and consolidation timing were assessed using radiographs. Control examinations with radiographs were performed every 10 days. During the examination, external fixator stability, joint function, and the presence of neurological and vascular disorders were evaluated. Based on the radiological appearance of the regenerate and assessment of joint mobility, the distraction rate was corrected (either decreased to 0.75 mm/day or increased to 2 mm/day). During the stabilization period, when performing joint development, an emphasis was placed on increasing muscle strength. Moreover, physical therapy classes remained intense, and the patients were taught to walk without additional support.

After reaching the possible segment length, the distraction process for the regenerate was halted, and the patients were examined monthly during the consolidation phase. After removing the fixators, a period of functional adaptation began that lasted up to 18 months after surgery. A key principle during this stage involved a gradual and appropriate increase in load. The treatment approach involved massaging the muscles of the thigh, lower leg, and humerus, coupled with physical therapy and thermal procedures. Furthermore, passive mobilization of all ranges of motion in the hip and knee joints was undertaken, with an emphasis on enhancing knee joint flexion. Patients were recommended to swim and exercise using simulators. Additionally, sanatorium-resort treatment was geared toward recovering all body systems following inpatient surgical treatment. Patients and parents were trained in the proper care of the medical device and rods and were instructed to adhere to the prescribed limb lengthening (distraction) schedule.

Quality of Life Assessment

Postoperative pain is a complex response to tissue trauma during surgery. A pronounced postoperative pain syndrome increases the likelihood of postoperative complications, prolongs the patient's recovery period and subsequent rehabilitation, reduces physical activity, and worsens the patient's psychoemotional state. Postoperative pain intensity is determined not only by the extent of damage but also by psychological factors (accompanying emotional state and anxiety). In this regard, postoperative pain syndrome, physical activity, and patients' emotional states were considered when assessing quality of life.

The Wong-Baker Faces Rating Scale was used to assess the pain syndrome [22]. When working with this rating scale, a child had to choose 1 of the 6 faces drawn that corresponded to how they felt. The first face represented 0 points and indicated "no pain," while the sixth face represented 5 points and indicated "severe pain." Pain was assessed in the latency and distraction phases.

To assess the quality of life, a questionnaire was administered using the Russified Pediatric Quality of Life (PedsQL) v4.0 questionnaire [23]. This questionnaire has 23 five-point scales reflecting the patients' current state: level of physical activity, emotional state, satisfaction with social role (satisfaction with communication with peers), and engagement in kindergarten/school. During this study, it was not feasible to correctly assess outcomes related to social role satisfaction and kindergarten/school attendance using the scales while the patients were still in the hospital. Therefore, quality of life was assessed only on the scales of level of physical activity and emotional state. The questionnaire consists of 2 parts: an assessment of a child's quality of life (from age 5 years) and an assessment of a child's quality of life by their legal representative. The children and their parents were instructed to select a number that reflected the frequency of difficult situations over a certain period, where 0 was never, 1 was almost never, 2 was sometimes, 3 was often, and 4 was almost always. The number of points was calculated by the questionnaire key. First, the results were reversed and converted to a linear 100-point scale, where 0 was 100, 1 was 75, 2 was 50, 3 was 25, and 4 was 0. Next, the survey results were tallied. The results of each item in the block were added up, and the resulting sum was divided by the number of items in the block. A score higher than 75 was considered optimal. In the third stage, the authors calculated the total score for each item and divided the result by the number of items. The questionnaire was administered in the preoperative, latency, distraction, and consolidation phase, as well as during dynamic follow-up (6, 12, and 18 months after surgery). The questionnaires were processed blindly.

Statistical Analysis

The *t* test for the independent samples was used to assess the reliability of the differences between the experimental and control groups. The Student *t* test for dependent samples was also used to assess the reliability of differences within the groups at different stages of the study [24]. At $P<.05$, the null hypothesis of no relation between the parameters was rejected. Statistical calculations were performed using the SPSS software (IBM Corp).

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Ethical Considerations

The research was conducted in accordance with the Standard of Good Clinical Practices (GCP) to the Order of the Minister of Health and Social Protection of Kazakhstan (May 27, 2015; no 392) and the ethical standards of the Declaration of Helsinki, amended in 2013. Parents were informed in advance about the purpose of the planned surgery. Parents or legal guardians signed informed consent for the surgical intervention, rehabilitation treatment, and publication of the findings without identifying themselves. The study was reviewed and approved by the Human Research Ethical Committee of Astana Medical University (reference number 333).

Results

In 9 (64%) patients in the experimental group, the lengthening results were evaluated as ”excellent.” This means that the planned elongation value had been reached, the deformation of the bone regenerate did not exceed 2 degrees, joint function was excellent (absence of contractures), and consolidation was successful based on radiographs. In 4 (29%) of patients, the lengthening results were evaluated as “good,” indicating the planned elongation value had been attained, with slight deformation of the bone regenerate (not exceeding 4 degrees), the presence of easily treatable contractures, and successful consolidation confirmed by radiographs. In 1 (7%) of cases, the results were classified as “satisfactory.” In these cases, the planned elongation was not fully achieved, there was some deformation of the bone regenerate (not exceeding 8 degrees), and there was a presence of contractures, but consolidation was successful according to radiographs.

Most patients achieved a lengthening value close to the planned value and correction of deformity, with minimal deviation that was not statistically significant. The average lengthening values were 8.5 (SD 0.6) cm, with the humerus length increasing by an average of 53% (SD 5%), the tibia by 52% (SD 8.2%), and the femur by 30% (SD 6%). The fixation period, including the distraction phase, averaged 83.8 (SD 3.7) days, with a specific average duration of 76 (SD 1) days for the humerus, 83.9 (SD 3.2) days for the tibia, and 87.5 (SD 2.5) days for the femur.

No contractures were observed during the latency phase or after the end of the distraction phase. However, during the distraction stage, 1 (7%) patient experienced knee joint contractures during hip lengthening, and 2 (14%) patients had ankle joint contractures due to heel tendon shortening, which resulted from failure to follow the treatment regime and joint development recommendations. The most common complaint reported by patients and their parents was minor inflammation of the soft tissues around the rods, which was resolved with conservative treatment. No cases necessitating rod removal or a second operation were noted. In the control group, the fixation time in the device averaged 101.4 (SD 5.4) days and the length of the regenerate averaged 6.6 (SD 0.8) cm. In 4 (29%) cases, knee joint contracture persisted, and 1 (7%) case of needle fracture was recorded.

Regarding pain, on the second day after the operation, the pain index in 13 (93%) patients in the experimental group was rated at 3 points on the Wong-Baker scale and at 4 points for 1 (7%) patient. However, by the end of the latency phase, the pain index in all patients was 0. In the control group, the Wong-Baker pain score was 4.1 (SD 1.02) on the second day and decreased to 1.7 (SD 0.8) at the end of the latency phase.

Before the surgery, quality of life scores on the PedsQL v4.0 questionnaire (measuring physical activity and emotional state) in the experimental group averaged 78.67 (SD 5) in the children's responses and 78.25 (SD 5.1) in their parents' responses. In the control group, these scores were 78.8 (SD 4.4) for the children and 78.0 (SD 5.4) for their parents. Thus, there were no differences in quality-of-life scores between the 2 groups before surgery.

As expected, during the latency phase following surgery, there was a significant decrease in physical activity and emotional state scores on the PedsQL v4.0 questionnaire in both groups when compared to the preoperative period. However, this decrease was more pronounced in the control group, with scores averaging 52.4 (SD 4.8) points by the children and 52.8 (SD 5.5) points by their parents. In contrast, in the experimental group, these quality-of-life scores decreased to 59.5 (SD 6.8) points according to the children's responses and 61.33 (SD 6.5) points according to their parents. These differences between the groups were statistically significant ($P<.05$ for the children's answers and $P<.01$ for their parents). At the same time, the experimental group showed a statistically more pronounced decline in the quality of life when the humerus was lengthened compared to the tibia and femur ($P<.01$). However, in the control group, such differences in quality-of-life changes between the lengthened segments were not observed.

By 6 months after surgery, there were improvements in physical activity and emotional state scores in both groups. These quality-of-life indicators on the PedsQL v4.0 questionnaire in the experimental group averaged 70.25 (SD 4.8) points according to the children's responses and 70.54 (SD 4.2) points according to their parents. In the control group, the corresponding scores were 69.64 (SD 5.6) points and 69.35 (SD 6.2) points, respectively. There was no statistically significant difference between the groups. There was also no difference between the lengthening segments in either group.

At 18 months after surgery, quality-of-life indicators (physical activity and emotional state scores) in both groups exceeded preoperative scores. In the experimental group, the average score was 84.3 (SD 2.5) group for the children and 85 (SD 2.5) points for their parents. These increases were statistically significant ($P<.01$). In the control group, the average score was 81.33 (SD 3.5) points for the children and 82.0 (SD 3.6) points for their parents, but the differences from preoperative scores were statistically unreliable. Furthermore, differences in quality-of-life scores between the experimental and control groups 18 months after surgery were statistically unreliable. The results of the PedsQL v4.0 quality of life questionnaire, completed by the patients and their parents in both groups, are shown in Tables 1 and 2.

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Table 1. Results of transosseous osteosynthesis using the advanced rod monolateral external fixator and PedsQL[a] v4.0 questionnaire scores completed by patients and their parents in the experimental group (N=14).

Gender	Age (years)	Segment	Consolidation period (days)	Planned lengthening (cm)	Lengthening results (cm)	PedSQL[a] v4.0 questionnaire scores			
						Preoperatively	Latency phase (7-10 days after surgery)	6 months after surgery	18 months after surgery
Male	5	Tibia	82	10	Right: 8.3 Left: 8.5	Child: 72 Parent: 70	Child: 65 Parent: 68	Child: 68 Parent: 68	Child: 86 Parent: 86
Male	7	Tibia	85	10	Right: 8.9 Left: 8.4	Child: 78.3 Parent: 75	Child: 67 Parent: 66	Child: 66 Parent: 68	Child: 80 Parent: 83
Male	5	Tibia	85	10	Right: 7.9 Left: 8.2	Child: 80 Parent: 80	Child: 55 Parent: 55.3	Child: 66 Parent: 68	Child: 83 Parent: 86
Female	5	Tibia	79	10	Right: 8.3 Left: 8.3	Child: 78 Parent: 77	Child: 58 Parent: 57.3	Child: 66 Parent: 65.3	Child: 79.1 Parent: 80
Male	6	Tibia	80	10	Right: 10 Left: 10.2	Child: 87 Parent: 78.3	Child: 60 Parent: 62	Child: 68.3 Parent: 66	Child: 88.3 Parent: 86
Male	5	Tibia	88	10	Right: 9.1 Left: 8.9	Child: 75 Parent: 75	Child: 57 Parent: 57	Child: 66 Parent: 68.3	Child: 86 Parent: 85
Male	6	Tibia	87	10	Right: 10.3 Left: 9.9	Child: 77 Parent: 76	Child: 62 Parent: 65	Child: 65 Parent: 65	Child: 80 Parent: 78.3
Female	8	Tibia	85	10	Right: 8.2 Left: 8.5	Child: 80 Parent: 80	Child: 63 Parent: 64	Child: 72 Parent: 70	Child: 86 Parent: 85
Female	8	Femur	85	8.5	Right: 8.3 Left: 8.3	Child: 83 Parent: 84	Child: 60 Parent: 65	Child: 75 Parent: 75	Child: 86 Parent: 88.3
Female	12	Femur	90	8.5	Right: 7.2 Left: 7.2	Child: 82 Parent: 83	Child: 70 Parent: 72	Child: 78.3 Parent: 77	Child: 84 Parent: 84
Male	9	Femur	90	8.5	Right: 9 Left: 9	Child: 70 Parent: 71	Child: 52.3 Parent: 55	Child: 72 Parent: 70	Child: 78.3 Parent: 80
Male	6	Femur	85	8	Right: 8 Left: 8.2	Child: 80 Parent: 82	Child: 52 Parent: 56	Child: 80 Parent: 77	Child: 86 Parent: 88
Female	15	Humerus	75	9	Right: 7.5 Left: 7.8	Child: 85.3 Parent: 86	Child: 45 Parent: 50	Child: 75 Parent: 78.3	Child: 88.3 Parent: 87
Female	10	Humerus	77	8	Right: 8.1 Left: 8.2	Child: 80 Parent: 78.3	Child: 55.3 Parent: 56	Child: 72 Parent: 72	Child: 86 Parent: 86

[a]PedSQL: Pediatric Quality of Life.

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Table 2. Results of transosseous osteosynthesis using the circular multiaxis system and PedsQL[a] v4.0 questionnaire scores completed by patients and their parents in the control group (N=9).

Gender	Age (years)	Segment	Consolidation period (days)	Lengthening results (cm)	PedsQL[a] v4.0 questionnaire scores			
					Preoperatively	Latency phase (7-10 days after surgery)	6 months after surgery	18 months after surgery
Female	7	Humerus	90	Right: 7 Left: 7	Child: 75 Parent: 74	Child: 52 Parent: 48	Child: 62 Parent: 57	Child: 86 Parent: 82
Female	6	Tibia	92	Right: 8 Left: 8	Child: 80 Parent: 75	Child: 57 Parent: 56	Child: 62 Parent: 66	Child: 82 Parent: 84
Female	7	Femur	105	Right: 8 Left: 8	Child: 80 Parent: 78	Child: 52 Parent: 56	Child: 66 Parent: 67	Child: 86 Parent: 86
Female	9	Femur	107	Right: 8 Left: 8	Child: 75 Parent: 73	Child: 58 Parent: 59	Child: 68 Parent: 66	Child: 80 Parent: 82
Male	8	Femur	102	Right: 6 Left: 6	Child: 88.3 Parent: 86	Child: 62 Parent: 60	Child: 67 Parent: 65	Child: 87 Parent: 88
Male	9	Tibia	95	Right: 6 Left: 6	Child: 83 Parent: 83	Child: 47 Parent: 52	Child: 68 Parent: 67	Child: 82 Parent: 83
Female	13	Femur	105	Right: 7 Left: 7	Child: 76 Parent: 76	Child: 56 Parent: 58	Child: 63 Parent: 65	Child: 78 Parent: 80
Female	14	Tibia	103	Right: 7 Left: 7	Child: 78.3 Parent: 78	Child: 46 Parent: 42	Child: 68 Parent: 66	Child: 80 Parent: 82
Female	14	Tibia	110	Right: 5 Left: 6	Child: 76 Parent: 72	Child: 56 Parent: 52	Child: 77 Parent: 75	Child: 78 Parent: 76
Male	7	Femur	107	Right: 5 Left: 5	Child: 76 Parent: 73	Child: 56 Parent: 58	Child: 76 Parent: 77	Child: 82 Parent: 84
Male	6	Tibia	95	Right: 6 Left: 6	Child: 73 Parent: 71	Child: 48 Parent: 49	Child: 72 Parent: 72	Child: 76 Parent: 80
Male	7	Femur	107	Right: 6 Left: 6	Child: 86 Parent: 85	Child: 56 Parent: 55	Child: 72 Parent: 76	Child: 85.3 Parent: 86
Female	6	Tibia	97	Right: 6 Left: 6.2	Child: 86 Parent: 86	Child: 46 Parent: 48	Child: 78 Parent: 80	Child: 79 Parent: 76
Female	7	Femur	105	Right: 6.5 Left: 6.5	Child: 80 Parent: 82	Child: 42 Parent: 46	Child: 76 Parent: 72	Child: 77.3 Parent: 79

[a]PedSQL: Pediatric Quality of Life.

Figure 2a-c also shows the postoperative progression of a 10-year-old patient diagnosed with achondroplasia who underwent paired limb lengthening with a rod external fixator equipped with the authors' modified distraction control. The patient and her parents reported a significant improvement in her quality of life after the surgical intervention and rehabilitation.

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Figure 2. The postoperative dynamics of a 10-year-old patient diagnosed with achondroplasia who underwent paired limb lengthening with a rod external fixator and modified distraction control developed by the authors. (a) Patient 3 days after surgery (latent phase); (b) patient 3 months after surgery (consolidation phase); (c) progress 1 month after removal of the fixators (functional adaptation phase).

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Discussion

Principal Findings

This study compared quality-of-life indicators (measured by postoperative pain syndrome, physical activity, and emotional state) in children with a genetically confirmed diagnosis of achondroplasia undergoing transosseous distraction osteosynthesis using 2 different external fixators systems: a rod system with the authors' modified distraction control and a circular multiaxial system (Ilizarov system).

As expected, the results confirmed a decline in the quality of life for patients in both groups during the latency phase. However, patients in the control group (using the circular multiaxial system) experienced a more significant decrease in quality-of-life satisfaction, as reported by both the children and their parents/caregivers, compared to the experimental group using the rod fixator with the authors' modified distraction control. Moreover, the control group reported more intense pain syndrome compared to the patients using the authors' modified semicircular distraction system. During the later postoperative period under a dynamic observation, these differences decreased, and the level of satisfaction with the quality of life was statistically significantly higher in the main group 18 months after surgery than in the preoperative period.

Although orthopedic surgery for the treatment of achondroplasia has made significant advancements and continues to evolve, most practitioners have yet to agree on a surgical approach to the treatment of children and adolescents with this condition. Furthermore, the optimal fixator compositions for different age groups of patients are not specified [9]. A high rate of complications persists, which may be due to noncompliance with age-specific aspects of surgical treatment [17]. Several postoperative management issues remain unresolved [16].

In a recent study utilizing the PedsQL 4.0 questionnaire to assess the quality of life in children with achondroplasia (reported by the children and their parents/caregivers), it was observed that parents perceived their child's quality to be lower in all domains compared to people of average height. This is due to physical limitations, barriers, and various challenges reported by children and adolescents to their parents. Notably, the children themselves also rated their quality of life significantly lower than the healthy control group, except in the emotional domain, where their scores were similar to the healthy group. It is possible that children with achondroplasia have learned to accept themselves as they are and find contentment despite experiencing significant physical limitations in their quality of life, both in school and social contexts [7]. It is important to understand that the diagnosis of achondroplasia and its consequences impact not only a child but also the entire family, as family members must adapt to the unique needs of the child [7].

Surveys conducted among patients with achondroplasia and their family members, both before and after treatment, consistently answer in favor of the need for limb augmentation [8,17]. Currently, the primary method for addressing growth deficit in patients with achondroplasia involves surgical distraction osteosynthesis [9,10]. The possibility of drug-assisted limb lengthening, particularly with the drug Vosoritide, is being studied. While the results are encouraging, at present, this trend cannot serve as an alternative to surgical treatment [4].

During surgical treatment, transosseous osteosynthesis is the most commonly used method, involving the use of external bone-anchored supports placed above the skin's surface. However, patients are required to wear these systems throughout the distraction and consolidation period of the regenerate, which can last up to 18 months, depending on the planned degree of limb lengthening. This inevitably impacts a patient's quality of life. In response to this concern, internal fixation systems have

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been developed, such as the Precice system with magnetic control over distraction speed [25,26], and combined systems like LON (Lengthening Over Nail) and LATN (Lengthening and Then Nailing), which halve the time of fixator use [27-29]. However, these systems cannot always serve as an alternative to fixators because they use expensive titanium rods. The Precice system has limitations in bone diameter, cannot be used for humerus lengthening, and the procedure itself must be well planned since no postoperative changes (other than distraction rate) can be made [27]. The LON and LATN systems require additional surgical intervention. Consequently, the development of lighter and more comfortable fixators remains urgent.

Traditionally, limb lengthening for patients in this nosological group has been performed using a multiaxial system, known as the Ilizarov system. While this system shows good results in reparative tissue regeneration processes, its complex design and cumbersomeness can impact patients' quality of life, which is especially significant in pediatric practice [9,16,17]. To address this, rod fixators built on a semicircular frame with a simpler and lighter design are gaining popularity [20,21]. The authors have introduced a rod fixator with modified distraction control. A previous article demonstrated the advantage of this system over the circular multiaxial system, highlighting improvements in fixation time, achieved regenerative length, correction of deformities, pain intensity, and complication rates [11].

This study establishes that the authors' rod fixation with modified distraction control facilitates an improved standard of living compared to a circular multiaxial system in the latent phase. Consequently, this advancement not only allows patients with achondroplasia to move freely from the first days after surgery but also to gradually develop strength in the lengthened limb.

Conclusions

The rod fixator with modified distraction control developed by the authors significantly enhances the quality of life compared to the circular multiaxial system in the latency phase. Employing this fixator technique for paired surgical lengthening in children with achondroplasia ensures stability throughout the distraction process, provides a strong and uniform regenerate, contributes to a significant reduction in complications, and allows patients to regain full physical activities in a shorter time. With its high stability, the device creates favorable conditions for psychological and physical adaptation during treatment and demonstrates a significant advantage over the circular multiaxial system. Considering the cost-effectiveness of this developed fixation system, it can contribute to delivering quality orthopedic care for patients with achondroplasia.

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Declaration of Patient Consent

The patient's parent has given informed consent for the patient's images and other clinical information to be published in a medical journal. The patient's parent understands that the patient's name and initials will not be published and due efforts will be made to conceal their identity, but complete anonymity cannot be guaranteed.

Data Availability

The data sets generated and/or analyzed during this study are available from the corresponding authors upon reasonable request.

Authors' Contributions

All authors contributed to the study's conception and design. VT, BD, VL, SK, AD, AA, AP, and OZ performed the material preparation, data collection, and analysis. VT wrote the first draft of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ICD: International Classification of Diseases
FGFR3: fibroblast growth factor receptor-3
GCP: Good Clinical Practice
LON: Lengthening Over Nail
LATN: Lengthening and Then Nailing
PedsQL: Pediatric Quality of Life

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Editorial

Introducing JMIR Rehabilitation and Assistive Technologies: A Venue for Publishing Interdisciplinary Research on the Development, Implementation, and Evaluation of Health Innovations and Emerging Technologies in the Field of Rehabilitation

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Abstract

Rehabilitation supports the affected individual and their caregivers in managing the health condition and its associated symptoms, altering the environment to accommodate needs, adapting tasks for safe and independent performance, facilitating self-management, and using assistive devices and technologies. *JMIR Rehabilitation and Assistive Technologies* focuses on pragmatic yet rigorous and impactful science that reports on the development, implementation, and evaluation of health innovations and interventions as well as emerging technologies in the field of rehabilitation.

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KEYWORDS

rehabilitation; assistive technologies; JMIR Rehabilitation and Assistive Technologies; digital; online

Background

As defined by the World Health Organization, rehabilitation is “a set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment” [1]. The World Health Organization elaborates that rehabilitation helps individuals of all ages become as independent as possible in daily activities and promotes meaningful participation in many aspects of life, including education, work, recreation, and looking after family. Rehabilitation enables this participation and independence by supporting the affected individual and their caregivers in addressing the health condition and its associated symptoms, altering the environment to accommodate needs, adapting tasks for safe and independent performance, supporting self-management, and using assistive devices and technologies. These strategies can help the individual and their caregiver to overcome challenges in thinking, seeing, hearing, communicating, eating, and mobilizing [1].

The benefits of rehabilitation are multifaceted and can reduce the impact of acute and chronic health conditions, illnesses, and injuries. Rehabilitation can also support other health interventions, such as medical or surgical procedures, to achieve optimal outcomes. Furthermore, rehabilitation is highly person driven, meaning that the interventions selected for each individual are tailored to their unique goals and preferences. Rehabilitation can be provided in many different settings, such as in inpatient or outpatient hospital settings, or community settings such as an individual’s home, a school, a workplace, and increasingly, remotely [1,2]. Indeed, an overview of telerehabilitation and its fields of application, with an analysis

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of the benefits and the drawbacks related to its use, is the most cited paper in *JMIR Rehabilitation and Assistive Technologies* [3], reflecting the increasing prominence of telerehabilitation, especially since the COVID-19 pandemic.

Approximately 2.4 billion people have a health condition that would benefit from or need rehabilitation [1,4]. Notably, the need for rehabilitation is estimated to increase as people live longer and with more chronic conditions and disability. There are substantial unmet needs in some low- and middle-income countries, with more than 50% of individuals not receiving the rehabilitation services they require. Conflicts, natural disasters, and disease outbreaks can increase these rehabilitation needs and disrupt existing services. Global needs remain unmet due to various factors, including a lack of available rehabilitation services outside urban areas, long waiting times, ineffective and underutilized referral pathways to rehabilitation, and lack of resources, including equipment and assistive technologies [1].

Scope

JMIR Rehabilitation and Assistive Technologies focuses on pragmatic yet rigorous and impactful science that reports on the development, implementation, and evaluation of health innovations and interventions as well as emerging technologies in the field of rehabilitation. These innovations may also relate to a program such as a self-management intervention, clinical pathway, or device. Furthermore, we are interested in submissions that describe the need for rehabilitation interventions and innovations (eg, gaps in the transition from acute care to rehabilitation). We also welcome original research articles, review articles, viewpoints, or research letters [5] related to methodological advances in the study of rehabilitation and its assistive technologies. In particular, we are interested in papers that engage relevant knowledge users (eg, patients, families, etc) in developing, implementing, and evaluating these health innovations and interventions and emerging technologies. Mixed methods studies are highly relevant for studying the complexities of rehabilitation [6] and thus are also welcomed submissions. Consistent with the field of rehabilitation, we believe that *JMIR Rehabilitation and Assistive Technologies* is a venue for publishing interdisciplinary research between, for example, rehabilitation clinicians, scientists, and relevant knowledge users, including patients and families. Similarly, JMIR Publications, one of the first open access publishers, aims to reach wide audiences.

This engagement of multidisciplinary experts and community members will advance scientific knowledge and innovative care for rehabilitation services, and we look forward to your submissions to *JMIR Rehabilitation and Assistive Technologies*.

Conflicts of Interest

SEPM is the editor-in-chief of *JMIR Rehabilitation and Assistive Technologies*.

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