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Original Paper

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

Isabella Zsoldos[1], PhD; Eléonore Trân[1], MSc; Hippolyte Fournier[1], PhD; Franck Tarpin-Bernard[2], PhD; Joan Fruitet[2], PhD; Mélodie Fouillen[2], PhD; Gérard Bailly[3], PhD; Frédéric Elisei[3], PhD; Béatrice Bouchot[4], MSc; Patrick Constant[5], PhD; Fabien Ringeval[6], PhD; Olivier Koenig[1], PhD; Hanna Chainay[1], PhD

[1]Laboratoire d'Étude des Mécanismes Cognitifs, Université Lumière Lyon 2, Lyon, France

[2]SBT Humans Matter, Lyon, France

[3]GIPSA-Lab, Université Grenoble Alpes, Grenoble, France

[4]Atos, Echirolles, France

[5]Pertimm, Asnières-sur-Seine, France

[6]Laboratoire d'Informatique de Grenoble, Université Grenoble Alpes, Grenoble, France

Corresponding Author:
Isabella Zsoldos, PhD
Laboratoire d'Étude des Mécanismes Cognitifs
Université Lumière Lyon 2
5 Avenue Pierre Mendès France
Lyon, 69500
France
Phone: 33 478774335
Email: isabella.zsoldos@hotmail.fr

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

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

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,

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.

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.

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

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.

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.

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

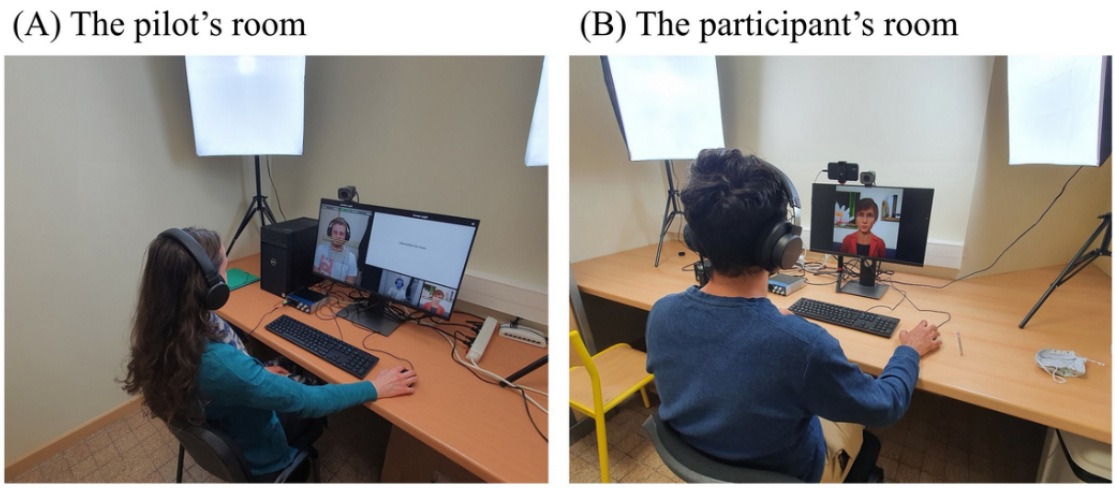
Dimensions examined, scores calculated, and items	Response (visual analog scales)
Overall appreciation of the virtual assistant	
"**Appreciation"**	
In general, did you find that the virtual assistant accompanied you well during the cognitive training session?	From "not at all" to "absolutely"
If you 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.

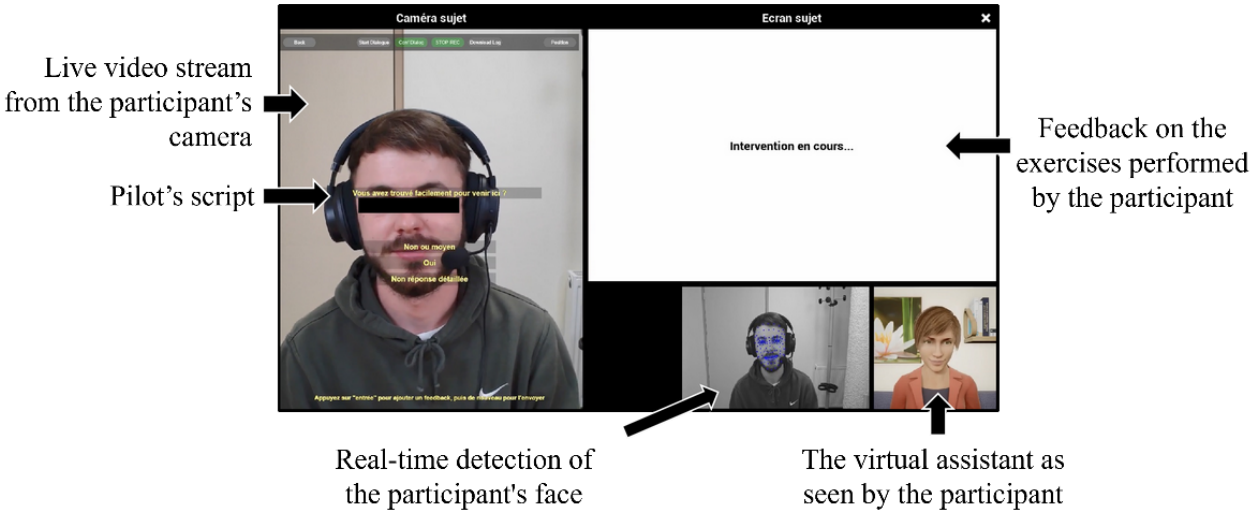
Figure 1. Wizard of Oz device.



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.

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

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.

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).

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.

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,

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

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.

References

1. Dementia. World Health Organization. 2023. URL: https://www.who.int/news-room/fact-sheets/detail/dementia [accessed 2024-04-29]
2. Albert MS, DeKosky ST, Dickson D, Dubois B, Feldman HH, Fox NC, et al. The diagnosis of mild cognitive impairment due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. Alzheimers Dement 2011 May;7(3):270-279 [FREE Full text] [doi: 10.1016/j.jalz.2011.03.008] [Medline: 21514249]
3. Tricco AC, Soobiah C, Berliner S, Ho JM, Ng CH, Ashoor HM, et al. Efficacy and safety of cognitive enhancers for patients with mild cognitive impairment: a systematic review and meta-analysis. CMAJ 2013 Nov 05;185(16):1393-1401 [FREE Full text] [doi: 10.1503/cmaj.130451] [Medline: 24043661]
4. Wong CW. Pharmacotherapy for dementia: a practical approach to the use of cholinesterase inhibitors and memantine. Drugs Aging 2016 Jul;33(7):451-460. [doi: 10.1007/s40266-016-0372-3] [Medline: 27154396]

5. Lissek V, Suchan B. Preventing dementia? Interventional approaches in mild cognitive impairment. Neurosci Biobehav Rev 2021 Mar;122:143-164. [doi: 10.1016/j.neubiorev.2020.12.022] [Medline: 33440197]
6. Vaci N, Koychev I, Kim CH, Kormilitzin A, Liu Q, Lucas C, et al. Real-world effectiveness, its predictors and onset of action of cholinesterase inhibitors and memantine in dementia: retrospective health record study. Br J Psychiatry 2021 May;218(5):261-267. [doi: 10.1192/bjp.2020.136] [Medline: 32713359]
7. Zucchella C, Sinforiani E, Tamburin S, Federico A, Mantovani E, Bernini S, et al. The multidisciplinary approach to Alzheimer's disease and dementia. A narrative review of non-pharmacological treatment. Front Neurol 2018;9:1058 [FREE Full text] [doi: 10.3389/fneur.2018.01058] [Medline: 30619031]
8. Hill NT, Mowszowski L, Naismith SL, Chadwick VL, Valenzuela M, Lampit A. Computerized cognitive training in older adults with mild cognitive impairment or dementia: a systematic review and meta-analysis. Am J Psychiatry 2017 Apr 01;174(4):329-340. [doi: 10.1176/appi.ajp.2016.16030360] [Medline: 27838936]
9. Lampit A, Hallock H, Valenzuela M. Computerized cognitive training in cognitively healthy older adults: a systematic review and meta-analysis of effect modifiers. PLoS Med 2014 Nov;11(11):e1001756 [FREE Full text] [doi: 10.1371/journal.pmed.1001756] [Medline: 25405755]
10. Leung IH, Walton CC, Hallock H, Lewis SJ, Valenzuela M, Lampit A. Cognitive training in Parkinson disease: a systematic review and meta-analysis. Neurology 2015 Nov 24;85(21):1843-1851 [FREE Full text] [doi: 10.1212/WNL.0000000000002145] [Medline: 26519540]
11. Gavelin HM, Domellöf ME, Leung I, Neely AS, Launder NH, Nategh L, et al. Computerized cognitive training in Parkinson's disease: a systematic review and meta-analysis. Ageing Res Rev 2022 Sep;80:101671. [doi: 10.1016/j.arr.2022.101671] [Medline: 35714854]
12. Hu M, Wu X, Shu X, Hu H, Chen Q, Peng L, et al. Effects of computerised cognitive training on cognitive impairment: a meta-analysis. J Neurol 2021 May;268(5):1680-1688. [doi: 10.1007/s00415-019-09522-7] [Medline: 31650255]
13. Belleville S, Boller B, Val LP. Cognitive training in mild cognitive impairment. In: Strobach T, Karbach J, editors. Cognitive Training: An Overview of Features and Applications. Cham, Switzerland: Springer; 2016:187-197.
14. Butler M, McCreedy E, Nelson VA, Desai P, Ratner E, Fink HA, et al. Does cognitive training prevent cognitive decline?: a systematic review. Ann Intern Med 2018 Jan 02;168(1):63-68 [FREE Full text] [doi: 10.7326/M17-1531] [Medline: 29255842]
15. Gates NJ, Rutjes AW, Di Nisio M, Karim S, Chong LY, March E, et al. Computerised cognitive training for 12 or more weeks for maintaining cognitive function in cognitively healthy people in late life. Cochrane Database Syst Rev 2020 Feb 27;2(2):CD012277 [FREE Full text] [doi: 10.1002/14651858.CD012277.pub3] [Medline: 32104914]
16. Gates NJ, Vernooij RW, Di Nisio M, Karim S, March E, Martínez G, et al. Computerised cognitive training for preventing dementia in people with mild cognitive impairment. Cochrane Database Syst Rev 2019 Mar 13;3(3):CD012279 [FREE Full text] [doi: 10.1002/14651858.CD012279.pub2] [Medline: 30864747]
17. Mowszowski L, Batchelor J, Naismith SL. Early intervention for cognitive decline: can cognitive training be used as a selective prevention technique? Int Psychogeriatr 2010 Jun;22(4):537-548. [doi: 10.1017/S1041610209991748] [Medline: 20170585]
18. Stern Y. What is cognitive reserve? Theory and research application of the reserve concept. J Int Neuropsychol Soc 2002 Mar;8(3):448-460. [Medline: 11939702]
19. Stern Y. Cognitive reserve in ageing and Alzheimer's disease. Lancet Neurol 2012 Nov;11(11):1006-1012 [FREE Full text] [doi: 10.1016/S1474-4422(12)70191-6] [Medline: 23079557]
20. Gaitán A, Garolera M, Cerulla N, Chico G, Rodriguez-Querol M, Canela-Soler J. Efficacy of an adjunctive computer-based cognitive training program in amnestic mild cognitive impairment and Alzheimer's disease: a single-blind, randomized clinical trial. Int J Geriatr Psychiatry 2013 Jan;28(1):91-99. [doi: 10.1002/gps.3794] [Medline: 22473855]
21. Kallio EL, Öhman H, Kautiainen H, Hietanen M, Pitkälä K. Cognitive training interventions for patients with Alzheimer's disease: a systematic review. J Alzheimers Dis 2017;56(4):1349-1372. [doi: 10.3233/JAD-160810] [Medline: 28222505]
22. Clare L, Woods RT. Cognitive training and cognitive rehabilitation for people with early-stage Alzheimer's disease: a review. Neuropsychol Rehabil 2004 Sep;14(4):385-401. [doi: 10.1080/09602010443000074]
23. Jaeggi SM, Buschkuehl M, Shah P, Jonides J. The role of individual differences in cognitive training and transfer. Mem Cognit 2014 Apr;42(3):464-480. [doi: 10.3758/s13421-013-0364-z] [Medline: 24081919]
24. F Corbett C, M Combs E, J Wright P, L Owens O, Stringfellow I, Nguyen T, et al. Virtual home assistant use and perceptions of usefulness by older adults and support person dyads. Int J Environ Res Public Health 2021 Jan 27;18(3):1113 [FREE Full text] [doi: 10.3390/ijerph18031113] [Medline: 33513798]
25. Arnold A, Kolody S, Comeau A, Miguel Cruz A. What does the literature say about the use of personal voice assistants in older adults? A scoping review. Disabil Rehabil Assist Technol 2024 Jan;19(1):100-111. [doi: 10.1080/17483107.2022.2065369] [Medline: 35459429]
26. Bolaños M, Collazos C, Gutiérrez F. Adapting a virtual assistant device to support the interaction with elderly people. In: Proceedings of the 6th International Conference on Information and Communication Technologies for Ageing Well and e-Health. 2020 Presented at: ICT4AWE '20; May 3-5, 2020; Prague, Czech Republic p. 291-298 URL: https://www.scitepress.org/Papers/2020/98401/98401.pdf [doi: 10.5220/0009840102910298]

27. Jegundo AL, Dantas C, Quintas J, Dutra J, Almeida AL, Caravau H, et al. Perceived usefulness, satisfaction, ease of use and potential of a virtual companion to support the care provision for older adults. Technol 2020 Jul 25;8(3):42. [doi: 10.3390/technologies8030042]
28. Yaghoubzadeh R, Kramer M, Pitsch K, Kopp S. Virtual agents as daily assistants for elderly or cognitively impaired people. In: Proceedings of the 13th International Conference on Intelligent Virtual Agents. 2013 Presented at: IVA '13; August 29-31, 2013; Edinburgh, UK p. 79-91 URL: https://link.springer.com/chapter/10.1007/978-3-642-40415-3_7 [doi: 10.1007/978-3-642-40415-3_7]
29. Velciu M, Kaczmarek M, M'rzan M, Teunissen B, Andrushevich A, Spiru L. Virtual assistant for healthy aging: benefits perceived by elders. In: Proceedings of the 4th International Conference on Neuroscience and Cognitive Brain Information. 2019 Presented at: BRAININFO '19; June 30-July 4, 2019; Rome, Italy p. 12-15 URL: https://personales.upv.es/thinkmind/dl/conferences/braininfo/braininfo_2019/braininfo_2019_1_30_90029.pdf
30. Góngora Alonso S, Hamrioui S, de la Torre Díez I, Motta Cruz E, López-Coronado M, Franco M. Social robots for people with aging and dementia: a systematic review of literature. Telemed J E Health 2019 Jul;25(7):533-540. [doi: 10.1089/tmj.2018.0051] [Medline: 30136901]
31. Ter Stal S, Broekhuis M, van Velsen L, Hermens H, Tabak M. Embodied conversational agent appearance for health assessment of older adults: explorative study. JMIR Hum Factors 2020 Sep 04;7(3):e19987 [FREE Full text] [doi: 10.2196/19987] [Medline: 32886068]
32. Straßmann C, Krämer NC. A categorization of virtual agent appearances and a qualitative study on age-related user preferences. In: Proceedings of the 17th International Conference on Intelligent Virtual Agents. 2017 Presented at: IVA '17; August 27-30, 2017; Stockholm, Sweden p. 27-30 URL: https://link.springer.com/chapter/10.1007/978-3-319-67401-8_51 [doi: 10.1007/978-3-319-67401-8_51]
33. Straßmann C, Krämer NC, Buschmeier H, Kopp S. Age-related differences in the evaluation of a virtual health agent's appearance and embodiment in a health-related interaction: experimental lab study. J Med Internet Res 2020 Apr 23;22(4):e13726 [FREE Full text] [doi: 10.2196/13726] [Medline: 32324146]
34. Tsiourti C, Joly E, Wings C, Moussa MB, Wac K. Virtual assistive companions for older adults: qualitative field study and design implications. In: Proceedings of the 8th International Conference on Pervasive Computing Technologies for Healthcare. 2014 Presented at: PervasiveHealth '14; May 20-23, 2014; Oldenburg, Germany p. 57-64 URL: https://dl.acm.org/doi/10.4108/icst.pervasivehealth.2014.254943 [doi: 10.4108/icst.pervasivehealth.2014.254943]
35. Esposito A, Amorese T, Cuciniello M, Riviello MT, Esposito AM, Troncone A, et al. Elder user's attitude toward assistive virtual agents: the role of voice and gender. J Ambient Intell Human Comput 2019 Aug 20;12(4):4429-4436. [doi: 10.1007/s12652-019-01423-x]
36. Foukarakis M, Karuzaki E, Adami I, Ntoa S, Partarakis N, Zabulis X, et al. Quality assessment of virtual human assistants for elder users. Electron 2022 Sep 26;11(19):3069. [doi: 10.3390/electronics11193069]
37. Rampioni M, Stara V, Felici E, Rossi L, Paolini S. Embodied conversational agents for patients with dementia: thematic literature analysis. JMIR Mhealth Uhealth 2021 Jul 16;9(7):e25381 [FREE Full text] [doi: 10.2196/25381] [Medline: 34269686]
38. Park EA, Jung AR, Lee KA. The humanoid robot Sil-Bot in a cognitive training program for community-dwelling elderly people with mild cognitive impairment during the COVID-19 pandemic: a randomized controlled trial. Int J Environ Res Public Health 2021 Aug 03;18(15):8198 [FREE Full text] [doi: 10.3390/ijerph18158198] [Medline: 34360490]
39. Bickmore TW, Mitchell SE, Jack BW, Paasche-Orlow MK, Pfeifer LM, O'donnell J. Response to a relational agent by hospital patients with depressive symptoms. Interact Comput 2010 Jul 01;22(4):289-298 [FREE Full text] [doi: 10.1016/j.intcom.2009.12.001] [Medline: 20628581]
40. Koebel K, Lacayo M, Murali M, Tarnanas I, Çöltekin A. Expert insights for designing conversational user interfaces as virtual assistants and companions for older adults with cognitive impairments. In: Proceedings of the 5th International Workshop on Chatbot Research and Design. 2022 Presented at: CONVERSATIONS '21; November 23-24, 2021; Virtual Event p. 23-38 URL: https://link.springer.com/chapter/10.1007/978-3-030-94890-0_2 [doi: 10.1007/978-3-030-94890-0_2]
41. Liu N, Pu Q, Shi Y, Zhang S, Qiu L. Older adults' interaction with intelligent virtual assistants: the role of information modality and feedback. Int J Hum Comput Interact 2022 May 30;39(5):1162-1183. [doi: 10.1080/10447318.2022.2074667]
42. Tarpin-Bernard F, Fruitet J, Vigne JP, Constant P, Chainay H, Koenig O, et al. THERADIA: digital therapies augmented by artificial intelligence. In: Proceedings of the AHFE 2021 Virtual Conferences on Neuroergonomics and Cognitive Engineering, Industrial Cognitive Ergonomics and Engineering Psychology, and Cognitive Computing and Internet of Things. 2021 Presented at: AHFE '21; July 25-29, 2021; New York, NY p. 478-485. [doi: 10.1007/978-3-030-80285-1_55]
43. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res 1975 Nov;12(3):189-198. [doi: 10.1016/0022-3956(75)90026-6] [Medline: 1202204]
44. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. J Pers Soc Psychol 1988 Jun;54(6):1063-1070. [doi: 10.1037//0022-3514.54.6.1063] [Medline: 3397865]
45. Bradley MM, Lang PJ. Measuring emotion: the self-assessment manikin and the semantic differential. J Behav Ther Exp Psychiatry 1994 Mar;25(1):49-59. [doi: 10.1016/0005-7916(94)90063-9] [Medline: 7962581]

46. Mayer JD, Gaschke YN. The experience and meta-experience of mood. J Pers Soc Psychol 1988 Jul;55(1):102-111. [doi: 10.1037//0022-3514.55.1.102] [Medline: 3418484]
47. Gauthier J, Bouchard S. Adaptation canadienne-française de la forme révisée du state–trait anxiety inventory de spielberger. Can J Behav Sci 1993 Oct;25(4):559-578. [doi: 10.1037/h0078881]
48. Gosling SD, Rentfrow PJ, Swann WB. A very brief measure of the Big-Five personality domains. J Res Pers 2003 Dec;37(6):504-528. [doi: 10.1016/S0092-6566(03)00046-1]
49. Guay F, Mageau GA, Vallerand RJ. On the hierarchical structure of self-determined motivation: a test of top-down, bottom-up, reciprocal, and horizontal effects. Pers Soc Psychol Bull 2003 Aug;29(8):992-1004. [doi: 10.1177/0146167203253297] [Medline: 15189618]
50. Reitan RM. Validity of the trail making test as an indicator of organic brain damage. Percept Mot Skills 1958 Dec;8(7):271-276. [doi: 10.2466/PMS.8.7.271-276]
51. Dubois B, Slachevsky A, Litvan I, Pillon B. The FAB: a frontal assessment battery at bedside. Neurology 2000 Dec 12;55(11):1621-1626. [doi: 10.1212/wnl.55.11.1621] [Medline: 11113214]
52. Cowppli-Bony P, Fabrigoule C, Letenneur L, Ritchie K, Alpérovitch A, Dartigues JF, et al. Validity of the five-word screening test for Alzheimer's disease in a population based study. Rev Neurol (Paris) 2005 Dec;161(12 Pt 1):1205-1212 [FREE Full text] [doi: 10.1016/s0035-3787(05)85194-x] [Medline: 16340916]
53. Fontaine JR, Scherer KR, Roesch EB, Ellsworth PC. The world of emotions is not two-dimensional. Psychol Sci 2007 Dec;18(12):1050-1057. [doi: 10.1111/j.1467-9280.2007.02024.x] [Medline: 18031411]
54. Scherer KR. The dynamic architecture of emotion: evidence for the component process model. Cogn Emot 2009 Nov;23(7):1307-1351. [doi: 10.1080/02699930902928969]
55. Morey RD, Rouder JN, Jamil T, Urbanek S, Forner K, Ly A. BayesFactor: computation of bayes factors for common designs. Version 0.9.12-4.7. Cran R. 2022. URL: https://cran.r-project.org/package=BayesFactor [accessed 2024-04-29]
56. Rouder JN, Morey RD, Speckman PL, Province JM. Default Bayes factors for ANOVA designs. J Math Psychol 2012 Oct;56(5):356-374. [doi: 10.1016/j.jmp.2012.08.001]
57. Makowski D, Ben-Shachar M, Lüdecke D. bayestestR: describing effects and their uncertainty, existence and significance within the Bayesian Framework. J Open Source Softw 2019 Aug;4(40):1541. [doi: 10.21105/joss.01541]
58. Kruschke JK. Bayesian estimation supersedes the t test. J Exp Psychol Gen 2013 May;142(2):573-603. [doi: 10.1037/a0029146] [Medline: 22774788]
59. Kruschke JK. Tools in the trunk. In: Kruschke JK, editor. Doing Bayesian Data Analysis: A Tutorial with R, JAGS, and Stan. 2nd edition. Cambridge, MA: Academic Press; 2014:721-736.
60. Kass RE, Raftery AE. Bayes factors. J Am Stat Assoc 1995 Jun;90(430):773-795. [doi: 10.1080/01621459.1995.10476572]
61. Curtis RG, Bartel B, Ferguson T, Blake HT, Northcott C, Virgara R, et al. Improving user experience of virtual health assistants: scoping review. J Med Internet Res 2021 Dec 21;23(12):e31737 [FREE Full text] [doi: 10.2196/31737] [Medline: 34931997]
62. Soubelet A, Salthouse TA. Influence of social desirability on age differences in self-reports of mood and personality. J Pers 2011 Aug;79(4):741-762 [FREE Full text] [doi: 10.1111/j.1467-6494.2011.00700.x] [Medline: 21682727]
63. Hitchcott PK, Penna MP, Fastame MC. Age trends in well-being and depressive symptoms: the role of social desirability. Psychiatr Q 2020 Jun;91(2):463-473. [doi: 10.1007/s11126-020-09711-y] [Medline: 31983016]
64. Betts LR, Hill R, Gardner SE. "There's not enough knowledge out there": examining older adults' perceptions of digital technology use and digital inclusion classes. J Appl Gerontol 2019 Aug;38(8):1147-1166. [doi: 10.1177/0733464817737621] [Medline: 29165038]
65. Turunen M, Hokkanen L, Bäckman L, Stigsdotter-Neely A, Hänninen T, Paajanen T, et al. Computer-based cognitive training for older adults: determinants of adherence. PLoS One 2019;14(7):e0219541 [FREE Full text] [doi: 10.1371/journal.pone.0219541] [Medline: 31291337]
66. Clare L, Woods RT, Moniz Cook ED, Orrell M, Spector A. Cognitive rehabilitation and cognitive training for early-stage Alzheimer's disease and vascular dementia. Cochrane Database Syst Rev 2003(4):CD003260. [doi: 10.1002/14651858.CD003260] [Medline: 14583963]
67. EU AI Act: first regulation on artificial intelligence. European Parliament. 2023 Jun 08. URL: https://www.europarl.europa.eu/news/en/headlines/society/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence
68. Cuffaro L, Di Lorenzo F, Bonavita S, Tedeschi G, Leocani L, Lavorgna L. Dementia care and COVID-19 pandemic: a necessary digital revolution. Neurol Sci 2020 Aug;41(8):1977-1979 [FREE Full text] [doi: 10.1007/s10072-020-04512-4] [Medline: 32556746]
69. Corbett CF, Wright PJ, Jones K, Parmer M. Voice-activated virtual home assistant use and social isolation and loneliness among older adults: mini review. Front Public Health 2021;9:742012 [FREE Full text] [doi: 10.3389/fpubh.2021.742012] [Medline: 34708017]

Abbreviations

BF10: Bayes factor

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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Original Paper

Preliminary Validity and Acceptability of Motion Tape for Measuring Low Back Movement: Mixed Methods Study

Audrey Lee[1], MS; Elijah Wyckoff[2], MS; Emilia Farcas[3], PhD; Job Godino[3,4], PhD; Kevin Patrick[3,5], MD, MS; Spencer Spiegel[6], BA; Rose Yu[7], PhD; Arun Kumar[7], PhD; Kenneth J Loh[2], PhD; Sara Gombatto[8], PhD

[1]Department of Bioengineering, San Diego State University, San Diego, CA, United States

[2]Active, Responsive, Multifunctional, and Ordered-materials Research (ARMOR) Laboratory, Department of Structural Engineering, University of California San Diego, La Jolla, CA, United States

[3]Qualcomm Institute, University of California San Diego, La Jolla, CA, United States

[4]Laura Rodriguez Research Institute, Family Health Centers of San Diego, San Diego, CA, United States

[5]School of Public Health, University of California San Diego, La Jolla, CA, United States

[6]Department of Mathematics and Statistics, San Diego State University, San Diego, CA, United States

[7]Computer Science and Engineering and Halicioglu Data Science Institute, University of California San Diego, La Jolla, CA, United States

[8]School of Physical Therapy, San Diego State University, San Diego, CA, United States

Corresponding Author:
Kenneth J Loh, PhD
Active, Responsive, Multifunctional, and Ordered-materials Research (ARMOR) Laboratory
Department of Structural Engineering
University of California San Diego
9500 Gilman Dr MC 0085
SME 445E
La Jolla, CA, 92093-0085
United States
Phone: 1 858 822 0431
Fax: 1 858 534 1310
Email: kenloh@ucsd.edu

Abstract

Background: Low back pain (LBP) is a significant public health problem that can result in physical disability and financial burden for the individual and society. Physical therapy is effective for managing LBP and includes evaluation of posture and movement, interventions directed at modifying posture and movement, and prescription of exercises. However, physical therapists have limited tools for objective evaluation of low back posture and movement and monitoring of exercises, and this evaluation is limited to the time frame of a clinical encounter. There is a need for a valid tool that can be used to evaluate low back posture and movement and monitor exercises outside the clinic. To address this need, a fabric-based, wearable sensor, Motion Tape (MT), was developed and adapted for a low back use case. MT is a low-profile, disposable, self-adhesive, skin-strain sensor developed by spray coating piezoresistive graphene nanocomposites directly onto commercial kinesiology tape.

Objective: The objectives of this study were to (1) validate MT for measuring low back posture and movement and (2) assess the acceptability of MT for users.

Methods: A total of 10 participants without LBP were tested. A 3D optical motion capture system was used as a reference standard to measure low back kinematics. Retroreflective markers and a matrix of MTs were placed on the low back to measure kinematics (motion capture) and strain (MT) simultaneously during low back movements in the sagittal, frontal, and axial planes. Cross-correlation coefficients were calculated to evaluate the concurrent validity of MT strain in reference motion capture kinematics during each movement. The acceptability of MT was assessed using semistructured interviews conducted with each participant after laboratory testing. Interview data were analyzed using rapid qualitative analysis to identify themes and subthemes of user acceptability.

Results: Visual inspection of concurrent MT strain and kinematics of the low back indicated that MT can distinguish between different movement directions. Cross-correlation coefficients between MT strain and motion capture kinematics ranged from –0.915 to 0.983, and the strength of the correlations varied across MT placements and low back movement directions. Regarding

user acceptability, participants expressed enthusiasm toward MT and believed that it would be helpful for remote interventions for LBP but provided suggestions for improvement.

Conclusions: MT was able to distinguish between different low back movements, and most MTs demonstrated moderate to high correlation with motion capture kinematics. This preliminary laboratory validation of MT provides a basis for future device improvements, which will also involve testing in a free-living environment. Overall, users found MT acceptable for use in physical therapy for managing LBP.

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KEYWORDS

low back pain; fabric; nanocomposite; sensor acceptability; sensor validation; skin; strain; wearable

Introduction

Prevalence and Impact of Low Back Pain

Low back pain (LBP) is a highly prevalent and burdensome health condition, with approximately 568.4 million existing cases, 223.5 million new cases, and 63.7 million cases involving years lived with disability reported worldwide in 2019 [1]. It is anticipated that approximately 70% to 85% of adults will experience at least 1 episode of LBP during their lifetime [2,3], and once susceptible to LBP, individuals face twice the likelihood of experiencing recurring episodes [4].

The costs of diagnosing and treating LBP in the United States are substantial, collectively amounting to US $12 billion annually [5,6] and an economic impact including 149 million missed workdays per year [7]. Worldwide, the total annual costs associated with LBP are nearly US $100 billion, including lost wages and diminished productivity within businesses [8]. Given the high prevalence and burden to the individual and society, LBP is an important health condition to address clinically and in research.

Physical Therapy for LBP

Physical therapy (PT) is effective for the conservative, nonpharmacologic, and nonsurgical management of LBP. Specifically, active interventions such as exercises prescribed by physical therapists are effective for both preventing and treating LBP [9,10]. In PT, a licensed physical therapist conducts a comprehensive initial examination to identify musculoskeletal and neuromuscular impairments associated with the LBP problem by closely observing the patient's low back posture and movement. Subsequently, the physical therapist works with the patient to develop a plan of care for in-clinic sessions and with an assigned home exercise program based on the PT evaluation and patient goals to enhance strength, stability, and mobility [2,11,12]. These interventions collectively aim to alleviate pain and mitigate disability [13,14]. Monitoring the patient's posture and movement, along with other patient outcomes, is an important component of the PT examination, evaluation, and intervention for LBP.

Leveraging Technology for Posture and Movement Assessment

Traditional methods for assessing posture and movement in PT include visual assessments by clinicians or use of low-technology tools such as goniometers and inclinometers to measure gross range of motion [15]. However, advances in sensor technology allow for more detailed objective measures and enable remote monitoring [16,17]. Remote monitoring can be useful for patient assessment in free-living environments where people engage in diverse activities at home and work [18]. Quantifying the repetitive nature of specific movement patterns, whether at home or in the workplace, can help identify posture and movement factors that may be linked to the risk of developing and perpetuating LBP [19-21].

Remote monitoring of low back posture and movement can also be used to monitor patient performance of and adherence to their prescribed home exercise program. Customized by physical therapists, these home exercise programs offer practical and cost-effective management of LBP [2,7]. Adherence to and proper execution of home exercises correlate with better pain management, function, and self-perceived progress [12,22-25]. However, people with LBP have several obstacles that hinder exercise performance at home [7,11]. Impaired proprioception in patients with LBP limits their ability to sense whether they are performing home exercises accurately [15,26,27]. Moreover, the absence of clinician oversight affects patient engagement with exercises [28,29]. Previous investigators have identified that this lack of monitoring and engagement leads to diminished exercise accuracy and adherence [25].

Remote monitoring for the assessment of low back posture and movement and home exercise adherence also has the potential to enhance the emerging practice of PT via telehealth, or telerehabilitation [30,31]. Successfully implementing telerehabilitation remains challenging, primarily due to limitations in conducting movement assessments, evaluating exercise performance, and providing corrective guidance. Each of these components can be addressed using mobile sensor technologies.

Existing Technologies for Movement Assessment

The reference standard for objective measurement of low back posture and movement is marker-based optical motion capture [32,33]. These systems offer exceptional precision and accuracy, but their use is constrained by space requirements, cost, and the expertise needed to operate them.

Several wearable and minimally invasive devices have been developed to address these limitations. In a systematic review, authors reported on various devices for measuring low back movement, which use accelerometers, electrogoniometers, gyroscopes, and strain gauges [34]. Specifically, inertial measurement units (IMUs) are commonly used portable devices for measuring lumbar spine posture and movement that use a

variety of sensors, including accelerometers, gyroscopes, and magnetometers, making them well suited for capturing acceleration and orientation in real-world settings [35]. However, challenges with IMUs include their rigid structure, susceptibility to soft-tissue artifacts, misalignment, misplacement, and reduced precision during slow movements [36,37]. In addition, IMUs are not able to account for factors such as skin deformation [38] and the complex multisegmental nature of the spine [34]. Multiple IMUs are needed to evaluate spine posture and movement, which can become burdensome to the wearer [39]. Recently, flexible or fabric-based devices using piezoresistive sensors or other types of strain sensors have been used to address some of these previous limitations [37,40,41]. Table 1 shows a summary of existing sensor types for measuring low back posture and movement, characteristics that are measured, and benefits and limitations.

Table 1. Categories of low back sensors—characteristics, benefits, and limitations.

	Optical motion capture system	Electromyography	IMU[a]	Flexible or fabric-based sensors
Characteristic measured				
Kinematics	✓[b]	×[c]	✓	✓
Muscle engagement	×	✓	×	—[d]
Benefits and limitations				
Wearable	×	—	✓	✓
Use in free-living environment	×	—	—	✓
Assumption that spine segments are rigid	✓	N/A[e]	✓	×

[a]IMU: inertial measurement unit.

[b]Yes.

[c]No.

[d]Depends on the sensor.

[e]N/A: not applicable.

Motion Tape

Given the challenges with objective clinical assessment and the limitations of previous portable sensor systems, there is a need for an accurate, low-profile, wireless, wearable device that can be comfortably used both in the clinic and in an individual's free-living environment to assess low back posture and movement. Motion Tape (MT) is a flexible, fabric-based sensor using commercial kinesiology tape designed to be self-adhesive and disposable [42-46]. MT has been tested on the shoulder and ankle joints in human participants [46,47] and has demonstrated the capability to measure skin strain and joint angles in the shoulder and ankle when compared to IMUs and optical motion capture systems [48]. MT has the potential to be applied to the low back and used to measure posture and movement both in the clinic and in a free-living environment.

However, the complexity in using MT for a low back use case is that the lumbar spine is multisegmental and exhibits multiplanar movements with substantial variability in skin stretch when compared to the other extremities tested previously. Therefore, these sensors must be validated for a low back use case.

Purpose and Hypothesis

The purpose of this study was to (1) validate MT for measuring low back posture and movement and (2) assess user acceptability of MT. This is the first step in developing a use case for MT for measuring low back posture and movement. A device that is valid and acceptable in the laboratory could then be tested for use in the clinic and free-living environment for LBP diagnosis, treatment, and prevention and to further improve patient engagement and adherence to a home exercise program.

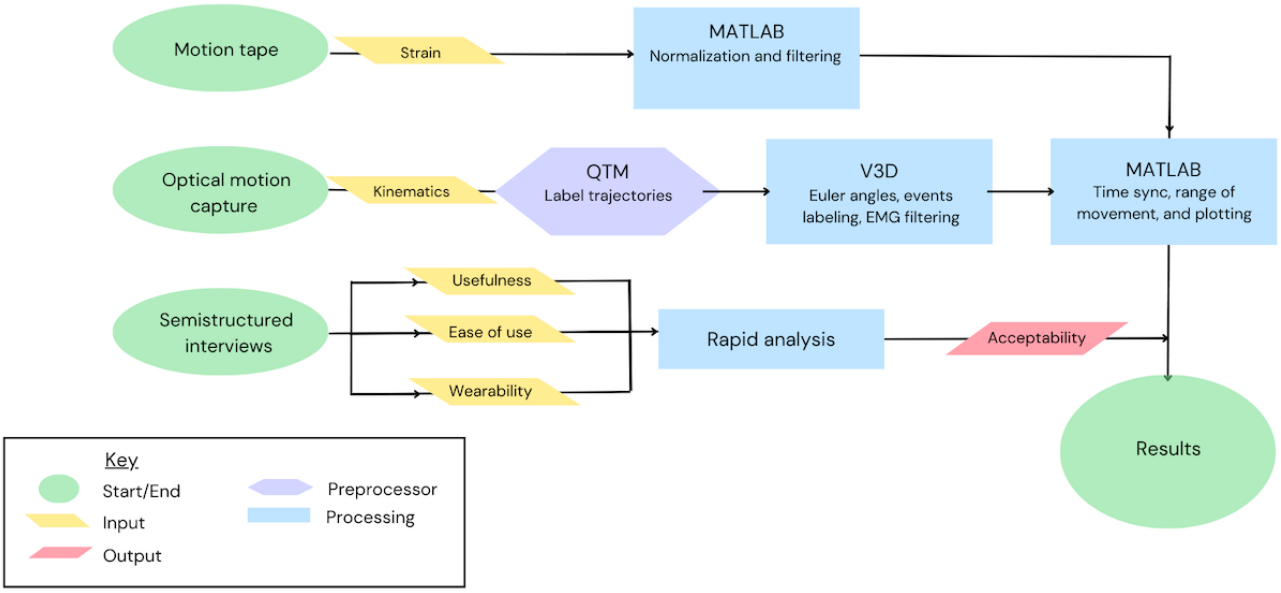
The primary hypothesis of this study was that strain-derived measures from the MT will be correlated with low back kinematics derived from a reference-standard optical motion capture system. The secondary hypothesis of this study was that users would find MT acceptable in terms of usefulness, ease of use, and wearability for the low back use case.

Methods

Design

This study had a cross-sectional, observational, mixed methods (quantitative and qualitative) design (Figure 1), which was used to (1) validate MT for measuring low back posture and movement and (2) evaluate user acceptability of MT using semistructured interviews. Findings from this study will provide a basis for future sensor improvements.

Figure 1. Research overview: evaluation of Motion Tape validity and acceptability. EMG: electromyography; QTM: Qualisys Track Manager; V3D: Visual3D.



Participants

A total of 10 participants were recruited from a university campus using flyers emailed to students, faculty, and staff in the kinesiology and PT programs. A sample size of 10 participants was considered adequate for a preliminary validation and acceptability study to provide a basis for improvement of the prototype device for subsequent testing in larger samples of healthy controls and people with LBP.

People were eligible to participate if they were between the ages 18 and 65 years and reported no history of LBP within the last year. People were excluded from participation if they were (1) unable to follow instructions in English; (2) unable to perform movements such as walking, sitting, and bending of the low back; and (3) unwilling to wear tight-fitting shorts and a sports bra (women) or no shirt (men). Recruitment and testing took place from January 2023 to March 2023. All data collection was conducted in the Rehabilitation Biomechanics Laboratory at San Diego State University.

Ethical Considerations

This study was approved by the San Diego State University Institutional Review Board (HS-2022-0269), and each participant provided written informed consent before taking part. All participant data were coded, and participants were provided US $50 in compensation for their participation time.

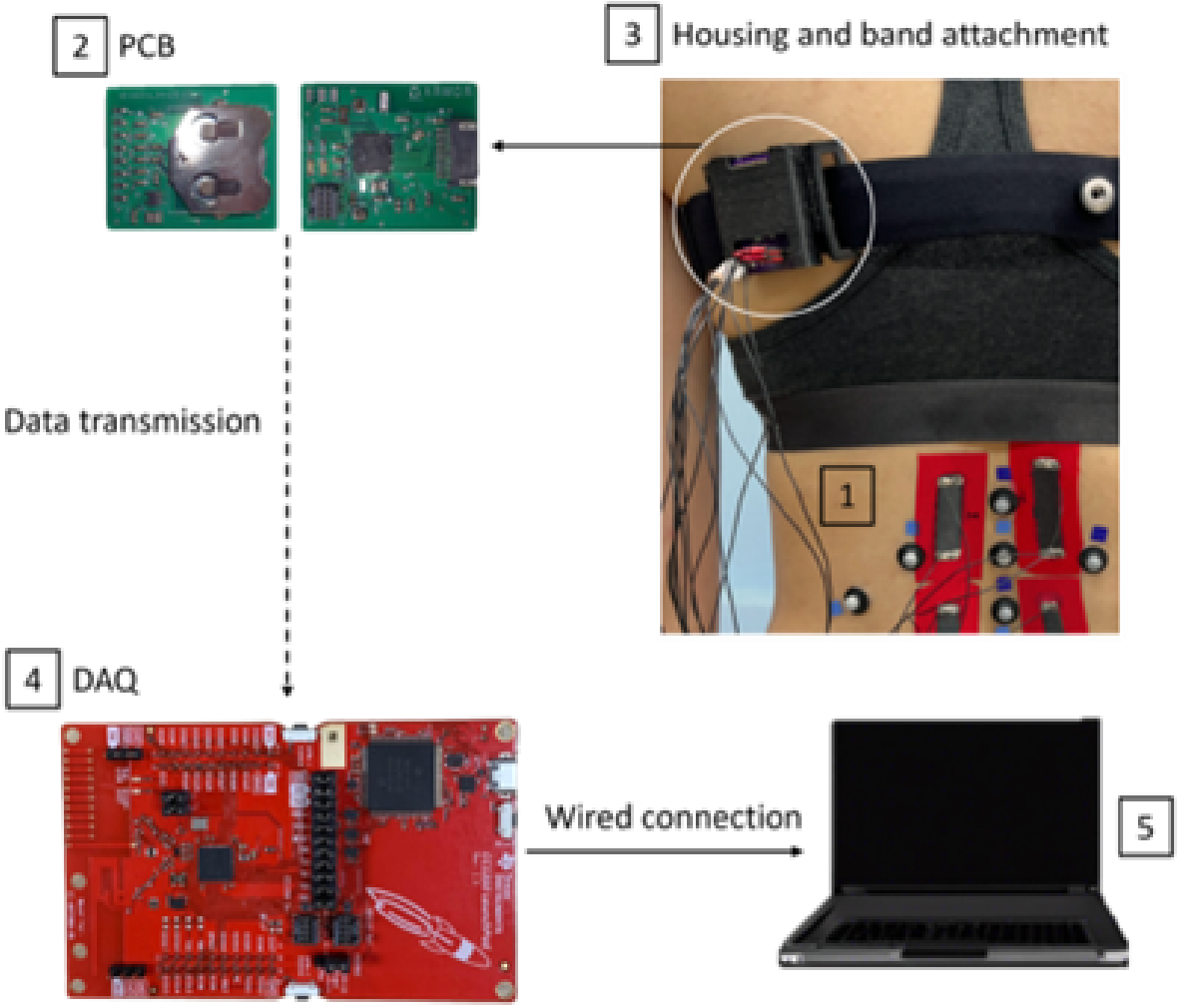
Equipment

MT is made by spray coating commercially available kinesiology tape with a thin film of graphene nanosheets (GNS) and ethyl cellulose (EC) in an ethyl alcohol solution 3 times [49]. To improve overall nanocomposite uniformity and electrical conductivity, a final layer of GNS and EC thin film is added through drop casting [48-50]. A flexible conductive ink is used to cover the sensor, and multistrand wires are soldered on for measurement electrodes at opposite ends of the GNS and EC sensing element [48]. MT has strain sensing due to piezoresistive properties of the integrated nanosheets in the tape [46], described in equation 1, which gives the direct relationship between measured resistance and strain. From previous research, MT has shown stable performance under cyclic strains [46,47].

In equation 1, R is the resistance; K is the constant of proportionality, or gauge factor; and ϵ is the strain.

The conductive wiring that attaches to the tape can directly measure distributed strains with an electrical impedance tomography measurement technique and conductivity reconstruction algorithm. The conductive wires are attached to a custom printed circuit board, which is attached to a band that can be worn on the chest or waist. The board has a Bluetooth module (Bluetooth Low Energy 4.0) transmitter, which transmits the measured signals to the MT data acquisition 2.2 board (CC1350 microcontroller; Texas Instruments), which has a Bluetooth module receiver (Bluetooth Low Energy 4.0). The MT data acquisition board was connected via micro-USB cable to the laboratory desktop computer and saved data in SmartRF Studio (version 7.1; Texas Instruments). The components of the MT system are shown in Figure 2.

Figure 2. The Motion Tape (MT) system includes (1) conductive wiring that transmits the signal from the MT sensing element to a (2) custom printed circuit board (PCB) contained in (3) housing attached to the participant using an elastic band; the PCB sends a signal via a Bluetooth module transmitter to the (4) data acquisition (DAQ) board using a Bluetooth module receiver. The DAQ is then connected via micro-USB cable to (5) a laboratory computer.



An optical motion capture system (Qualisys North America, Inc) was used as the reference standard for the quantitative validation of MT. The motion capture system consists of 16 infrared cameras (sampling rate: 179 Hz) that measure the position of reflective markers on the participant's low back and pelvis (average calibration error values: 0.57, SD 0.10 mm across all participants). Data from the MT and Qualisys software programs were collected simultaneously on the same desktop computer in the laboratory to facilitate time synchronization of measurements using alignment of start times based on time stamps in postprocessing.

Procedure for MT Validation

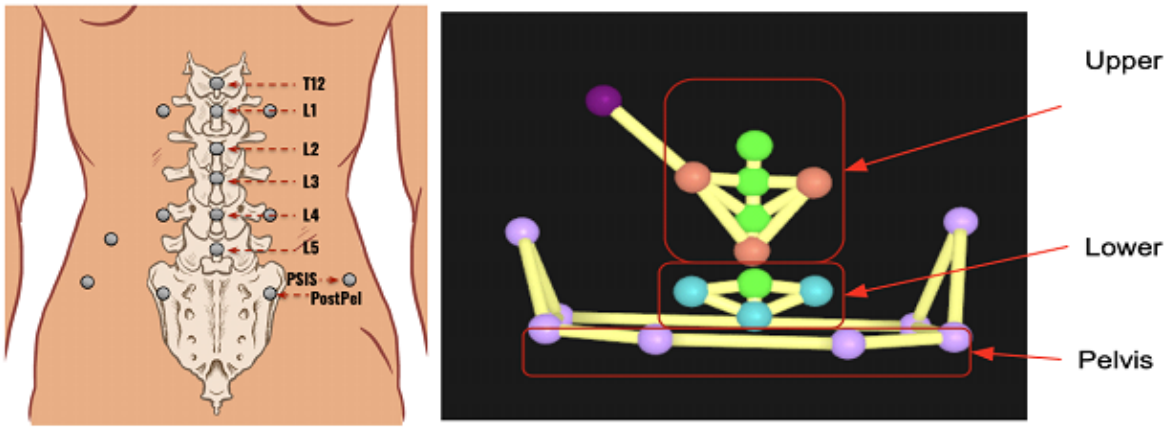
Overview

A physical therapist investigator (SG) with >20 years of experience in motion capture of the spine located the primary anatomical landmarks of the lumbar spine (spinous processes) and pelvis (posterior superior iliac spine, anterior superior iliac spine, and iliac crests) on each participant to place the reflective markers for the optical motion capture system and the MT. The same investigator measured height, weight, and body anthropometrics for each participant. Body anthropometrics were measured in centimeters using a flexible measuring tape and included spine length (T12-S2 and L1-L5), waist circumference at the narrowest part of the waist above the iliac crests, and hip circumference at the widest part of the hips adjacent to the greater trochanter. Hip-to-waist ratio was then calculated by dividing hip circumference by waist circumference. Each participant self-reported their age and sex at birth.

Optical Motion Capture Marker Placement

Reflective motion capture markers were placed on the spinous processes from T12 to L5 and bilaterally to the left and right of L1 and L4 approximately 4 cm from the spinal column (Figure 3). These markers were then used to create a modified version of the multisegmental spine model that has been previously validated and used to collect lumbar spine posture and movement [51]. The upper lumbar segment was defined by the left and right markers lateral to the L1 spinous process and the single marker on the spinous process of L3. The lower lumbar segment was defined by the left and right markers lateral to the L4 spinous process and the single marker on the spinous process of L5. Markers were also placed bilaterally on the posterior superior iliac spine, anterior superior iliac spine, posterior pelvis, and iliac crests, which were used to define the pelvis segment.

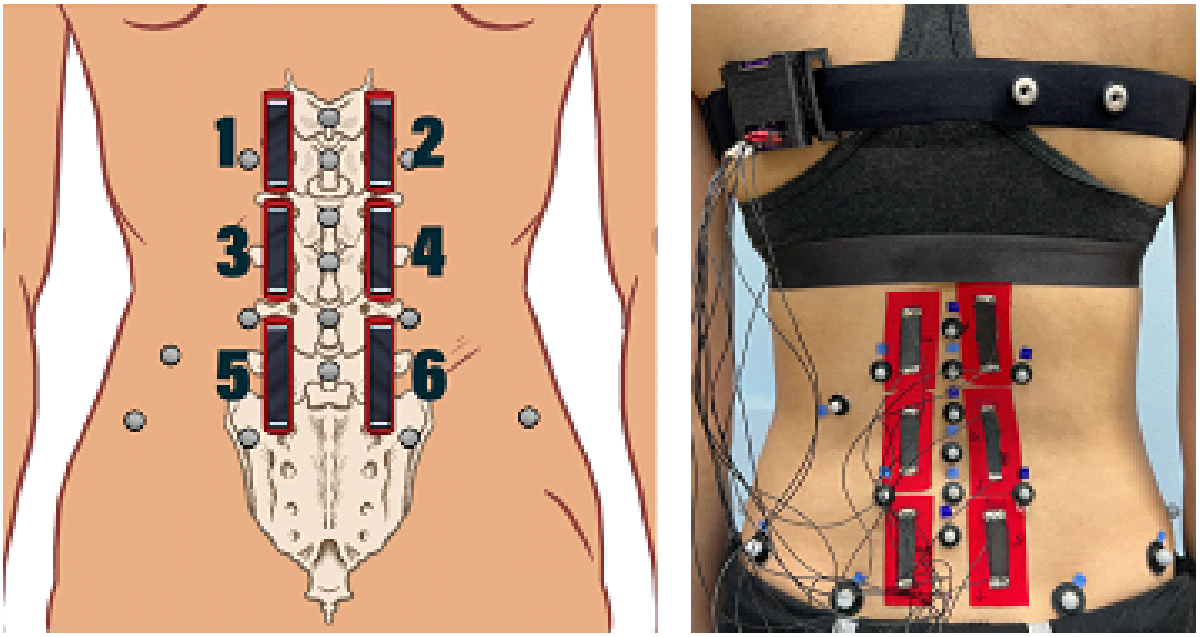
Figure 3. Reflective marker placement and multisegmental lumbar spine model for optical motion capture measurements. postpel: posterior pelvis; PSIS: posterior superior iliac spine.



MT Placement

A total of 6 MTs were placed on the low back just lateral to the spinal column in a 3 × 2 matrix pattern (Figure 4). Specifically, placement of the MTs started with the middle MTs (sensors 3 and 4) such that the bottom edges of the middle MTs were placed at a level just above the L4 spinous process and crossed the L2-to-L3 and L3-to-L4 junctions for most participants. The superior MTs (sensors 1 and 2) were placed above the middle MTs such that the superior MTs crossed the T12-to-L1 and L1-to-L2 junctions for most participants. Finally, the inferior MTs (sensors 5 and 6) were placed below the middle tapes such that the inferior MTs ideally crossed the L4-to-L5 and L5-to-S1 junctions. This placement was achieved for all but 10% (1/10) of the participants, for whom the inferior MT did not cross the L5-to-S1 junction. For this study, placement of MT was chosen to best parallel the spine model used with the motion capture system [51,52] and help distinguish low back movements in all planes of motion.

Figure 4. Motion Tape sensor placement.



Measured Movements

Participants were asked to perform several simple trunk movements (forward flexion, extension, right and left lateral flexion, and right and left seated rotation) while data were simultaneously being captured by the motion capture system and the MT (Figure 4). The complete list of tested movements is shown in Table 2.

Table 2. Trunk movements, positions, repetitions, and range of movement.

Movement	Position	Repetitions
Lateral bending	Standing	3 repetitions to end range on each side (left and right)
Rotation	Seated	3 repetitions to end range on each side (left and right)
Extension	Standing	3 repetitions to approximately 50% of end range[a]
Forward flexion	Standing	2 repetitions to approximately 50% of end range[a] and 1 repetition to 100% of end range

[a]50% range was used to avoid maximum capacity of sensors before the end of the session.

Data Processing for MT Validation

Overview

Kinematic data from the optical motion capture system were processed in Qualisys Track Manager (Qualisys North America, Inc) to label marker trajectories and interpolate missing marker data. Kinematic data were then imported into Visual3D (C-Motion, Inc), where a previously developed multi-segmental spine model (Figure 3) was applied and lumbar spine kinematic angles were computed for each movement trial [51]. Lumbar spine kinematic angles were calculated using Euler angles (XYZ sequence) among the upper lumbar, lower lumbar, and pelvis segments (Textbox 1). Processed kinematic angles were then imported into MATLAB (release 2021b; MathWorks) for analysis with MT strain data.

Textbox 1. Kinematic measurements from the optical motion capture system.

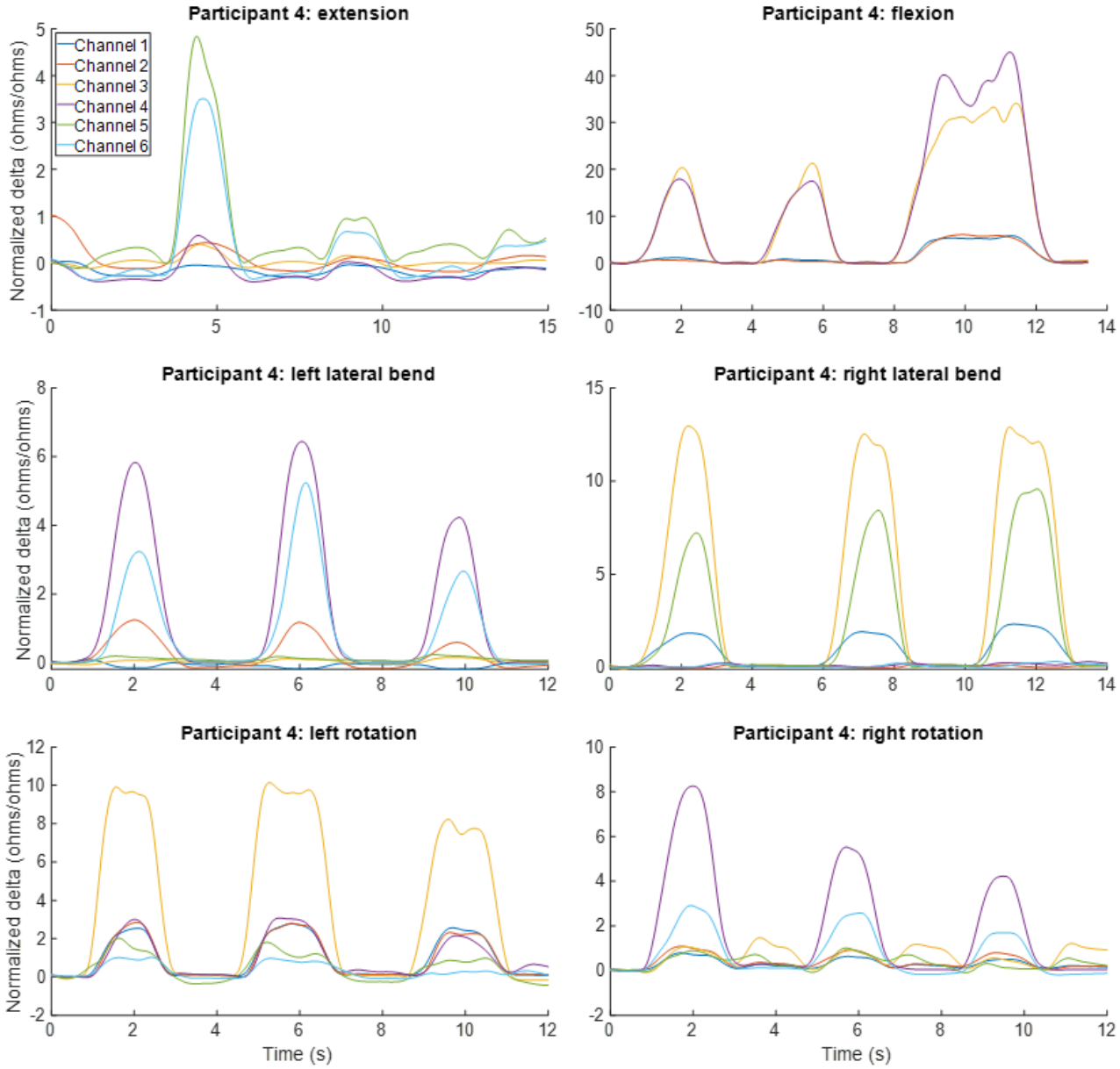
Lumbar spine angle and relative segments

- Upper lumbar angle: upper lumbar segment (L1-L3) relative to lower lumbar segment (L4-L5)
- Lower lumbar angle: lower lumbar segment (L4-L5) relative to pelvis segment

Raw resistance data from the 6 MTs were imported into MATLAB and converted from hexadecimal characters to decimal values. The change in resistance was divided by the baseline resistance individually for each sensor and each movement trial to derive strain (equation 1). Resistance values were then read and stored in an array where time vectors were generated linearly from start to end using time stamps. Once all MT resistance files were imported, stored, and converted to readable time series, they were filtered using a Hampel filter to remove outliers. The filter is based on the median and median absolute deviation of the data set. For some MT placements and some movements (eg, lower MTs during forward flexion), MT stretch exceeded resistance thresholds for the sensing element, resulting in data with excessive levels of noise. These data streams were identified and removed using a threshold criterion of resistance of >10 SDs from the mean resistance across participants for the given movement.

To illustrate the ability of MT to capture data across all test movements, strain measured using the 6 MTs for 1 representative participant is illustrated in Figure 5. Data for MTs 5 and 6 are omitted for forward flexion because the stretch during this movement exceeded the MT strain threshold for this participant.

Figure 5. Motion Tape strains for all movements for a representative participant.



Motion capture kinematic data and MT strain data were aligned in MATLAB using the computer time stamp for the start of each trial from the motion capture system. Excess data at the start and end of the trial for strain were then trimmed to ensure identical start and end times for kinematics and strain. MT strain data and motion capture kinematic data were normalized separately for each trial to allow for the use of MATLAB's cross-correlation function. The strain data were normalized from –1 to 1 such that –1 corresponded to peak sensor compression and 1 corresponded to peak sensor tension. The strain-derived data were then shifted such that each movement started at zero strain. Kinematic data were also normalized from –1 to 1 such that –1 and 1 corresponded to peak movement in each direction. For analysis purposes, the normalized kinematic data from forward flexion, left lateral bending, and right-seated rotation were multiplied by –1 such that all kinematic measurements were positive for the primary movement direction (eg, upper lumbar flexion is a positive angle for the forward flexion movement).

Analysis for MT Validation

In previous studies, MT has been validated to measure strain using ground truth input from a TestResources 100R load frame, where resistance was recorded using a Keysight 34401A digital multimeter [48]. This study used an accepted reference standard (optical motion capture) for validating kinematic measurements using MT. Cross-correlation was used to test concurrent validity of MT strain in reference to motion capture kinematics [53]. Cross-correlation is a measure of the association between 2 data series as a function of the time displacement (phase shifts) of one relative to the other. Strain data from the 6 MTs were compared to motion capture kinematics for adjacent low back segments, as outlined in Textbox 2. Cross-correlation coefficients at zero phase shift were derived to ensure that both the magnitude and timing of MT strain were considered for evaluation of concurrent validity. Coefficients were calculated separately for each participant, movement trial, and MT. Positive cross-correlation values reflect MT tension with changes in

kinematic angle, and negative values reflect MT compression with changes in kinematic angle. Median values and range of cross-correlation coefficients at zero phase shift were calculated across all participants.

Textbox 2. Lumbar spine kinematics used as reference for validating Motion Tape.

Motion Tapes (Figure 4) and lumbar spine angle (Figure 3)

- 1 and 2: upper lumbar angle
- 3 and 4: upper lumbar angle
- 5 and 6: lower lumbar angle

Procedure for User Acceptability

Semistructured Interviews

To assess user acceptability of MT, semistructured interviews were conducted with all participants (N=10) after laboratory testing. A semistructured interview guide (Multimedia Appendix 1) was developed by investigators based on the technology acceptance model (TAM) [54-56]. The guide included open-ended questions designed to evaluate user perceptions of MT in 3 key domains of the TAM: usefulness, ease of use, and wearability. Perceived *usefulness* was defined as the extent to which participants believed that using MT could improve treatment of LBP [54-56]. Specific interview questions related to (1) potential advantages of using MT in PT treatment and recovery, (2) potential impact of MT use on adherence to home exercise programs, and (3) physical attributes of MT that could positively or negatively affect its usefulness. Perceived *easeof use* was defined as the extent to which participants believed that using MT would be effortless for evaluation and treatment of LBP [54-56]. This domain was evaluated using questions related to participants' perceptions regarding (1) potential ease of learning to use MT, (2) level of instruction required for effective use of MT, and (3) ease of using MT unsupervised in a home setting. *Wearability* was defined as the extent to which participants believed that MT sensors provided a comfortable and secure fit when applied to their back [57]. To assess wearability, interview questions explored participants' views on various aspects of MT, including its adhesion, fit, feel, and comfort level with the application and prescription of MT by a medical professional to monitor posture and movements at home. Finally, additional interview questions were included to gather participant suggestions for future improvements of MT. Interviews were recorded using digital voice recorders and transcribed for subsequent analysis.

Analysis for User Acceptability

Rapid qualitative analysis (RQA) was conducted to assess the interview responses effectively and efficiently to identify major themes [58]. Codes and themes for the RQA were deductively developed based on the TAM framework and the study objective. The codes and themes for the RQA allowed for quick sorting of interview dialogue. To ensure rigor and consistency, a constant comparative approach was used at each stage. First, the 4 data analysts independently completed a summary report for each interview with quotes and relevant topics under identified themes. Once the individual coding and summary reports for all interviews were completed, the investigators consolidated them into a combined RQA summary report for each interview, unifying themes and reconciling discrepancies by consensus through discussion. Summary reports for each participant were then transferred into a matrix where each row was a participant quote and each column was a domain. From this matrix, investigators identified underlying themes and subthemes across the 10 interviews.

Results

Demographics

A total of 10 people participated in the study (n=5, 50% male and n=5, 50% female; mean age 22.4, SD 2.1 y). Participant ages and anthropometric measurements are presented in Table 3.

Table 3. Participant age and anthropometric measurements.

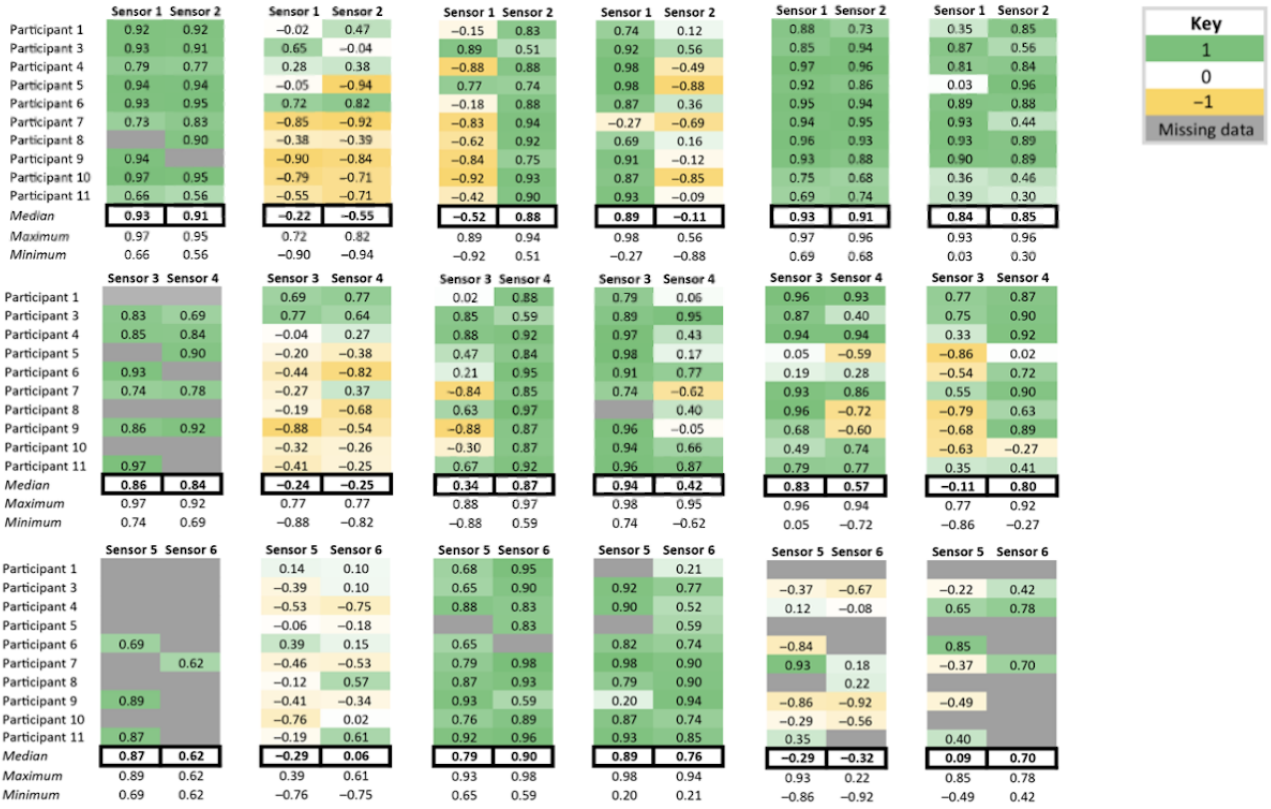
Demographics	Male participants (n=5)	Female participants (n=5)
Age (y), mean (SD)	23.6 (2.9)	21.2 (1.8)
Height (in), mean (SD)	70.9 (3.7)	64.2 (4.0)
Weight (pounds), mean (SD)	178.8 (41.6)	125.1 (11.4)
Hip-to-waist ratio (cm), mean (SD)	1.2 (0.04)	1.3 (0.3)
Spine length (T12-S2; cm), mean (SD)	16.8 (1.9)	16.4 (1.3)
Spine length (L1-L5; cm), mean (SD)	10.7 (1.2)	9.7 (0.6)

MT Validation

Values for cross-correlation coefficients at zero phase shift between MT and motion capture low back kinematic measurements across the 6 movements for all 10 participants are presented in Figure 6. Across movement trials, 13.9% (50/360) of MTs had missing data because resistance exceeded the threshold of 10 SDs. There are two potential explanations for why sensors exceeded the resistance threshold: (1) the level of strain for the low back region exceeded the capacity of the

sensor and (2) sensor resistance increased across trials due to sensor fatigue, resulting in high resistance values even at lower strains. The former was most common during flexion movements, and the latter occurred more often in trials near the end of the testing protocol, such as rotation movements.

Figure 6. Cross-correlation values at zero phase shift for low back Motion Tape strain versus motion capture kinematics. The level of correlation is depicted using a color scale, with green denoting a positive correlation with a maximum of +1 (Motion Tape tension), yellow denoting a negative correlation with a maximum of –1 (Motion Tape compression), and no color for cross-correlation values near 0. Shades of each color reflect magnitudes of correlation, with lower correlations in lighter colors and higher correlations in darker colors. Trials with missing data are colored in gray.

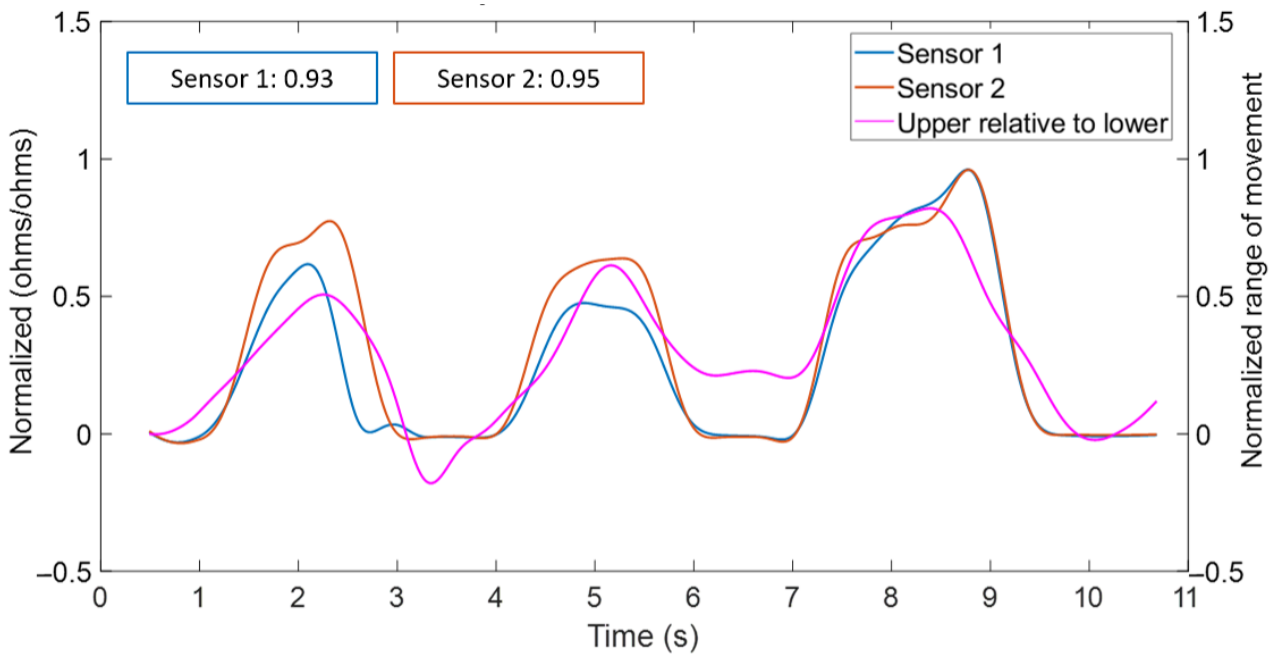


Forward Flexion Movement

For *forwardflexion* movements, cross-correlations were mostly positive (green) and moderate to high (median 0.62-0.93), indicating that MT sensors were in tension and closely paralleled motion capture kinematic measures during forward flexion (Figure 6). However, there was a high rate of sensor failure for flexion movements (45%; 27/60), particularly for lower lumbar MTs.

To illustrate the association between MT strain and motion capture kinematics during forward flexion, data for sensor 1, sensor 2, and the upper lumbar angle are shown in Figure 7 for a single participant. In this example, upper lumbar MT strains are highly correlated with the upper lumbar angle (R=0.94 for sensor 1 and R=0.95 for sensor 2). These positive correlations reflect MT tension, which was consistent for all forward flexion movements.

Figure 7. Case example of high positive cross-correlation between Motion Tape strain for Sensor 1 and 2 and motion capture upper lumbar angle during forward flexion.

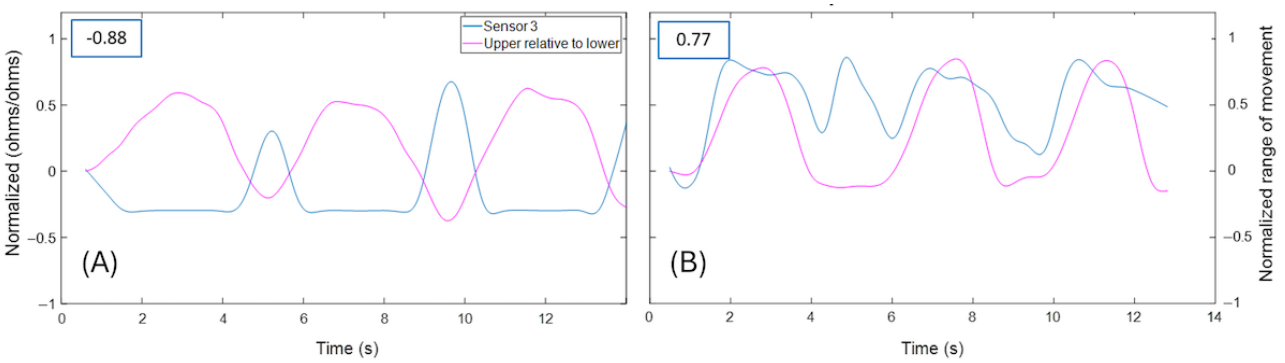


Extension Movement

For *extension* movements, many cross-correlation coefficients were negative, indicating MT compression. However, there were also several positive cross-correlations that had varying magnitudes. This resulted in many cross-correlations that were high in magnitude for individual MTs and participants but median values that were low (median –0.55 to 0.06), indicating that strain measures closely paralleled kinematic measures but were sometimes in tension and sometimes in compression.

To illustrate varied patterns of MT strain when compared to motion capture kinematics during extension, Figure 8 shows sensor 3 strain data and upper lumbar angle measures for 2 different participants who performed extension. For the first participant (left), MT measured compression (negative deflection) during the extension movement, resulting in a high negative cross-correlation value (R=–0.88). For this participant, sensor 3 also appeared to show a limit in the ability to measure maximal compression values, as evidenced by a flattening of the strain curve at peak extension. The second participant (right) showed an unexpected pattern during extension, in which MT measured tension (positive deflection) during the extension movement, resulting in a high positive cross-correlation value (R=0.77). For both participants, an increase in MT strain was also evident when the participant was returning to an upright position from the extension movement, which did not appear to align with the decrease in the kinematic measures.

Figure 8. Case examples of different cross-correlation values between sensor 3 strain and motion capture upper lumbar angle for 2 different participants during extension.



Lateral Bending Movements

For *right and left lateral bending movements*, cross-correlation coefficients were positive and high (median 0.87-0.94) on the side opposite the direction of the lateral bend, indicating that MT was typically in tension and closely paralleled kinematic measures during the lateral bend movements. Cross-correlation coefficients for MT sensors on the side ipsilateral to the lateral bend movement were more variable (median –0.52 to 0.79). This illustrates that some ipsilateral sensors (upper) were in compression during the trunk lateral bending movement but correlations were low to moderate, whereas other sensors (lower) were in tension and showed high positive correlations. The middle sensors on the side ipsilateral to the lateral bending

movement showed participant-to-participant variability in both direction and magnitude of cross-correlations.

Figure 9 illustrates a case example of the expected MT strains for right and left lateral bending, in which the ipsilateral MT strain is negatively correlated (compression) and the contralateral MT strain is positively correlated (tension) with the motion capture upper lumbar angle. In contrast, Figure 10 illustrates a case example of a positive correlation between MT strain and motion capture kinematics on both sides of the low back during left lateral bending, suggesting that both MTs were in tension during this movement. However, during right lateral bending for the same participant, the expected MT tension on the contralateral side and compression on the ipsilateral side were observed.

Figure 9. Case example of upper sensor positively correlated (tension) with upper lumbar angle on the contralateral side and negatively correlated (compression) on the ipsilateral side during left (A) and right (B) lateral bending.

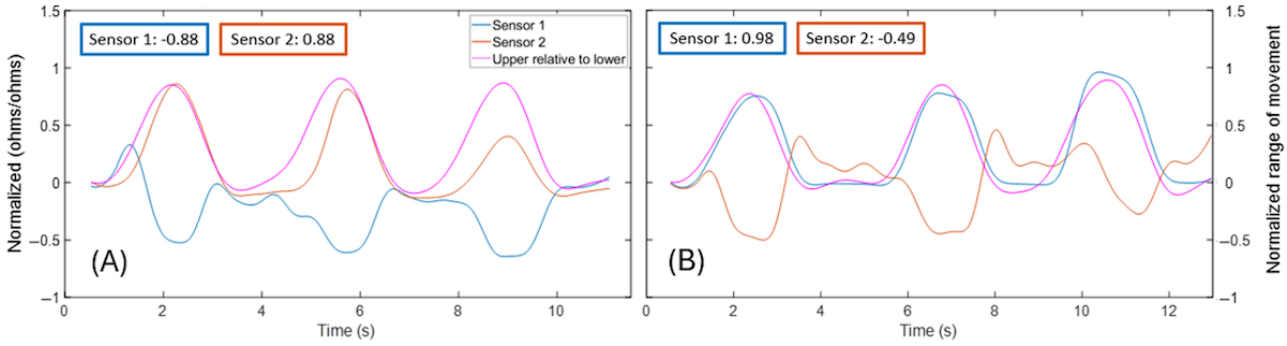
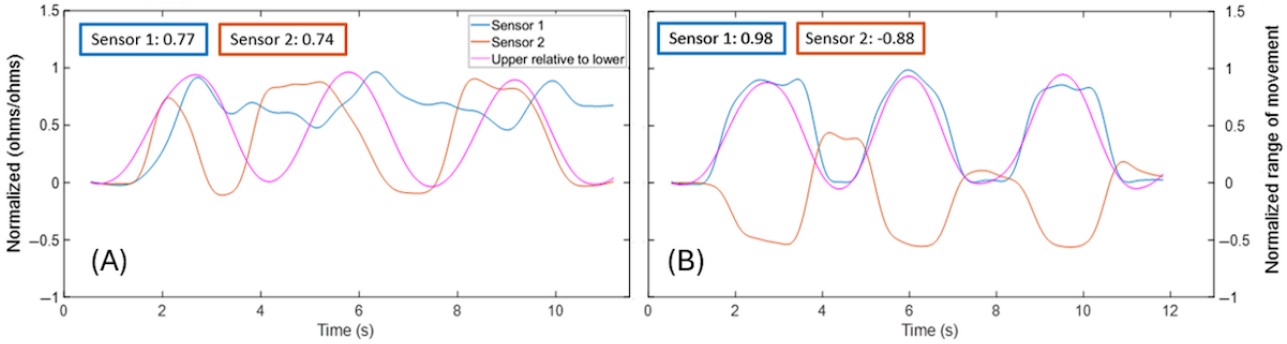


Figure 10. Case examples of positive correlation (tension) between bilateral upper sensors and upper lumbar angle during left (A) lateral bending, but not with right (B) lateral bending.



Rotation Movements

For *right and left rotation movements*, cross-correlation coefficients were positive and high (median 0.84-0.93) for both upper MTs for both movement directions, indicating tension and strong association with motion capture kinematics. Cross-correlation coefficients for middle and lower MTs were more variable (median –0.11 to 0.83). Most middle sensors were in tension on the side *ipsilateral* to the rotation movement, and MT strain was highly correlated with motion capture kinematics (median 0.80-0.83 for sensors 3 and 4). However, on the side contralateral to the rotation movement, the middle sensors showed wide participant-to-participant variability in both direction and magnitude of cross-correlations. Cross-correlations between lower sensors and motion capture kinematics varied widely on the sides both ipsilateral and contralateral to the rotation movement (median –0.32 to 0.70).

Figure 11 illustrates a case example for data from middle MTs (sensors 3 and 4) for right and left rotation for a participant, in which the ipsilateral MT exhibited a positive correlation (tension) and the contralateral MT exhibited a negative correlation (compression) with the upper lumbar angle for both rotation directions. In contrast, a second case example (Figure 12) illustrates middle MTs that were both positively correlated with the upper lumbar angle during both left and right rotation, suggesting that both sensors were in tension during these movements.

Figure 11. Case example of ipsilateral positive correlation (tension) and contralateral negative correlation (compression) between middle sensors and upper lumbar angle during seated left (A) rotation and right (B) rotation.

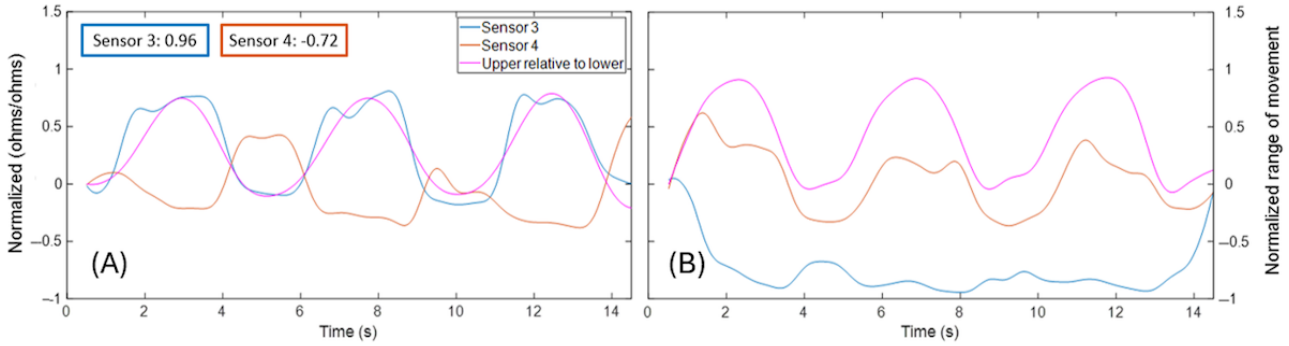
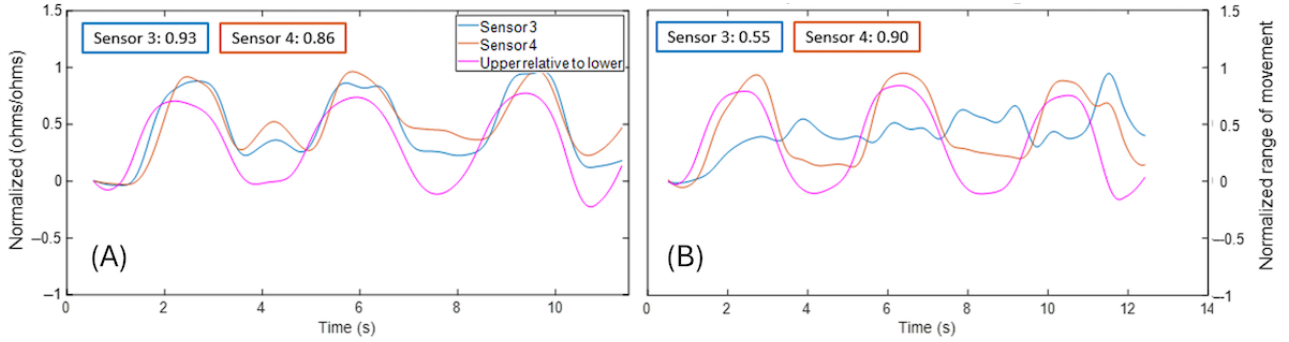


Figure 12. Case example of bilateral positive correlation (tension) between middle sensors and upper lumbar angle during seated left (A) rotation and right (B) rotation.



User Acceptability

Overview

Qualitative results from participant interviews on user acceptability of MT were organized based on the domains of the TAM, including perceived wearability, perceived usefulness, and perceived ease of use (Table 4) [54-56]. A total of 13 subthemes were also identified and designated as having a "positive," "negative," or "neutral" valence. Positive subthemes were those that the participants perceived as a positive attribute of MT, negative subthemes were those perceived by participants as negative, and neutral subthemes were those perceived as neither positive nor negative.

Table 4. Themes (n=3), subthemes (n=13), and valences of user acceptability of Motion Tape (MT).

Theme, valence, and subthemes	Respondents (n=10), n (%)
Theme 1: perceived wearability	
Positive valence	
MT has secure adhesive properties.	10 (100)
MT removal process is not painful.	10 (100)
MT is a good fit on low back anatomy.	9 (90)
MT causes minimal discomfort and is not very noticeable during low-intensity movements.	8 (80)
Negative valence	
Concerns with MT's wiring and attachment band	7 (70)
Awareness of MT may limit ROM[a] and exercises for some people.	4 (40)
Theme 2: perceived usefulness	
Positive valence	
MT may offer positive benefits for use in physical therapy.	10 (100)
Potential benefits for MT use in telehealth	10 (100)
MT could increase patient adherence to and motivation to perform home exercise programs.	5 (50)
MT offers benefits for personalized medicine.	5 (50)
Negative valence	
Overall concerns about MT usability and durability	6 (60)
Theme 3: perceived ease of use	
Neutral valence	
MT is easy to use but may be difficult for a patient to apply themselves.	6 (60)
Mixed perceptions on whether one could use the MT on their own at home	6 (60)

[a]ROM: range of motion.

Domain 1: Wearability

Regarding perceived *wearability*, most participants were familiar with commercially available kinesiology tape. Thus, their thoughts on perceived wearability reflected both their experience with kinesiology tape and their experience wearing MT during laboratory testing. Generally, participants felt comfortable wearing MT and would feel comfortable if a medical professional prescribed MT for them to wear. All participants felt that MT was secure on their back during validation testing. One participant stated that the tape was "pretty secure and stretched with your body."

Participants predicted that the tape would remain adhered on their back for approximately 2 to 3 days depending on various factors such as the level of activity, temperature, and moisture. One participant gave an example of how the adhesive properties would change:

> *If you worked out or did something really physical it could get less sticky over time, but I think that the tape is pretty stable otherwise.*

Regarding the *fit* of MT, most participants felt that it was a good size and did not hinder their movements. They noted that it adhered closely to their skin, was not bulky, and could be stored easily. However, one taller participant mentioned the following:

> *Since I'm a taller individual, some strips weren't long enough for my back.*

Regarding the *feel* of the MT on their skin, most participants were aware of its presence but generally found it comfortable and unobtrusive; one participant stated the following:

> *It didn't feel like it was in the way of anything, and it didn't feel like it was there.*

While they could feel a slight pull on their skin during movements with larger ranges, this was not perceived as a significant problem. One participant said the following:

> *When I was bending down [flexion], I could feel it more. But otherwise, it wasn't that bad. I kind of got used to it.*

Regarding *awareness* of MT while exercising, participants had varied responses. Most perceived that the tape would not impede their exercise performance, but some had concerns. They noted being aware of and concerned about damaging or dislodging the sensor wires during exercises, especially with intense workouts. They generally preferred a wireless design and found that the MT wires were "messy," "hard to handle," and "somewhat restrictive." In addition, participants anticipated that they would feel the sensors on their bodies, especially when their clothing rubbed against them. One participant thought the following:

> *The Motion Tape sensor's adhesion is pretty strong, but if it started to peel off, then I might be more aware of not letting it come off.*

A few participants also expressed concerns about the attachment band for the MT system, particularly around the chest. They believed that this feature might be uncomfortable for larger or female individuals. Regarding removal of the MT, participants reported minimal pain and discomfort; several participants likened the sensation to removing a Band-Aid and did not find it very painful.

Domain 2: Perceived Usefulness

Regarding a *PT use case*, participants felt that the MT offered several useful benefits. For example, several participants agreed that this would be helpful for identifying the cause of pain and give medical providers that information. A few participants mentioned that the MT could be used by the physical therapist:

> *To monitor stress that's being put on a specific part of the back and spine and figure out a way to adjust or to alleviate some of that pain and tension.*
>
> *To give much more insight into what I am actually feeling.*
>
> *To track the patterns of your movement and recruitment of your muscles, and check if there is any irregularity.*

In addition, participants expressed that the MT could offer continuous monitoring for them even when the physical therapist is not present, allowing for better patient management. One participant suggested that it could detect if "you're moving a certain way that could be further injuring you."

Most participants felt that the use of MT to monitor and record their PT exercises would serve as a good reminder or external cue to increase their adherence to their prescribed home exercise program. Participants noted that having their exercises recorded and monitored would provide them with more motivation to do their exercises and perform them more regularly and correctly. For example, one participant stated that they would "probably do the PT exercises more regularly, especially since it's being recorded. Can't really lie about that."

Furthermore, participants expressed that MT offers advantages for personalized medicine and precise data on back pain. Participants felt that the MT would be helpful for pain management, injury rehabilitation, and providing a better understanding of movement. One participant stated that MT "offers an opportunity to measure movement of the human body in a new way [for treatment and recovery]."

Furthermore, participants expressed that it would also be particularly useful for older people who are not able to make appointments with their provider:

> *For the older patients who aren't able to make their doctor's appointments, if they had [motion] tape applied to them and then they were sent home, I think it would be pretty easy for them...*

Thus, participants generally felt that the MT was beneficial and advantageous for monitoring movements in a free-living environment to assist with PT management.

Regarding a *telehealth use case*, participants felt that there was some potential usefulness for MT. Some participants expressed that they perceived the use of MT for telehealth more convenient and easier than attending in-person PT appointments. Participants predicted that there would be an increase in remote visits because they felt that the MT would allow them to be more independent and do PT on their own time without having to schedule in-person appointments and leave their homes. One participant explained the following:

> *It would save people a trip outside, or if they were busy, they could just do it whenever they could, instead of having to schedule an appointment. I think it could definitely benefit people.*

Participants also expressed that they could envision MT increasing their compliance and adherence to therapy, leading to better outcomes. They felt that the MT would allow the physical therapist to see what is going on and whether patients are performing their exercises correctly, which would lead to increased engagement of the patient in their own treatment and incentivizing adherence to the home exercise program. One participant explained the following:

> *Patients would feel like they're more involved in the treatment, rather than just the PT evaluating them over a call and then telling them exercises to do.*

However, a few participants did not feel that MT would increase remote PT sessions. For example, one participant expressed concerns regarding the use of the MT with older individuals as the older generations may find it challenging to use the technology and some prefer in-person visits with a physical therapist. In addition, another participant expressed that, while the device may be helpful on days when in-person visits are not possible, some individuals still prefer to use the equipment available in the clinic. Therefore, while there are potential benefits, the use of the device and technology for telehealth may not be suitable for everyone and should be carefully considered on a case-by-case basis.

Domain 3: Perceived Ease of Use

Regarding the *application process* for MT, participants felt that MT would be easy to use but difficult to apply to one's own back. Specifically, participants expressed that older or less flexible individuals would struggle in applying it to their back. One participant stated the following:

> *Grandma would struggle, but someone mobile enough wouldn't struggle after getting thorough instructions and doing it a couple of times.*

Perceptions of the application process also affected how the participants felt about whether the average person would be able to use the MT on their own at home. Some participants indicated that they would prefer that a physical therapist apply it to their back, whereas others felt that they would be able to apply MT themselves if shown how to apply it appropriately.

Regarding the *use* of MT, participants expressed that it would be generally easy to use but they would also need detailed instructions on how to use it properly. Participants suggested a variety of instructional methods, including written instructions, pictures, videos, in-person visits, and demonstration by a physical therapist; visuals and demonstrations were emphasized as most important. Participants also noted that they needed information on the calibration process, how to turn the sensors on, how to charge the sensor, how to reapply the tape if it falls off, how to care for the tape or reattach wires if they fall off, and whether the tape is safe to wear in water. There were some concerns expressed about ease of use. Specifically, some participants mentioned that lack of access to technological support could make it difficult for some individuals to use the MT without assistance.

Discussion

MT Validation

MT demonstrated the ability to measure low back movement in multiple directions and in a manner comparable to that of a reference-standard motion capture system. Cross-correlations between MT strain and motion capture kinematic measures were moderate to high for most movement directions and appeared to better reflect kinematics for movement directions in which MT was in tension (Figure 6). Patterns of MT strain appeared different for different low back movements (eg, flexion, extension, lateral bending, and rotation), suggesting that MT can distinguish between different movement directions (Figure 5).

However, for several movements and sensors, there was variability in magnitude and direction of association between MT strain and motion capture kinematics. Figures 8-12 show case examples that demonstrate variability in direction (positive vs negative) of cross-correlations during extension, lateral bending, and rotation movements. Variability in direction of association, which reflects MT tension (positive) versus compression (negative), may be the result of differing movement strategies performed by each participant. As an example, Figure 10 illustrates a positive correlation between MT strain on *both* sides of the low back and the lumbar angle during *left* lateral bending (tension bilaterally) but a positive correlation only on the *contralateral* side (tension) and a negative correlation on the *ipsilateral* side (compression) during *right* lateral bending. These data may suggest that lateral bending movements are performed, in some cases, by lengthening the spine (Figure 10; bilateral tension with left lateral bending) and, in other cases, by compressing or pivoting at spinal segments (Figure 10; tension and compression with right lateral bending). Low back kinematics during lateral bending were not different between sides for this case example, suggesting that MT was able to capture a level of data that is different from motion capture, which could be useful for identifying new impairments in people with LBP.

A limiting factor of the existing lower back sensing technologies summarized in Table 1 is that some can only capture movement in a single plane [59]. Other existing devices that can capture multiple planes of movement often rely on more rigid sensors [38,60]. Ensuring that the device seamlessly integrates with the wearer's natural movements and environment is a common challenge faced for wearable sensor technology [61]. MT provides a cost-effective solution for capturing kinematics in multiple planes and that has the potential for longer-term use in a free-living environment [60]. MT's capability to stretch and conform with the skin sets it apart from other fabric-based and flexible sensors, providing more comprehensive measurement of lumbar posture and movement [37,51,62,63]. Therefore, MT holds the potential to become a valuable tool for the assessment, treatment, and monitoring of LBP.

User Acceptability

Several key themes emerged related to the wearability, usefulness, and ease of use of MT. Concerning wearability, participants observed that MT securely adhered to their backs during the validation testing, and they anticipated that it would stay in place for approximately 2 to 3 days, with some variation due to external factors. This aligns with the typical time frame of use for commercially available kinesiology tape, estimated to last for 2 to 3 days [57,64]. The flush-with-skin fit and feel were perceived as not likely to disrupt daily activities, but participants expressed concerns about the wired design, the chest band attachment, and potential friction between clothing and the sensors. The current MT system design, with wires and a chest band attachment, may not be optimal [61]. Previous research has highlighted the widespread adoption and use of *wireless* technologies in various fields, particularly in the domain of health care wearable devices [58]. Therefore, a future iteration of MT that minimizes the wires and chest band attachments would be ideal to improve user perceptions of wearability.

Regarding usefulness, participants believed that MT had the potential to enhance personalized PT treatment and, importantly, serve as a helpful reminder to engage in and adhere to prescribed exercises. Devices that allow for remote monitoring of patients have the potential to broaden the scope of assessments, enhance treatment outcomes, and enable physical therapists to make informed decisions for future patients [61]. Nevertheless, certain design limitations might hinder the usefulness of this device by older, less flexible, or larger individuals. Our findings align with earlier research studies emphasizing the need for wearable sensors to be not only useful and convenient but also inclusive and accessible to a diverse population [65]. Therefore, future iterations of MT should address inclusivity and accessibility concerns to enhance user perceptions of usefulness.

The *ease of use* of a wearable device is closely intertwined with its usability and the user's confidence in its correct operation [62]. Regarding ease of use, participants acknowledged that applying MT might be challenging without assistance, but they anticipated that it would be straightforward if accompanied by detailed instructions. Providing comprehensive information about the device fosters confidence and competence in its correct use, leading to reduced errors and improved user acceptability [63,66]. Failing to provide adequate use instructions could result in the incorrect use of MT, potentially adversely affecting patient outcomes and decreasing user acceptability.

Overall, participants expressed enthusiasm and curiosity regarding the innovative nature of MT and believed that it could

offer more personalized and insightful treatment for LBP, particularly due to its potential for remote monitoring. However, they also highlighted certain aspects that would require attention in future iterations to enhance user acceptability.

Limitations and Opportunities for Future Research

The participants in this study were primarily university students in exercise and nutritional science programs who were young and fit, may have more knowledge of low back anatomy and PT, and may be more inclined to accept new technologies than people from other demographics. Collectively, this negatively impacts the generalizability of the findings to other clinical populations. Older adults or individuals with obesity may display different skin strains due to differing characteristics of skin and subcutaneous fat, which could impact the validity of MT measurements. In addition, patients with LBP may display limited movement or different movement characteristics, which were not tested in this study. Furthermore, MT may be less acceptable to older patients, who may have a preference against use of technology as part of PT treatment. However, starting with validity testing in healthy young participants allowed for testing of the full range of movement for MT measures, which may not be possible in other populations. The standardized verification, analytical validation, and clinical validation for biometric monitoring technologies recommends conducting analytical validation in a healthy population first, followed by validation in a clinical population [67]. Future research is needed to test MT acceptability and validity for measuring low back movement in a more diverse patient population, including people of different ages, with a variety of body types, and with LBP. Comparing results between people with and without LBP will also help differentiate movement patterns between the 2 groups.

In addition to assessing patient user acceptability, it is important to evaluate provider acceptability for use of new technologies in clinical practice. While this study did not assess provider acceptability of MT, we conducted a preliminary study to evaluate physical therapist acceptability of MT, and these findings are reported elsewhere [68]. As a first step in validating MT for a low back use case, this study was limited to a laboratory environment. Future studies including sensor improvements and development of a mobile app will allow the MT system to be used and tested for acceptability and validity in a free-living environment.

Because of their standard size, the location of MTs relative to spine anatomy may be slightly different for each person. As previously mentioned, the inferior MTs (5 and 6) were placed below the middle tapes such that the inferior MTs ideally crossed the L4-to-L5 and L5-to-S1 junctions. However, for 1 taller participant, the inferior row was not long enough to span the L5-to-S1 junction. Therefore, an additional limitation may be variable strain readings due to variability in sensor placement relative to participant anatomy. Our study team is currently investigating the impact of variability in placement on skin-strain measurements.

MT performed well when measuring mid ranges of movement that resulted in tension on the sensor but was limited in its ability to measure maximal tension and compression. Daily tasks are rarely performed at end ranges of movement; thus, the ability to distinguish movement in mid ranges may be the most critical for ecological monitoring. However, future sensor iterations will focus on increasing limits for measuring maximal tension and compression. Second, there were some instances of increases in MT strain that do not appear to correspond with motion capture kinematics (eg, Figure 8; return from extension). It is possible that this increase in strain could reflect increased muscle engagement associated with the phase of movement. Because MT measures skin strain, it may have the potential to detect changes in skin strain as a result of muscle engagement. The instances of MT strain that did not correspond with motion capture kinematics may indicate that the MT detected another physiological phenomenon, such as muscle engagement. This has been demonstrated empirically in other areas of the body, including the biceps and gastrocnemius muscles [48]. Research is currently underway to investigate the extent to which MT has the capability to capture muscle engagement in the low back.

It is also possible that increases in MT strain that do not correspond with motion capture kinematics may be due to a sensor rebound effect. Preliminary laboratory tests conducted by investigators confirmed a rebound effect when a compressed MT returns to a neutral position (Wyckoff E, unpublished data, February 2024). Due to the piezoresistive property of MT, the resistance may momentarily increase due to a delayed mechanical relaxation of the GNS and EC ink matrix, causing a temporary increase in the distance between conductive pathways. This rebound effect has also been observed in piezoresistive carbon [69]. The rebound effect could explain some of the lower correlations observed for movements that result in compression of MT. Following compression movements, there were positive strain values that did not correspond to the kinematics but, rather, may reflect this rebound effect. Additional research is needed to investigate the extent and true nature of the rebound effect and determine how this effect can be accounted for in measures of low back strain.

Conclusions

In this study, MT demonstrated moderate to high association with most low back motion capture kinematic measurements and can distinguish among multiple directions of movement. The median cross-correlation values were highest for lateral bending (0.87-0.94) and rotation (0.84-0.93) but varied more during forward flexion (0.62-0.93). For movements with expected positive correlations (MT tension), the highest correlations were observed in the upper MTs, 1 and 2 (0.84 and 0.80, respectively). However, several measurement limitations exist for the current version of MT, including limited ability to measure compression as demonstrated by poor to moderate median cross-correlation values for extension movements (–0.55 to 0.06). The MT also demonstrated limited capacity for measuring maximal tension associated with end ranges of certain movements (eg, flexion). User acceptability assessment indicates primarily positive feedback in the domains of perceived wearability and usefulness but more equivocal feedback related to ease of use in its current form. Future sensor developments and testing will be focused on addressing these issues.

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Data Availability

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

Conflicts of Interest

Coauthor KJL is a cofounder of JAK Labs Inc, a company that may potentially benefit from the research results. JAK Labs intends to commercialize Motion Tape for the physical therapy and rehabilitation market, among other markets. The terms of this arrangement have been reviewed and approved by the University of California, San Diego, in accordance with its conflict of interest policies.

Multimedia Appendix 1
A semistructured interview guide based on the technology acceptance model.
[PDF File (Adobe PDF File), 46 KB - rehab_v11i1e57953_app1.pdf]

References

1. Chen S, Chen M, Wu X, Lin S, Tao C, Cao H, et al. Global, regional and national burden of low back pain 1990-2019: a systematic analysis of the Global Burden of Disease study 2019. J Orthop Translat 2022 Jan;32:49-58 [FREE Full text] [doi: 10.1016/j.jot.2021.07.005] [Medline: 34934626]
2. Henchoz Y, Kai-Lik So A. Exercise and nonspecific low back pain: a literature review. Joint Bone Spine 2008 Oct;75(5):533-539. [doi: 10.1016/j.jbspin.2008.03.003] [Medline: 18801686]
3. Andersson GB. Epidemiological features of chronic low-back pain. Lancet 1999 Aug 14;354(9178):581-585. [doi: 10.1016/S0140-6736(99)01312-4] [Medline: 10470716]
4. Hestbaek L, Leboeuf-Yde C, Manniche C. Low back pain: what is the long-term course? a review of studies of general patient populations. Eur Spine J 2003 Apr;12(2):149-165 [FREE Full text] [doi: 10.1007/s00586-002-0508-5] [Medline: 12709853]
5. Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. Spine J 2008 Jan;8(1):8-20. [doi: 10.1016/j.spinee.2007.10.005] [Medline: 18164449]
6. Marrache M, Prasad N, Margalit A, Nayar SK, Best MJ, Fritz JM, et al. Initial presentation for acute low back pain: is early physical therapy associated with healthcare utilization and spending? a retrospective review of a National Database. BMC Health Serv Res 2022 Jul 02;22(1):851 [FREE Full text] [doi: 10.1186/s12913-022-08255-0] [Medline: 35778738]
7. Anar S. The effectiveness of home-based exercise programs for low back pain patients. J Phys Ther Sci 2016 Oct;28(10):2727-2730 [FREE Full text] [doi: 10.1589/jpts.28.2727] [Medline: 27821923]
8. Katz JN. Lumbar disc disorders and low-back pain: socioeconomic factors and consequences. J Bone Joint Surg Am 2006 Apr;88 Suppl 2:21-24. [doi: 10.2106/JBJS.E.01273] [Medline: 16595438]
9. Saragiotto BT, Maher CG, Yamato TP, Costa LO, Menezes Costa LC, Ostelo RW, et al. Motor control exercise for chronic non-specific low-back pain. Cochrane Database Syst Rev 2016 Jan 08;2016(1):CD012004 [FREE Full text] [doi: 10.1002/14651858.CD012004] [Medline: 26742533]
10. Steffens D, Maher CG, Pereira LS, Stevens ML, Oliveira VC, Chapple M, et al. Prevention of low back pain: a systematic review and meta-analysis. JAMA Intern Med 2016 Feb 01;176(2):199-208. [doi: 10.1001/jamainternmed.2015.7431] [Medline: 26752509]
11. Palazzo C, Klinger E, Dorner V, Kadri A, Thierry O, Boumenir Y, et al. Barriers to home-based exercise program adherence with chronic low back pain: patient expectations regarding new technologies. Ann Phys Rehabil Med 2016 Apr;59(2):107-113 [FREE Full text] [doi: 10.1016/j.rehab.2016.01.009] [Medline: 27050664]
12. Holden MA, Haywood KL, Potia TA, Gee M, McLean S. Recommendations for exercise adherence measures in musculoskeletal settings: a systematic review and consensus meeting (protocol). Syst Rev 2014 Feb 10;3(1):10 [FREE Full text] [doi: 10.1186/2046-4053-3-10] [Medline: 24512976]
13. Marich AV, Lanier VM, Salsich GB, Lang CE, van Dillen LR. Immediate effects of a single session of motor skill training on the lumbar movement pattern during a functional activity in people with low back pain: a repeated-measures study. Phys Ther 2018 Jul 01;98(7):605-615 [FREE Full text] [doi: 10.1093/ptj/pzy044] [Medline: 29660077]

14. Nelson BW, O'Reilly E, Miller M, Hogan M, Wegner JA, Kelly C. The clinical effects of intensive, specific exercise on chronic low back pain: a controlled study of 895 consecutive patients with 1-year follow up. Orthopedics 1995 Oct;18(10):971-981. [doi: 10.3928/0147-7447-19951001-05] [Medline: 8584467]
15. Zheng Z, Wang Y, Wang T, Wu Y, Li Y. A systematic review and meta-analysis on comparative kinematics in the lumbopelvic region in the patients suffering from spinal pain. J Healthc Eng 2022 Mar 19;2022:7369242-7369249 [FREE Full text] [doi: 10.1155/2022/7369242] [Medline: 35345658]
16. Alschuler KN, Hoodin F, Murphy SL, Geisser ME. Ambulatory monitoring as a measure of disability in chronic low back pain populations. Clin J Pain 2011 Oct;27(8):707-715. [doi: 10.1097/AJP.0b013e318217b7d0] [Medline: 21505322]
17. Schaller A, Rudolf K, Dejonghe L, Grieben C, Froboese I. Influencing factors on the overestimation of self-reported physical activity: a cross-sectional analysis of low back pain patients and healthy controls. Biomed Res Int 2016;2016:1497213 [FREE Full text] [doi: 10.1155/2016/1497213] [Medline: 27298820]
18. Dutta A, Ma O, Toledo M, Pregonero AF, Ainsworth BE, Buman MP, et al. Identifying free-living physical activities using lab-based models with wearable accelerometers. Sensors (Basel) 2018 Nov 12;18(11):3893 [FREE Full text] [doi: 10.3390/s18113893] [Medline: 30424512]
19. Silva FG, da Silva TM, Maher C, L Ferreira ML, Costa L, Costa LO. What triggers an episode of acute low back pain? a protocol of a replication case-crossover study. BMJ Open 2021 Feb 05;11(2):e040784 [FREE Full text] [doi: 10.1136/bmjopen-2020-040784] [Medline: 33550235]
20. Steffens D, Ferreira ML, Latimer J, Ferreira PH, Koes BW, Blyth F, et al. What triggers an episode of acute low back pain? a case-crossover study. Arthritis Care Res (Hoboken) 2015 Mar 24;67(3):403-410 [FREE Full text] [doi: 10.1002/acr.22533] [Medline: 25665074]
21. Karayannis NV, Jull GA, Hodges PW. Physiotherapy movement based classification approaches to low back pain: comparison of subgroups through review and developer/expert survey. BMC Musculoskelet Disord 2012 Feb 20;13(1):24 [FREE Full text] [doi: 10.1186/1471-2474-13-24] [Medline: 22348236]
22. Carpenter DM, Nelson BW. Low back strengthening for the prevention and treatment of low back pain. Med Sci Sports Exerc 1999 Jan;31(1):18-24. [doi: 10.1097/00005768-199901000-00005] [Medline: 9927005]
23. Pisters MF, Veenhof C, Schellevis FG, Twisk JW, Dekker J, de Bakker DH. Exercise adherence improving long-term patient outcome in patients with osteoarthritis of the hip and/or knee. Arthritis Care Res (Hoboken) 2010 Aug 03;62(8):1087-1094 [FREE Full text] [doi: 10.1002/acr.20182] [Medline: 20235201]
24. Tenforde AS, Borgstrom H, Polich G, Steere H, Davis IS, Cotton K, et al. Outpatient physical, occupational, and speech therapy synchronous telemedicine: a survey study of patient satisfaction with virtual visits during the COVID-19 pandemic. Am J Phys Med Rehabil 2020 Aug 17;99(11):977-981. [doi: 10.1097/phm.0000000000001571]
25. van Dillen LR, Norton BJ, Sahrmann SA, Evanoff BA, Harris-Hayes M, Holtzman GW, et al. Efficacy of classification-specific treatment and adherence on outcomes in people with chronic low back pain. a one-year follow-up, prospective, randomized, controlled clinical trial. Man Ther 2016 Aug;24:52-64 [FREE Full text] [doi: 10.1016/j.math.2016.04.003] [Medline: 27317505]
26. Ghamkhar L, Kahlaee AH. Pain and pain-related disability associated with proprioceptive impairment in chronic low back pain patients: a systematic review. J Manipulative Physiol Ther 2019 Mar;42(3):210-217. [doi: 10.1016/j.jmpt.2018.10.004] [Medline: 31029466]
27. Poesl M, Carvalho GF, Adamczyk WM, Schüßler B, Richter M, Luedtke K, et al. Widespread proprioceptive acuity impairment in chronic back pain: a cross-sectional study. Arch Phys Med Rehabil 2023 Sep;104(9):1439-1446. [doi: 10.1016/j.apmr.2023.02.016] [Medline: 36935031]
28. Stilwell PA. Barriers and facilitators to prescribed exercise adherence in chiropractic patients with non-specific chronic low back pain: a focused ethnography. Dalhousie University. 2015. URL: https://dalspace.library.dal.ca/bitstream/handle/10222/60773/Stilwell-Peter-MSc-PHYT-August-2015.pdf?sequence=1&isAllowed=y [accessed 2024-06-24]
29. Boutevillain L, Dupeyron A, Rouch C, Richard E, Coudeyre E. Facilitators and barriers to physical activity in people with chronic low back pain: a qualitative study. PLoS One 2017 Jul 25;12(7):e0179826 [FREE Full text] [doi: 10.1371/journal.pone.0179826] [Medline: 28742820]
30. Alexander M. Telerehabilitation: Principles and Practice. Philadelphia, PA: Elsevier; 2021.
31. Lee A. COVID-19 and the advancement of digital physical therapist practice and telehealth. Phys Ther 2020 Jul 19;100(7):1054-1057 [FREE Full text] [doi: 10.1093/ptj/pzaa079] [Medline: 32343836]
32. Shum GL, Crosbie J, Lee RY. Symptomatic and asymptomatic movement coordination of the lumbar spine and hip during an everyday activity. Spine (Phila Pa 1976) 2005 Dec 01;30(23):E697-E702. [doi: 10.1097/01.brs.0000188255.10759.7a] [Medline: 16319739]
33. Shum GL, Crosbie J, Lee RY. Effect of low back pain on the kinematics and joint coordination of the lumbar spine and hip during sit-to-stand and stand-to-sit. Spine (Phila Pa 1976) 2005 Sep 01;30(17):1998-2004. [doi: 10.1097/01.brs.0000176195.16128.27] [Medline: 16135992]
34. Papi E, Koh WS, McGregor AH. Wearable technology for spine movement assessment: a systematic review. J Biomech 2017 Nov 07;64:186-197 [FREE Full text] [doi: 10.1016/j.jbiomech.2017.09.037] [Medline: 29102267]

35. Victorino MN, Jiang X, Menon C. Chapter 7 - Wearable technologies and force myography for healthcare. In: Tong RK, editor. Wearable Technology in Medicine and Health Care. Cambridge, MA: Academic Press; 2018.
36. Ricci L, Taffoni F, Formica D. On the orientation error of IMU: investigating static and dynamic accuracy targeting human motion. PLoS One 2016 Sep 9;11(9):e0161940 [FREE Full text] [doi: 10.1371/journal.pone.0161940] [Medline: 27612100]
37. Zhang Y, Haghighi PD, Burstein F, Yap LW, Cheng W, Yao L, et al. Electronic skin wearable sensors for detecting lumbar-pelvic movements. Sensors (Basel) 2020 Mar 09;20(5):1510 [FREE Full text] [doi: 10.3390/s20051510] [Medline: 32182928]
38. Beaudette SM, Zwambag DP, Bent LR, Brown SH. Spine postural change elicits localized skin structural deformation of the trunk dorsum in vivo. J Mech Behav Biomed Mater 2017 Mar;67:31-39. [doi: 10.1016/j.jmbbm.2016.11.025] [Medline: 27978463]
39. Yun WS, Kim H, Ahn JH, Park YB, Park YJ. Individual characteristics of reliable lumbar coupling motions. Eur Spine J 2015 Sep 24;24(9):1917-1925. [doi: 10.1007/s00586-015-4081-0] [Medline: 26100279]
40. Vu LQ, Kim H, Schulze LJ, Rajulu SL. Evaluating lumbar shape deformation with fabric strain sensors. Hum Factors 2022 Jun;64(4):649-661. [doi: 10.1177/0018720820965302] [Medline: 33121286]
41. Vu LQ, Kim KH, Schulze LJ, Rajulu SL. Lumbar posture assessment with fabric strain sensors. Comput Biol Med 2020 Mar;118:103624. [doi: 10.1016/j.compbiomed.2020.103624] [Medline: 32174329]
42. Loh KJ, Kim J, Lynch JP, Kam NW, Kotov NA. Multifunctional layer-by-layer carbon nanotube–polyelectrolyte thin films for strain and corrosion sensing. Smart Mater Struct 2007 Feb 09;16(2):429-438. [doi: 10.1088/0964-1726/16/2/022]
43. Loh KJ, Lynch JP, Shim BS, Kotov NA. Tailoring piezoresistive sensitivity of multilayer carbon nanotube composite strain sensors. J Intell Mater Syst Struct 2007 Oct 17;19(7):747-764. [doi: 10.1177/1045389x07079872]
44. Loyola BR, La Saponara V, Loh KJ. In situ strain monitoring of fiber-reinforced polymers using embedded piezoresistive nanocomposites. J Mater Sci 2010 Jul 31;45(24):6786-6798. [doi: 10.1007/s10853-010-4775-y]
45. Wang L, Loh KJ. Wearable carbon nanotube-based fabric sensors for monitoring human physiological performance. Smart Mater Struct 2017 Apr 13;26(5):055018. [doi: 10.1088/1361-665X/aa6849]
46. Lin YA, Zhao Y, Wang L, Park Y, Yeh YJ, Chiang WH, et al. Graphene K‐Tape meshes for densely distributed human motion monitoring. Adv Mater Technol 2020 Dec 06;6(1):2000861. [doi: 10.1002/admt.202000861]
47. Lin YA, schraefel MC, Chiang WH, Loh KJ. Wearable nanocomposite kinesiology tape for distributed muscle engagement monitoring. MRS Advances 2021 Jan 28;6(1):6-13. [doi: 10.1557/s43580-021-00005-4]
48. Lin YA, Mhaskar Y, Silder A, Sessoms PH, Fraser JJ, Loh KJ. Muscle engagement monitoring using self-adhesive elastic nanocomposite fabrics. Sensors (Basel) 2022 Sep 07;22(18):6768 [FREE Full text] [doi: 10.3390/s22186768] [Medline: 36146120]
49. ARMOR Lab homepage. ARMOR Lab. URL: https://armor.ucsd.edu [accessed 2024-06-24]
50. Manna K, Wang L, Loh KJ, Chiang WH. Printed strain sensors using graphene nanosheets prepared by water‐assisted liquid phase exfoliation. Adv Mater Interfaces 2019 Feb 27;6(9):1900034. [doi: 10.1002/admi.201900034]
51. Gombatto SP, Brock T, DeLork A, Jones G, Madden E, Rinere C. Lumbar spine kinematics during walking in people with and people without low back pain. Gait Posture 2015 Oct;42(4):539-544. [doi: 10.1016/j.gaitpost.2015.08.010] [Medline: 26380913]
52. Berry DB, Hernandez A, Onodera K, Ingram N, Ward SR, Gombatto SP. Lumbar spine angles and intervertebral disc characteristics with end-range positions in three planes of motion in healthy people using upright MRI. J Biomech 2019 May 24;89:95-104. [doi: 10.1016/j.jbiomech.2019.04.020] [Medline: 31047693]
53. Nelson-Wong E, Howarth S, Winter DA, Callaghan JP. Application of autocorrelation and cross-correlation analyses in human movement and rehabilitation research. J Orthop Sports Phys Ther 2009 Apr;39(4):287-295. [doi: 10.2519/jospt.2009.2969] [Medline: 19346626]
54. Holden RJ, Karsh BT. The technology acceptance model: its past and its future in health care. J Biomed Inform 2010 Feb;43(1):159-172 [FREE Full text] [doi: 10.1016/j.jbi.2009.07.002] [Medline: 19615467]
55. Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. MIS Q 1989 Sep;13(3):319-340. [doi: 10.2307/249008]
56. Lange J, Schneider A, Jordi C, Lau M, Disher T. Formative study on the wearability and usability of a large-volume patch injector. Med Devices Evid Res 2021 Nov;Volume 14:363-377. [doi: 10.2147/mder.s337670]
57. Donec V, Kubilius R. The effectiveness of Kinesio Taping® for mobility and functioning improvement in knee osteoarthritis: a randomized, double-blind, controlled trial. Clin Rehabil 2020 Jul 06;34(7):877-889 [FREE Full text] [doi: 10.1177/0269215520916859] [Medline: 32372651]
58. Sun X, Zhao C, Li H, Yu H, Zhang J, Qiu H, et al. Wearable near-field communication sensors for healthcare: materials, fabrication and application. Micromachines (Basel) 2022 May 17;13(5):784 [FREE Full text] [doi: 10.3390/mi13050784] [Medline: 35630251]
59. O'Sullivan K, Verschueren S, Pans S, Smets D, Dekelver K, Dankaerts W. Validation of a novel spinal posture monitor: comparison with digital videofluoroscopy. Eur Spine J 2012 Dec;21(12):2633-2639 [FREE Full text] [doi: 10.1007/s00586-012-2440-7] [Medline: 22836364]

60. Mjøsund HL, Boyle E, Kjaer P, Mieritz RM, Skallgård T, Kent P. Clinically acceptable agreement between the ViMove wireless motion sensor system and the Vicon motion capture system when measuring lumbar region inclination motion in the sagittal and coronal planes. BMC Musculoskelet Disord 2017 Mar 21;18(1):124 [FREE Full text] [doi: 10.1186/s12891-017-1489-1] [Medline: 28327115]
61. Hodges PW, van den Hoorn W. A vision for the future of wearable sensors in spine care and its challenges: narrative review. J Spine Surg 2022 Mar;8(1):103-116 [FREE Full text] [doi: 10.21037/jss-21-112] [Medline: 35441093]
62. Consmüller T, Rohlmann A, Weinland D, Druschel C, Duda GN, Taylor WR. Comparative evaluation of a novel measurement tool to assess lumbar spine posture and range of motion. Eur Spine J 2012 Nov 29;21(11):2170-2180 [FREE Full text] [doi: 10.1007/s00586-012-2312-1] [Medline: 22543411]
63. Zaltieri M, Massaroni C, Lo Presti D, Bravi M, Sabbadini R, Miccinilli S, et al. A wearable device based on a fiber Bragg grating sensor for low back movements monitoring. Sensors (Basel) 2020 Jul 09;20(14):3825 [FREE Full text] [doi: 10.3390/s20143825] [Medline: 32659958]
64. Romano V, Smith K, Hanes-Romano K, Chambers J. Kinesio tape 14-day application cycle: a case study. Integr J Med Sci 2021 Feb 10;8. [doi: 10.15342/ijms.2021.392]
65. Patel S, Park H, Bonato P, Chan L, Rodgers M. A review of wearable sensors and systems with application in rehabilitation. J Neuroeng Rehabil 2012 Apr 20;9(1):21 [FREE Full text] [doi: 10.1186/1743-0003-9-21] [Medline: 22520559]
66. Su WC, Yeh SC, Lee SH, Huang HC. A virtual reality lower-back pain rehabilitation approach: system design and user acceptance analysis. In: Proceedings of the Universal Access in Human-Computer Interaction. Access to Learning, Health and Well-Being. 2015 Presented at: UAHCI 2015; August 2-7, 2015; Los Angeles, CA. [doi: 10.1007/978-3-319-20684-4_37]
67. Goldsack JC, Coravos A, Bakker JP, Bent B, Dowling AV, Fitzer-Attas C, et al. Verification, analytical validation, and clinical validation (V3): the foundation of determining fit-for-purpose for Biometric Monitoring Technologies (BioMeTs). NPJ Digit Med 2020;3:55 [FREE Full text] [doi: 10.1038/s41746-020-0260-4] [Medline: 32337371]
68. Lee A, Dionicio P, Farcas E, Godino J, Patrick K, Wyckoff E, et al. Physical therapists' acceptance of a wearable, fabric-based sensor system (motion tape) for use in clinical practice: qualitative focus group study. JMIR Hum Factors 2024 Feb 29;11:e55246 [FREE Full text] [doi: 10.2196/55246] [Medline: 38421708]
69. Shui X, Chung DD. A piezoresistive carbon filament polymer-matrix composite strain sensor. Smart Mater Struct 1999 Jan 01;5(2):243-246. [doi: 10.1088/0964-1726/5/2/014]

Abbreviations

EC: ethyl cellulose
GNS: graphene nanosheets
IMU: inertial measurement unit
LBP: low back pain
MT: Motion Tape
PT: physical therapy
RQA: rapid qualitative analysis
TAM: technology acceptance model

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

Eveline Prochaska[1,2], BSc, MSc; Elske Ammenwerth[1], MET, Prof Dr

[1]

[2]

Corresponding Author:
Eveline Prochaska, BSc, MSc

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

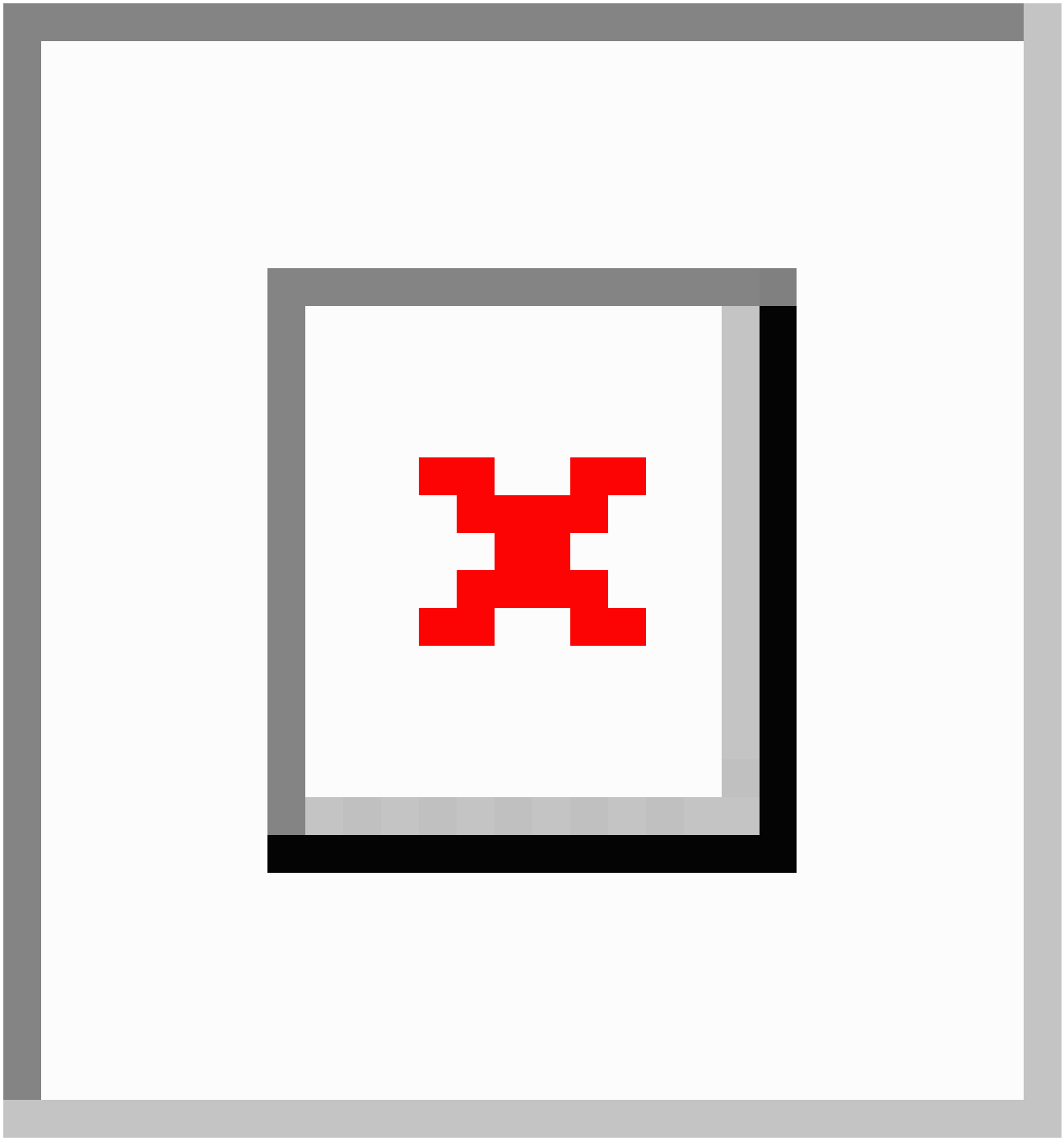
assessment; clinical utility; digital Box and Block Test; dBBT; hand dexterity; dexterity; usability

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].

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

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.

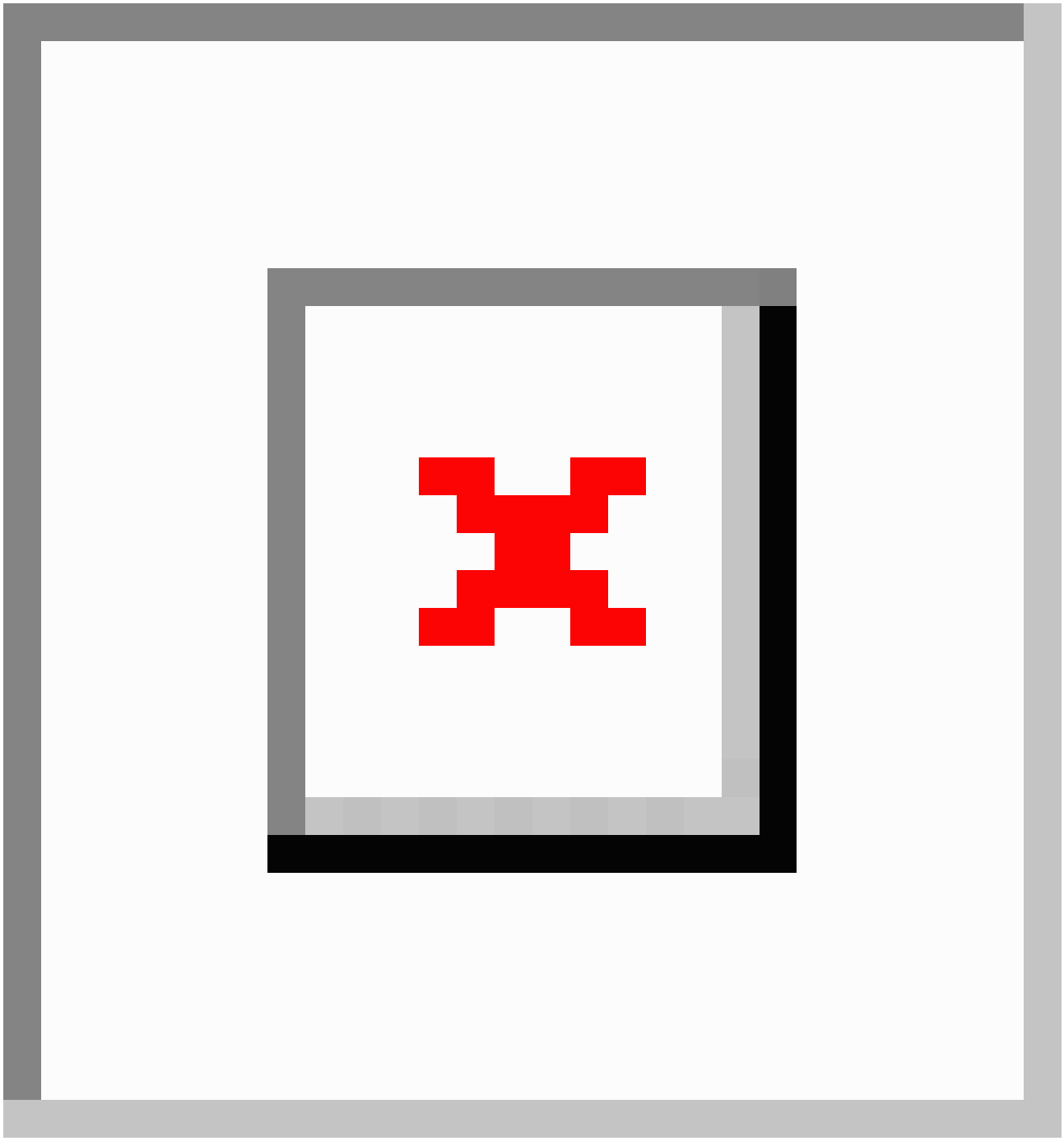
Ethical Considerations

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.

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

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).

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)

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

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.

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,

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.

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.

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.

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]

References

1. Gopal A, Hsu WY, Allen DD, Bove R. Remote assessments of hand function in neurological disorders: systematic review. JMIR Rehabil Assist Technol 2022 Mar 9;9(1):e33157. [doi: 10.2196/33157] [Medline: 35262502]
2. Acharya KA, Bhat S, Kanthi M, Rao BK. Fine motor assessment in upper extremity using custom-made electronic pegboard test. J Med Signals Sens 2022 Dec 28;12(1):76-83. [doi: 10.4103/jmss.JMSS_58_20] [Medline: 35265469]
3. Everard G, Otmane-Tolba Y, Rosselli Z, et al. Concurrent validity of an immersive virtual reality version of the Box and Block Test to assess manual dexterity among patients with stroke. J Neuroeng Rehabil 2022 Jan 22;19(1):7. [doi: 10.1186/s12984-022-00981-0] [Medline: 35065678]
4. Mathiowetz V, Volland G, Kashman N, Weber K. Adult norms for the Box and Block Test of manual dexterity. Am J Occup Ther 1985 Jun;39(6):386-391. [doi: 10.5014/ajot.39.6.386] [Medline: 3160243]
5. Desrosiers J, Bravo G, Hébert R, Dutil E, Mercier L. Validation of the Box and Block Test as a measure of dexterity of elderly people: reliability, validity, and norms studies. Arch Phys Med Rehabil 1994 Jul;75(7):751-755. [Medline: 8024419]
6. Oña Simbaña ED, Sánchez-Herrera Baeza P, Jardón Huete A, Balaguer C. Review of automated systems for upper limbs functional assessment in neurorehabilitation. IEEE Access 2019;7:32352-32367. [doi: 10.1109/ACCESS.2019.2901814]
7. Dong Y, Liu X, Tang M, et al. A haptic-feedback virtual reality system to improve the Box and Block Test (BBT) for upper extremity motor function assessment. Virtual Real 2023 Jun;27(2):1199-1219. [doi: 10.1007/s10055-022-00727-2]
8. Hsiao CP, Zhao C, Do EYL. The digital Box and Block Test automating traditional post-stroke rehabilitation assessment. In: 2013 IEEE International Conference on Pervasive Computing and Communications Workshops (PERCOM Workshops 2013): IEEE; 2013:360-363. [doi: 10.1109/PerComW.2013.6529516]
9. Zhang Y, Chen Y, Yu H, et al. Wearable sensors based automatic Box and Block Test system. In: 2019 IEEE SmartWorld, Ubiquitous Intelligence & Computing, Advanced & Trusted Computing, Scalable Computing & Communications, Cloud & Big Data Computing, Internet of People and Smart City Innovation (SmartWorld/SCALCOM/UIC/ATC/CBDCom/IOP/SCI): IEEE; 2019:952-959. [doi: 10.1109/SmartWorld-UIC-ATC-SCALCOM-IOP-SCI.2019.00189]
10. Lee TKM, Lim JG, Leo KH, Sanei S. Indications of neural disorder through automated assessment of the Box and Block Test. In: 2018 IEEE 23rd International Conference on Digital Signal Processing (DSP): IEEE; 2018:1-5. [doi: 10.1109/ICDSP.2018.8631815]
11. Cho S, Kim WS, Paik NJ, Bang H. Upper-limb function assessment using VBBTs for stroke patients. IEEE Comput Grap Appl 2016;36(1):70-78. [doi: 10.1109/MCG.2015.2]

12. Alvarez-Rodríguez M, López-Dolado E, Salas-Monedero M, et al. Concurrent validity of a virtual version of Box and Block Test for patients with neurological disorders. World J Neurosci 2020;10(1):79-89. [doi: 10.4236/wjns.2020.101009]
13. Oña ED, Jardón A, Cuesta-Gómez A, Sánchez-Herrera-Baeza P, Cano-de-la-Cuerda R, Balaguer C. Validity of a fully-immersive VR-based version of the Box and Blocks Test for upper limb function assessment in Parkinson's disease. Sensors (Basel) 2020 May 13;20(10):2773. [doi: 10.3390/s20102773] [Medline: 32414177]
14. Everard G, Burton Q, van de Sype V, et al. Extended reality to assess post-stroke manual dexterity: contrasts between the classic Box and Block Test, immersive virtual reality with controllers, with hand-tracking, and mixed-reality tests. J Neuroeng Rehabil 2024 Mar 15;21(1):36. [doi: 10.1186/s12984-024-01332-x] [Medline: 38491540]
15. Hashim NA, Abd Razak NA, Gholizadeh H, Abu Osman NA. Video game–based rehabilitation approach for individuals who have undergone upper limb amputation: case-control study. JMIR Serious Games 2021 Feb 4;9(1):e17017. [doi: 10.2196/17017] [Medline: 33538698]
16. Herrera V, Vallejo D, Castro-Schez JJ, et al. Rehab-immersive: a framework to support the development of virtual reality applications in upper limb rehabilitation. SoftwareX 2023 Jul;23:101412. [doi: 10.1016/j.softx.2023.101412]
17. Prochaska E, Ammenwerth E. A digital Box and Block Test for hand dexterity measurement: instrument validation study. JMIR Rehabil Assist Technol 2023 Sep 15;10:e50474. [doi: 10.2196/50474] [Medline: 37713251]
18. Smart A. A multi-dimensional model of clinical utility. Int J Qual Health Care 2006 Oct;18(5):377-382. [doi: 10.1093/intqhc/mzl034] [Medline: 16951425]
19. Ashcroft R. What is clinical effectiveness? Stud Hist Philos Biol Biomed Sci 2002 Jul;33(2):219-233. [doi: 10.1016/S0039-3681(02)00020-1]
20. Gray A. Critical appraisal of methods: economic evaluation. In: Dawes M, Davies P, Gray A, et al, editors. Evidence-Based Practice: A Primer for Healthcare Professionals, 2nd edition: Elsevier Churchill Livingstone; 2005.
21. First MB, Pincus HA, Levine JB, Williams JBW, Ustun B, Peele R. Clinical utility as a criterion for revising psychiatric diagnoses. Am J Psychiatry 2004 Jun;161(6):946-954. [doi: 10.1176/appi.ajp.161.6.946] [Medline: 15169680]
22. Jeffrey LIH. Aspects of selecting outcome measures to demonstrate the effectiveness of comprehensive rehabilitation. Br J Occup Ther 1993 Nov;56(11):394-400. [doi: 10.1177/030802269305601103]
23. Fawcett AL. Principles of Assessment and Outcome Measurement for Occupational Therapists and Physiotherapists: Theory, Skills and Application: John Wiley & Sons Inc; 2007.
24. Hyzy M, Bond R, Mulvenna M, et al. System Usability Scale benchmarking for digital health apps: meta-analysis. JMIR Mhealth Uhealth 2022 Aug 18;10(8):e37290. [doi: 10.2196/37290] [Medline: 35980732]
25. Döring N, Bortz J. Forschungsmethoden Und Evaluation in Den Sozial- Und Humanwissenschaften: Springer Berlin; 2016. [doi: 10.1007/978-3-642-41089-5]
26. Krueger RA, Casey MA. Focus Groups: A Practical Guide for Applied Research: SAGE Publications; 2008.
27. Faulkner L. Beyond the five-user assumption: benefits of increased sample sizes in usability testing. Behav Res Methods Instrum Comput 2003 Aug;35(3):379-383. [doi: 10.3758/bf03195514] [Medline: 14587545]
28. Tong A, Sainsbury P, Craig J. Consolidated Criteria for Reporting Qualitative Research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007 Dec;19(6):349-357. [doi: 10.1093/intqhc/mzm042] [Medline: 17872937]
29. Prochaska E. Validation of two digitized assessments for measuring hand function. Open Science Framework. 2022 Nov 7. URL: https://osf.io/bw2m4/ [accessed 2024-05-06]
30. Creswell JW. Research Design Qualitative, Quantitative, and Mixed Methods Approaches: SAGE Publications; 2018.
31. Tashakkori A, Teddlie C. Mixed Methodology: Combining Qualitative and Quantitative Approaches: SAGE Publications; 1998, Vol. 46.
32. Mayring P. Qualitative Content Analysis: A Step-by-Step Guide: SAGE Publications; 2021.
33. Kuckartz U. Qualitative Text Analysis: A Guide to Methods, Practice & Using Software: SAGE Publications; 2014. [doi: 10.4135/9781446288719]
34. Schreier M. Varianten qualitativer inhaltsanalyse: Ein Wegweiser im Dickicht der Begrifflichkeiten [Article in German]. Forum Qualitative Sozialforschung 2014 Jan;15(1):18 [FREE Full text]
35. Mayring P. Qualitative Inhaltsanalyse Grundlagen Und Techniken, 12th edition: Beltz; 2022.
36. Given L. The SAGE Encyclopedia of Qualitative Research Methods: SAGE Publications; 2008. [doi: 10.4135/9781412963909]
37. Maramba I, Chatterjee A, Newman C. Methods of usability testing in the development of eHealth applications: a scoping review. Int J Med Inform 2019 Jun;126:95-104. [doi: 10.1016/j.ijmedinf.2019.03.018] [Medline: 31029270]
38. Peres SC, Pham T, Phillips R. Validation of the System Usability Scale (SUS): SUS in the wild. Proc Hum Factors Ergon Soc Annu Meet 2013 Sep 30;57(1):192-196. [doi: 10.1177/1541931213571043]
39. Bangor A, Kortum P, Miller J. Determining what individual SUS scores mean: adding an adjective rating scale. Journal of User Experience 2009;4(3):114-123 [FREE Full text]
40. Malterud K. Qualitative research: standards, challenges, and guidelines. Lancet 2001 Aug 11;358(9280):483-488. [doi: 10.1016/S0140-6736(01)05627-6] [Medline: 11513933]

41. O'Reilly MA, Slevin P, Ward T, Caulfield B. A wearable sensor-based exercise biofeedback system: mixed methods evaluation of Formulift. JMIR Mhealth Uhealth 2018 Jan 31;6(1):e33. [doi: 10.2196/mhealth.8115] [Medline: 29386171]
42. Creswell JW, Plano Clark VL. Designing and Conducting Mixed Methods Research: SAGE Publications; 2011, Vol. 2.
43. Canny ML, Thompson JM, Wheeler MJ. Reliability of the Box and Block Test of manual dexterity for use with patients with fibromyalgia. Am J Occup Ther 2009;63(4):506-510. [doi: 10.5014/ajot.63.4.506] [Medline: 19708480]
44. Liang KJ, Chen HL, Shieh JY, Wang TN. Measurement properties of the Box and Block Test in children with unilateral cerebral palsy. Sci Rep 2021 Oct 25;11(1):20955. [doi: 10.1038/s41598-021-00379-3] [Medline: 34697312]
45. ChatGPT. OpenAI. URL: https://chatgpt.com/ [accessed 2024-05-09]

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

Chloé Sieber[1,2], PhD; Christina Haag[1,2], PhD; Ashley Polhemus[2], PhD; Sarah R Haile[2], PhD; Ramona Sylvester[3], MSc; Jan Kool[3], PhD; Roman Gonzenbach[3], MD, PhD; Viktor von Wyl[1,2], Prof Dr, PhD

[1]Institute for Implementation Science in Health Care, University of Zurich, Zurich, Switzerland

[2]Epidemiology, Biostatistics and Prevention Institute, University of Zurich, Zurich, Switzerland

[3]Valens Rehabilitation Centre, Valens, Switzerland

Corresponding Author:
Viktor von Wyl, Prof Dr, PhD
Institute for Implementation Science in Health Care
University of Zurich
Universitätstrasse 84
Zurich, 8006
Switzerland
Phone: 41 44 63 46380
Email: viktor.vonwyl@uzh.ch

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

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].

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).

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)

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)

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.

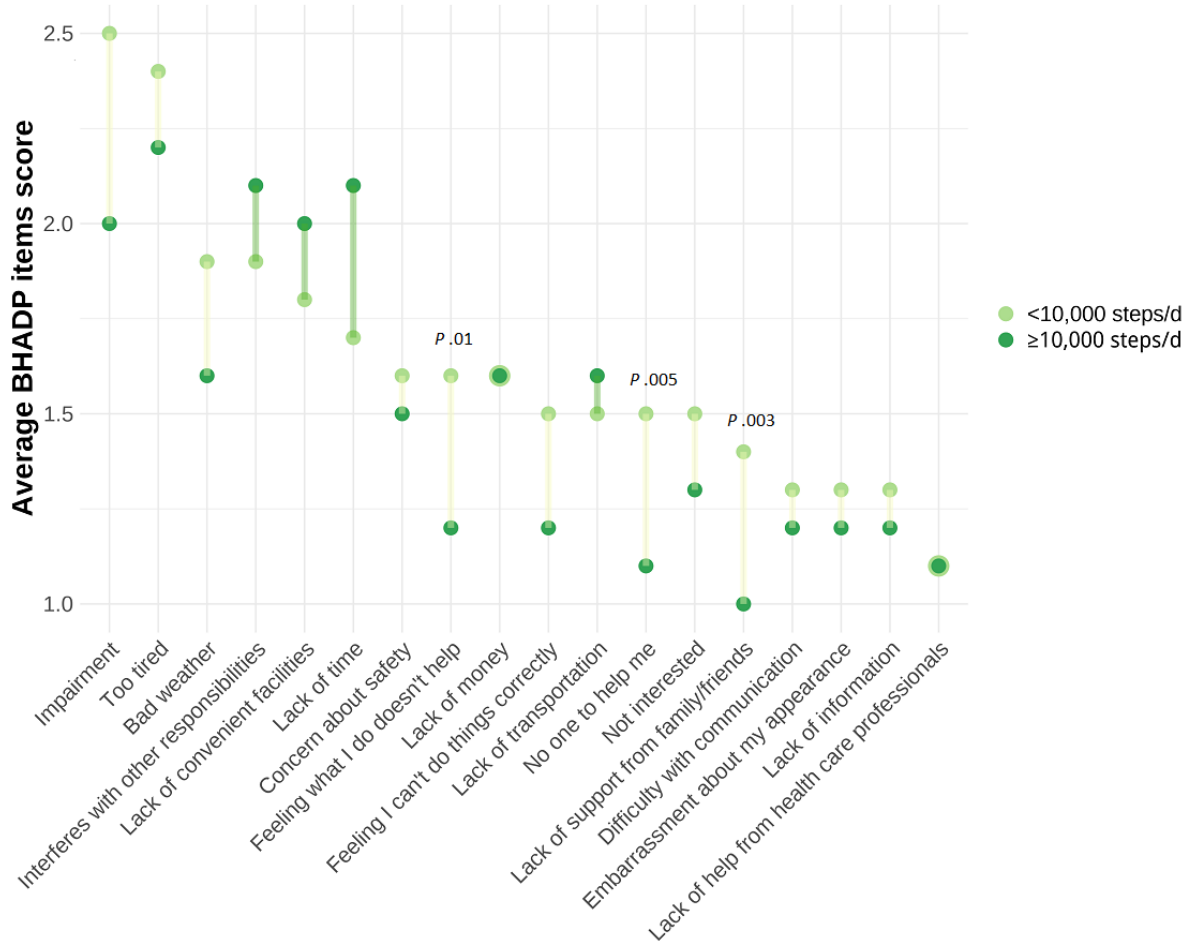
[c]Asthma, type 1 diabetes, osteoporosis, psoriasis, cancer, rheumatic diseases, elevated cholesterol level, colitis ulcerosa, fibromyalgia, shingles, Meniere disease, and cerebellar syndrome.

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.

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.

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.

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.

[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

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]

References

1. Proschinger S, Kuhwand P, Rademacher A, Walzik D, Warnke C, Zimmer P, et al. Fitness, physical activity, and exercise in multiple sclerosis: a systematic review on current evidence for interactions with disease activity and progression. J Neurol 2022 Jun;269(6):2922-2940 [FREE Full text] [doi: 10.1007/s00415-021-10935-6] [Medline: 35084560]
2. Petajan JH, Gappmaier E, White AT, Spencer MK, Mino L, Hicks RW. Impact of aerobic training on fitness and quality of life in multiple sclerosis. Ann Neurol 1996 Apr;39(4):432-441. [doi: 10.1002/ana.410390405] [Medline: 8619521]
3. Razazian N, Kazeminia M, Moayedi H, Daneshkhah A, Shohaimi S, Mohammadi M, et al. The impact of physical exercise on the fatigue symptoms in patients with multiple sclerosis: a systematic review and meta-analysis. BMC Neurol 2020 Mar 13;20(1):93 [FREE Full text] [doi: 10.1186/s12883-020-01654-y] [Medline: 32169035]
4. Dalgas U, Langeskov-Christensen M, Stenager E, Riemenschneider M, Hvid LG. Exercise as medicine in multiple sclerosis-time for a paradigm shift: preventive, symptomatic, and disease-modifying aspects and perspectives. Curr Neurol Neurosci Rep 2019 Nov 13;19(11):88. [doi: 10.1007/s11910-019-1002-3] [Medline: 31720862]

5. Wesnes K, Myhr KM, Riise T, Cortese M, Pugliatti M, Boström I, et al. Physical activity is associated with a decreased multiple sclerosis risk: the EnvIMS study. Mult Scler 2018 Feb;24(2):150-157. [doi: 10.1177/1352458517694088] [Medline: 28273774]
6. Kinnett-Hopkins D, Adamson B, Rougeau K, Motl RW. People with MS are less physically active than healthy controls but as active as those with other chronic diseases: an updated meta-analysis. Mult Scler Relat Disord 2017 Apr;13:38-43. [doi: 10.1016/j.msard.2017.01.016] [Medline: 28427699]
7. WHO guidelines on physical activity and sedentary behaviour. World Health Organization. 2020 Nov 25. URL: https://www.who.int/publications/i/item/9789240015128 [accessed 2024-02-15]
8. Tudor-Locke C, Bassett DR. How many steps/day are enough? preliminary pedometer indices for public health. Sports Med 2004;34(1):1-8. [doi: 10.2165/00007256-200434010-00001] [Medline: 14715035]
9. Wattanapisit A, Thanamee S. Evidence behind 10,000 steps walking. J Health Res 2017 Jun;31(3):241-248.
10. Paluch AE, Bajpai S, Bassett DR, Carnethon MR, Ekelund U, Evenson KR, et al. Daily steps and all-cause mortality: a meta-analysis of 15 international cohorts. Lancet Public Health 2022 Mar;7(3):e219-e228 [FREE Full text] [doi: 10.1016/S2468-2667(21)00302-9] [Medline: 35247352]
11. Alexander S, Peryer G, Gray E, Barkhof F, Chataway J. Wearable technologies to measure clinical outcomes in multiple sclerosis: a scoping review. Mult Scler 2021 Oct;27(11):1643-1656 [FREE Full text] [doi: 10.1177/1352458520946005] [Medline: 32749928]
12. Mehrabani G, Aminian S, Norton S, Motl RW, Manns PJ. Preliminary efficacy of the "SitLess with MS" intervention for changing sedentary behaviour, symptoms, and physical performance in multiple sclerosis. Disabil Rehabil 2022 Oct;44(21):6374-6381. [doi: 10.1080/09638288.2021.1966520] [Medline: 34433359]
13. Block VJ, Bove R, Zhao C, Garcha P, Graves J, Romeo AR, et al. Association of continuous assessment of step count by remote monitoring with disability progression among adults with multiple sclerosis. JAMA Netw Open 2019 Mar 01;2(3):e190570 [FREE Full text] [doi: 10.1001/jamanetworkopen.2019.0570] [Medline: 30874777]
14. Feehan LM, Geldman J, Sayre EC, Park C, Ezzat AM, Yoo JY, et al. Accuracy of Fitbit devices: systematic review and narrative syntheses of quantitative data. JMIR Mhealth Uhealth 2018 Aug 09;6(8):e10527 [FREE Full text] [doi: 10.2196/10527] [Medline: 30093371]
15. Irwin C, Gary R. Systematic review of Fitbit charge 2 validation studies for exercise tracking. Transl J Am Coll Sports Med 2022;7(4):1-7 [FREE Full text] [doi: 10.1249/tjx.0000000000000215] [Medline: 36711436]
16. Wong CK, Mentis HM, Kuber R. The bit doesn't fit: evaluation of a commercial activity-tracker at slower walking speeds. Gait Posture 2018 Jan;59:177-181. [doi: 10.1016/j.gaitpost.2017.10.010] [Medline: 29049964]
17. Katzan I, Schuster A, Kinzy T. Physical activity monitoring using a Fitbit device in ischemic stroke patients: prospective cohort feasibility study. JMIR Mhealth Uhealth 2021 Jan 19;9(1):e14494 [FREE Full text] [doi: 10.2196/14494] [Medline: 33464213]
18. Schaffer SD, Holzapfel SD, Fulk G, Bosch PR. Step count accuracy and reliability of two activity tracking devices in people after stroke. Physiother Theory Pract 2017 Oct;33(10):788-796. [doi: 10.1080/09593985.2017.1354412] [Medline: 28777710]
19. Block VJ, Zhao C, Hollenbach JA, Olgin JE, Marcus GM, Pletcher MJ, et al. Validation of a consumer-grade activity monitor for continuous daily activity monitoring in individuals with multiple sclerosis. Mult Scler J Exp Transl Clin 2019 Nov 21;5(4):2055217319888660 [FREE Full text] [doi: 10.1177/2055217319888660] [Medline: 31803492]
20. Lavelle G, Norris M, Flemming J, Harper J, Bradley J, Johnston H, et al. Validity and acceptability of wearable devices for monitoring step-count and activity minutes among people with multiple sclerosis. Front Rehabil Sci 2021 Jan 11;2:737384 [FREE Full text] [doi: 10.3389/fresc.2021.737384] [Medline: 36188762]
21. Polhemus A, Sieber C, Haag C, Sylvester R, Kool J, Gonzenbach R, et al. Non-equivalent, but still valid: establishing the construct validity of a consumer fitness tracker in persons with multiple sclerosis. PLOS Digit Health 2023 Jan 25;2(1):e0000171 [FREE Full text] [doi: 10.1371/journal.pdig.0000171] [Medline: 36812638]
22. Steinhubl SR, Muse ED, Topol EJ. The emerging field of mobile health. Sci Transl Med 2015 Apr 15;7(283):283rv3 [FREE Full text] [doi: 10.1126/scitranslmed.aaa3487] [Medline: 25877894]
23. Matthews PM, Block VJ, Leocani L. E-health and multiple sclerosis. Curr Opin Neurol 2020 Jun;33(3):271-276. [doi: 10.1097/WCO.0000000000000823] [Medline: 32324706]
24. Learmonth YC, Motl RW. Physical activity and exercise training in multiple sclerosis: a review and content analysis of qualitative research identifying perceived determinants and consequences. Disabil Rehabil 2016;38(13):1227-1242. [doi: 10.3109/09638288.2015.1077397] [Medline: 26314587]
25. Ploughman M. Breaking down the barriers to physical activity among people with multiple sclerosis – a narrative review. Phys Ther Rev 2017 Apr 19;22(3-4):124-132. [doi: 10.1080/10833196.2017.1315212]
26. Kayes NM, McPherson KM, Schluter P, Taylor D, Leete M, Kolt GS. Exploring the facilitators and barriers to engagement in physical activity for people with multiple sclerosis. Disabil Rehabil 2011;33(12):1043-1053. [doi: 10.3109/09638288.2010.520801] [Medline: 20874658]
27. Barriers to physical activity in people with MS (BarKA-MS). National Institutes of Health National Library of Medicine. URL: https://clinicaltrials.gov/study/NCT04746807 [accessed 2023-08-27]

28. Arend MG, Schäfer T. Statistical power in two-level models: a tutorial based on Monte Carlo simulation. Psychol Methods 2019 Feb;24(1):1-19. [doi: 10.1037/met0000195] [Medline: 30265048]
29. Sieber C, Haag C, Polhemus A, Sylvester R, Kool J, Gonzenbach R, et al. Feasibility and scalability of a fitness tracker study: results from a longitudinal analysis of persons with multiple sclerosis. Front Digit Health 2023;5:1006932 [FREE Full text] [doi: 10.3389/fdgth.2023.1006932] [Medline: 36926468]
30. Motl RW, Zhu W, Park Y, McAuley E, Scott JA, Snook EM. Reliability of scores from physical activity monitors in adults with multiple sclerosis. Adapt Phys Activ Q 2007 Jul;24(3):245-253. [doi: 10.1123/apaq.24.3.245] [Medline: 17916920]
31. DeepL Pro. URL: https://www.deepl.com/pro?cta=menu-pro/ [accessed 2021-11-03]
32. Straka M, Straková J. Tokenizing, POS tagging, lemmatizing and parsing UD 2.0 with UDPipe. In: Proceedings of the CoNLL 2017 Shared Task: Multilingual Parsing from Raw Text to Universal Dependencies. 2017 Presented at: CoNLL 2017; August 3-4, 2017; Vancouver, Canada URL: https://aclanthology.org/K17-3009/
33. udpipe: tokenization, parts of speech tagging, lemmatization and dependency parsing with the 'UDPipe' 'NLP' toolkit. The Comprehensive R Archive Network. 2023 Jan 6. URL: https://cran.r-project.org/package=udpipe [accessed 2023-03-03]
34. Plumpton CO, Morris T, Hughes DA, White IR. Multiple imputation of multiple multi-item scales when a full imputation model is infeasible. BMC Res Notes 2016 Jan 26;9:45 [FREE Full text] [doi: 10.1186/s13104-016-1853-5] [Medline: 26809812]
35. Madley-Dowd P, Hughes R, Tilling K, Heron J. The proportion of missing data should not be used to guide decisions on multiple imputation. J Clin Epidemiol 2019 Jun;110:63-73 [FREE Full text] [doi: 10.1016/j.jclinepi.2019.02.016] [Medline: 30878639]
36. van Buuren S, Groothuis-Oudshoorn K. mice : multivariate imputation by chained equations in R. J Stat Softw 2011;45(3):1-67. [doi: 10.18637/jss.v045.i03]
37. Nittas V, Mütsch M, Frey T, Braun J, Puhan MA. Effectiveness of a tailored web app on sun protection intentions and its implications for skin cancer prevention: a randomized controlled trial. PLOS Digit Health 2022 May 12;1(5):e0000032 [FREE Full text] [doi: 10.1371/journal.pdig.0000032] [Medline: 36812525]
38. McGuigan C, Hutchinson M. Confirming the validity and responsiveness of the Multiple Sclerosis Walking Scale-12 (MSWS-12). Neurology 2004 Jun 08;62(11):2103-2105. [doi: 10.1212/01.wnl.0000127604.84575.0d] [Medline: 15184625]
39. Penner IK, Raselli C, Stöcklin M, Opwis K, Kappos L, Calabrese P. The Fatigue Scale for Motor and Cognitive Functions (FSMC): validation of a new instrument to assess multiple sclerosis-related fatigue. Mult Scler 2009 Dec;15(12):1509-1517. [doi: 10.1177/1352458509348519] [Medline: 19995840]
40. Seebacher B, Mills RJ, Reindl M, Zamarian L, Kuisma R, Kircher S, et al. German translation, cultural adaption and validation of the unidimensional self-efficacy scale for multiple sclerosis: a study protocol. BMJ Open 2019 Aug 20;9(8):e029565 [FREE Full text] [doi: 10.1136/bmjopen-2019-029565] [Medline: 31434775]
41. Kroenke K, Strine TW, Spitzer RL, Williams JB, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. J Affect Disord 2009 Apr;114(1-3):163-173. [doi: 10.1016/j.jad.2008.06.026] [Medline: 18752852]
42. Barin L, Salmen A, Disanto G, Babačić H, Calabrese P, Chan A, et al. The disease burden of multiple sclerosis from the individual and population perspective: which symptoms matter most? Mult Scler Relat Disord 2018 Oct;25:112-121. [doi: 10.1016/j.msard.2018.07.013] [Medline: 30059895]
43. Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. Ann Med 2001 Jul;33(5):337-343. [doi: 10.3109/07853890109002087] [Medline: 11491192]
44. Fisk JD, Brown MG, Sketris IS, Metz LM, Murray TJ, Stadnyk KJ. A comparison of health utility measures for the evaluation of multiple sclerosis treatments. J Neurol Neurosurg Psychiatry 2005 Jan;76(1):58-63 [FREE Full text] [doi: 10.1136/jnnp.2003.017897] [Medline: 15607996]
45. Becker H, Stuifbergen AK, Sands D. Development of a scale to measure barriers to health promotion activities among persons with disabilities. Am J Health Promot 1991;5(6):449-454. [doi: 10.4278/0890-1171-5.6.449] [Medline: 10171668]
46. Becker H, Stuifbergen A. What makes it so hard? Barriers to health promotion experienced by people with multiple sclerosis and polio. Fam Community Health 2004;27(1):75-85. [doi: 10.1097/00003727-200401000-00008] [Medline: 14724504]
47. R: a language and environment for statistical computing. Global Biodiversity Information Facility. 2015 Feb 15. URL: https://www.gbif.org/tool/81287/r-a-language-and-environment-for-statistical-computing [accessed 2024-02-15]
48. RStudio: integrated development for R. RStudio. URL: http://www.rstudio.com/ [accessed 2024-02-15]
49. Marck CH, Learmonth YC, Chen J, van der Mei I. Physical activity, sitting time and exercise types, and associations with symptoms in Australian people with multiple sclerosis. Disabil Rehabil 2022 Apr;44(8):1380-1388. [doi: 10.1080/09638288.2020.1817985] [Medline: 32940535]
50. Ozdogar AT, Kahraman T, Ozakbas S, Achiron A, Kalron A. Fatigue is associated with physical inactivity in people with multiple sclerosis despite different environmental backgrounds: merging and comparing cohorts from Turkey and Israel. Mult Scler Relat Disord 2022 Jan;57:103456. [doi: 10.1016/j.msard.2021.103456] [Medline: 34896878]
51. Power M, Arafa N, Wenz A, Foley G. Perceptions of fatigue and fatigue management interventions among people with multiple sclerosis: a systematic literature review and narrative synthesis. Int J Ther Rehabil 2021 Jun 02;28(6):1-21. [doi: 10.12968/ijtr.2020.0144]

52. Wills OC, Probst YC. Understanding lifestyle self-management regimens that improve the life quality of people living with multiple sclerosis: a systematic review and meta-analysis. Health Qual Life Outcomes 2022 Nov 25;20(1):153 [FREE Full text] [doi: 10.1186/s12955-022-02046-1] [Medline: 36434609]
53. Motl RW. Exercise and multiple sclerosis. Adv Exp Med Biol 2020;1228:333-343. [doi: 10.1007/978-981-15-1792-1_22] [Medline: 32342468]
54. Ensari I, Motl RW, Pilutti LA. Exercise training improves depressive symptoms in people with multiple sclerosis: results of a meta-analysis. J Psychosom Res 2014 Jun;76(6):465-471. [doi: 10.1016/j.jpsychores.2014.03.014] [Medline: 24840141]
55. Adamson BC, Ensari I, Motl RW. Effect of exercise on depressive symptoms in adults with neurologic disorders: a systematic review and meta-analysis. Arch Phys Med Rehabil 2015 Jul;96(7):1329-1338. [doi: 10.1016/j.apmr.2015.01.005] [Medline: 25596001]
56. Herring MP, Fleming KM, Hayes SP, Motl RW, Coote SB. Moderators of exercise effects on depressive symptoms in multiple sclerosis: a meta-regression. Am J Prev Med 2017 Oct;53(4):508-518. [doi: 10.1016/j.amepre.2017.04.011] [Medline: 28602542]
57. Kasser SL, Kosma M. Social cognitive factors, physical activity, and mobility impairment in adults with multiple sclerosis. Behav Med 2018;44(4):306-313. [doi: 10.1080/08964289.2017.1368441] [Medline: 28862920]
58. Neal WN, Richardson EV, Motl RW. Informing the development of a mobile application for the physical activity guidelines in multiple sclerosis: a qualitative, pluralistic approach. Disabil Rehabil Assist Technol 2022 Dec 09:1-9. [doi: 10.1080/17483107.2022.2153937] [Medline: 36490227]
59. Kalb R, Brown TR, Coote S, Costello K, Dalgas U, Garmon E, et al. Exercise and lifestyle physical activity recommendations for people with multiple sclerosis throughout the disease course. Mult Scler 2020 Oct;26(12):1459-1469 [FREE Full text] [doi: 10.1177/1352458520915629] [Medline: 32323606]
60. Keller JL, Tian F, Fitzgerald KC, Mische L, Ritter J, Costello MG, et al. Using real-world accelerometry-derived diurnal patterns of physical activity to evaluate disability in multiple sclerosis. J Rehabil Assist Technol Eng 2022;9:20556683211067362 [FREE Full text] [doi: 10.1177/20556683211067362] [Medline: 35070348]

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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Barriers and Facilitators to the Use of Wearable Robots as Assistive Devices: Qualitative Study With Older Adults and Physiotherapists

Leah Reicherzer[1], MMedSc; Mandy Scheermesser[1], PhD; Adrian Kläy[1,2], MSc; Jaime E Duarte[3], PhD; Eveline S Graf[1], PhD

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Corresponding Author:
Leah Reicherzer, MMedSc

Abstract

Background: Light wearable robots have the potential to assist older adults with mobility impairments in daily life by compensating for age-related decline in lower extremity strength. Physiotherapists may be the first point of contact for older adults with these devices.

Objective: The aims of this study were to explore views of older adults and physiotherapists on wearable robots as assistive devices for daily living and to identify the barriers and facilitators to their use.

Methods: Six older adults (aged 72 - 88 years) tested a wearable robot (Myosuit) and participated in semistructured interviews. A focus group with 6 physiotherapists who had a minimum of 5 years of professional experience and specialized in geriatrics was conducted. Data were analyzed using thematic qualitative text analysis.

Results: Older adults perceived benefits and had positive use experiences, yet many saw no need to use the technology for themselves. Main barriers and facilitators to its use were the perception of usefulness, attitudes toward technology, ease of use, and environmental factors such as the support received. Physiotherapists named costs, reimbursement schemes, and complexity of the technology as limiting factors.

Conclusions: A light wearable robot—the Myosuit—was found to be acceptable to study participants as an assistive device. Although characteristics of the technology are important, the use and acceptance by older adults heavily depend on perceived usefulness and need.

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KEYWORDS

assistive device; barriers; facilitators; mobility; older adults; wearable robots

Introduction

The maintenance of mobility is fundamental for active aging and a key determinant for quality of life in older age [1,2]. Loss of mobility in older adults occurs when the physical capacities restrict the ability to walk due to increasing age, diseases, or injuries. Aging, especially in combination with a sedentary lifestyle, leads to a decline in muscle function and cardiorespiratory fitness, which eventually results in a reduced capacity to perform daily life activities and a loss of independence [3]. This loss of autonomy caused by the decline in physical mobility presents a major psychosocial implication of aging. Adequate exercise can help mitigate these changes [3,4]. Both structured exercise and general physical activity (PA) are known to be preventive for chronic diseases, such as diabetes, stroke, osteoporosis, or obesity, and to improve mobility, quality of life, and mental health among other benefits [3]. Despite the apparent health benefit of PA [5,6], a large percentage of older adults do not meet PA guidelines in their daily lives [7]. For adults with nonreversible mobility impairment, the use of assistive technologies is considered the best option to stay active and perform activities of daily living.

These assistive technologies range from traditional mobility aids, such as wheelchairs or rollators, to powered devices such as exoskeletons. Traditional walking aids such as the rollator, while promoting mobility and facilitating leisure activities or chores such as groceries, come with disadvantages, such as being too heavy or bulky for public transport or preventing the user from walking stairs [8]. In recent years, untethered lower limb exoskeletons have emerged as wearable, robotic mobility aids that allow individuals with motor impairment to walk independently [9]. Unlike older generations of exoskeletons

that present a rigid structure moving the human body, the latest wearable robots are significantly lighter and portable [10-13]. While the use of exoskeletons is mainly restricted to clinical and rehabilitation settings due to their weight, lightweight wearable robotics present a valuable alternative for private use. Therefore, they may have the potential to enable older adults to keep mobile and perform activities of daily living autonomously.

Potential benefits from the use of a wearable robot have been demonstrated by Lee et al [14], who found reduced energy expenditure and improved gait function in older adults using a soft hip assist robot. The Myosuit (MyoSwiss AG) is a recent, light wearable robot that provides users with antigravity support at the hip and the knee while standing, walking, climbing stairs, or during sit-stand transfers [15]. To date, the technology has successfully been used by people with neurological disorders such as multiple sclerosis, incomplete spinal cord injuries, or stroke. There is some evidence that activity-based training with the technology is safe, feasible, and well tolerated by patients with neurological gait disorders [16].

Experiences with other potential user groups of wearable robots as assistive devices, such as older adults, are limited. Jung and Ludden [17] found generally positive attitudes of older adults and clinicians toward the concept of exoskeleton technology but simultaneously found a reluctancy to try the technology. Shore et al [18,19] have identified several key functional requirements for designing exoskeletons for older adults, emphasizing the need for effectiveness, safety, facilitation of walking, hands-free usage, proper body support, ease of wear, and affordability to enhance their acceptance among this population. Understanding the needs and experiences of older adults and the professionals who care for them as potential user groups of wearable robots is crucial to inform future design decisions and guide implementation.

Therefore, this article explores views of older adults and physiotherapists (PTs) specialized in geriatrics on the Myosuit as an assistive device for daily living and identifies the barriers and facilitators to its use.

Methods

This study had a descriptive design with a qualitative approach using semistructured interviews with older adults and a focus group discussion with PTs.

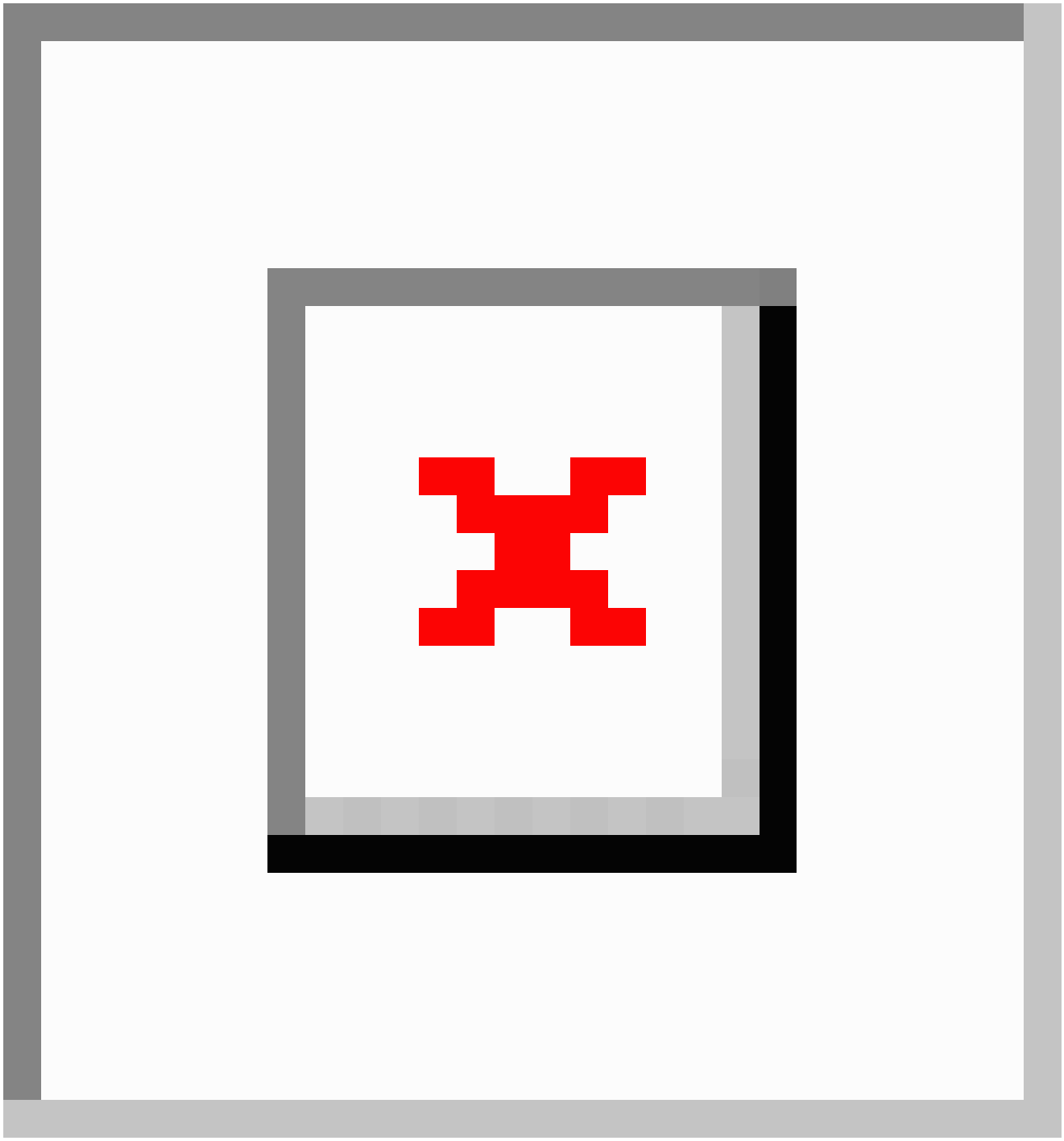
Ethical Considerations

According to the federal regulations (Swiss Human Research Act, 2020), ethical approval was not required for this study. A clarification of responsibility was obtained from the Ethics Committee Zurich (No. Req-2021‐00454). Information concerning the study participation and the right to withdraw at any time was provided to all focus group and interview participants. All participants signed an informed consent form.

The Technology

The Myosuit (Figure 1) is a wearable robot constructed in 3 layers that are inspired by ligaments, bones, and muscles of the human [15]. The general idea of the design is to transmit the forces over webbings and cables using different anchor points [20]. It can identify key coactivation patterns of the lower limb muscles in activities of daily life. The assistance level can be adjusted to provide forces continuously with gravity (eccentric behavior) or against gravity (concentric behavior) and for each leg individually, allowing for a high degree of personalization [21]. The current system weighs 5.56 kg including a lithium polymer battery that lasts up to 4 hours [15].

Figure 1. The Myosuit front and back perspective.



Participants and Recruitment

For PTs, a purposive sampling technique was used for recruitment. PTs were chosen and invited via email based on their expertise in working with older adults and represented different institutions (private practices, home care, clinics, and university). Six PTs with a minimum professional experience of 5 years agreed to participate in the focus group (Table 1). Two PTs worked regularly with the Myosuit and 4 had seen or tested it but were not using it in their daily practice.

Older adults were recruited face-to-face by PTs from 2 outpatient practices between September 2021 and December 2021. The inclusion criteria for older adults in the study were age more than 65 years; ability to walk 25 m without human assistance; reduced walking speed (<0.8 m/s and >0.4 m/s); the absence of secondary neurological conditions, such as stroke; no cognitive impairment; and body height and weight in accordance with the Myosuit requirements (height: 1.5-1.95 m; weight: 45-110 kg).

Six older adults (women: n=2; men: n=4; age: mean 78.8, SD 5.7 years) agreed to test the Myosuit and take part in a first interview. Of those, 2 participants volunteered to take the Myosuit home and participate in a second interview after the 2-week trial period at home (Table 2).

Table . Characteristics of physiotherapists (PTs) participating in focus groups.

ID	Sex	Setting
PT1	F[a]	Geriatric inpatient clinic
PT2	F	Geriatric inpatient clinic and university
PT3	F	Acute inpatient and outpatient setting
PT4	F	Neurological outpatient rehabilitation
PT5	F	Geriatric outpatient clinic
PT6	M[b]	Home care

[a]F: female.

[b]M: male.

Table . Characteristics of older adults (participants [P]).

P	Sex	Age (years)	Living situation	Interview 1	Interview 2
P1	M[a]	88	Alone, with support	✓	
P2	F[b]	72	With spouse	✓	
P3	F	77	Alone, with support	✓	✓
P4	M	85	With spouse	✓	
P5	M	75	Alone, no support needed	✓	✓
P6	M	76	Alone, no support needed	✓	

[a]M: male.

[b]F: female.

Data Collection

One web-based focus group with PTs (n=6), who specialized in geriatric care, was conducted to capture professionals' views on the technology. A semistructured topic guide was developed according to Benighaus and Benighaus [22] by the interdisciplinary team, involving a movement scientist (ESG), physiotherapist (LR), and social scientist (MS) experienced in qualitative data collection and usability or user experience research. The focus group was moderated by MS with LR present for note-taking and recording. Discussion topics revolved around the experts' opinions on a wearable robot as an assistive device for older adults and which barriers and facilitators they anticipate from a professional point of view. The duration of the focus group was 1.5 hours. The audio recording of the web-based discussion was transcribed verbatim.

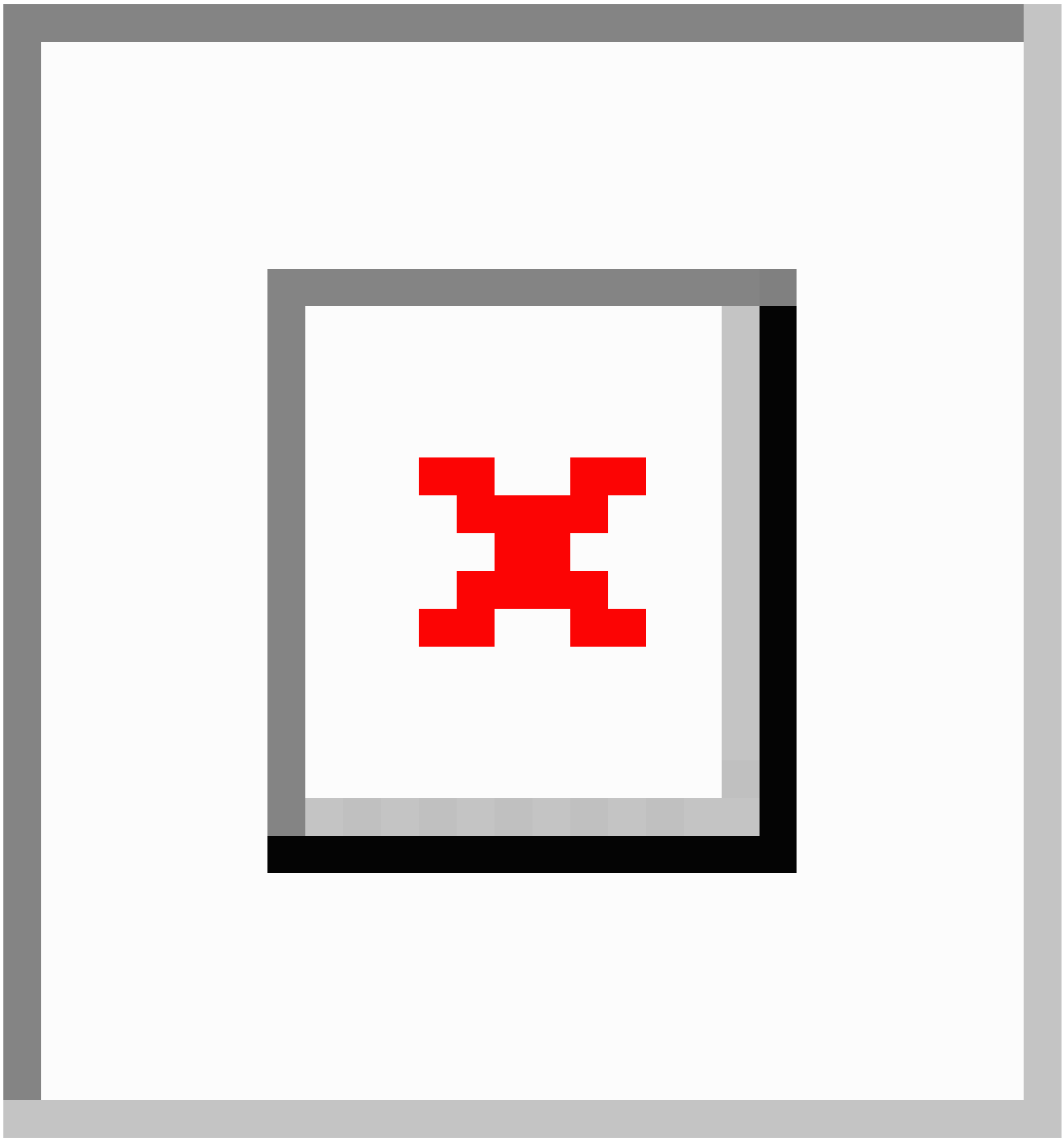
Older adults (n=6) were invited to try the Myosuit in a session with a physiotherapist (AK) and a physiotherapy research associate (LR), followed by a semistructured interview. The data collection took place at the participants' local physiotherapy practice or in suitable rooms at the university campus.

Before testing the Myosuit, the participants were informed about the study procedure and goals. Subsequently, written informed consent was obtained. Participants were introduced to the Myosuit in several steps: (1) a short explanation of the functions and purpose of the device, (2) individual adjustment of the straps and backpack to the participant, and (3) performance of a set of easy tasks with assistance of the Myosuit. These tasks included transferring weight from one leg to the other; standing up from a chair; and, once the participants felt confident, walking and stair climbing up and down using their habitual walking aid. The participants were encouraged to take the Myosuit off by themselves and put it back on. The introduction was video recorded.

Following the introduction, semistructured interviews were conducted by one of the authors (AK) in German. First, demographic information, such as age, gender, and living situation, was discussed, followed by general interest in technology and perception of individual health status and abilities. The main part of the interview focused on first impressions of the technology and the perceived barriers and facilitators to using the Myosuit in daily life. The topic guide (Multimedia Appendix 1) was developed by the interdisciplinary research team. The questions were informed by the theoretical domains framework [23,24], which provides a comprehensive, theory-informed approach to identify personal and environmental influences on a behavior (here: use of the wearable robot). For example, to address social influences, we included the following question: "How would you imagine your friends and family react to you using this technology?" A pilot test with 1 older adult was done to test the topic guide before conducting the interviews and to assess whether the steps for introducing the technology were feasible. Interviews lasted between 30 and 45 minutes and were audio recorded. Participants who volunteered to take the Myosuit home (n=2) received another training session with the Myosuit supervised

by a physiotherapist (AK) at the beginning of a 2-week period (Figure 2). Another visit was scheduled after 1 week in case the participants had questions about the use of the Myosuit. A second interview was conducted at the end of the 2 weeks of using the Myosuit at home. Audio recordings from all interviews and participants' statements from the video recordings were transcribed verbatim.

Figure 2. Data collection procedure for interviews with older adults.



Data Analysis

Two researchers (LR, MS) coded the transcripts of interviews from both time points and focus groups independently for a thematic qualitative text analysis according to Kuckartz [25], using the software ATLAS.ti (Windows Version 9.1.7). This approach allows for the thematic analysis of different types of interviews, as well as other types of data, such as focus groups [25]. The analysis process involves familiarization with the textual data through repeated reading, highlighting of important passages, identification of codes, and synthesis in larger thematic categories. The development of main topical categories was guided by the interview guidelines, but inductive analysis of unanticipated topics or meanings was also considered. After a first round of coding using the main categories, the initial categories were discussed and combined where deemed appropriate, and subcategories were determined. The category system was reviewed, discussed, and adapted until deemed comprehensive. The final category system comprised 8 main and 17 subcategories (Multimedia Appendix 2).

Once all data were coded using the final category system, the information with related meanings across interviews and focus groups was summarized, and redundant information was reduced. Finally, the categories were analyzed, and the content was organized into barriers and facilitators of using the Myosuit as an assistive device, considering factors related to the technology, the individual, and the environment.

Results

The results are presented for the main categories. Quotes and pseudonyms ("P" for the participating older adults and "PT" for physiotherapist) are used in the following sections to illustrate the categories.

The Technology

Regarding the technology, various usability aspects, such as the process of donning and doffing, the comfort, or sound, were identified as factors that may influence the use.

Usability of the Technology

While using the technology for the first time, the majority of participants felt that the initial donning and doffing was not as easy as they had imagined it but were also under the impression that they could don and doff independently: "It [handling] is quite good. You have to get used to it of course. But it's positive" (P5). PTs also considered independent donning and doffing as a challenge for older adults and were under the impression that most older adults would require assistance by family or care providers. One participant who had seen a video of the technology previously was under the impression that it had appeared to be easier to use in the video. More specifically, participants described an initial overwhelming feeling concerning the straps that need to be fixated at the right place on the user's body: "all these straps and I have no idea which one goes where" (P1). Enough hand strength was mentioned as a requirement:

> *You would have to think about making the buckles on the legs so that they are easier to click into place. Because for people with weak hands it can be quite difficult, because it also has to fit tightly.* [P3]

PTs brought up the comfort of wearing the technology, especially for extended periods of time, which would be necessary for an assistive device: "there is pressure on it when you wear it for a long time. And if you are sensitive to it now, it can be painful" (PT4). Indeed, a few participants noted that the force application does feel uncomfortable at times: "The settings sometimes are more comfortable or a bit more uncomfortable when it like jams or rumbles on the back" (P3). Three participants felt restricted in their mobility by the technology rather than feeling like it supported their movement, especially on the stairs. One user attributes this to the weight of the technology. One PT provided another explanation: she had observed that her patients who have more pronounced gait deviations initially struggle with the gait pattern of the Myosuit that supports hip and knee extension. For some participants, the technology felt rather heavy at first but was not as noticeable once the hip belt was properly attached.

Navigating the control unit and the manual selection of the appropriate modes (ie, concentric or isometric) were brought up by the experts as a potential difficulty to anticipate. However, the user interface was generally received positively by older adults. One participant made a statement that she would need practice to navigate the user interface and to train with someone who is experienced with the Myosuit.

> *It gets quite complicated; you have to be sure, but you also need to practice multiple times with someone who knows how to do it.* [P3]

After regular use, however, the display did not pose a challenge anymore.

Many participants observed and mentioned the sound the technology makes. For some, the sound was too loud: "Yes, maybe just the sound it makes. If I were to go for a walk with someone, if I were to do that, I wouldn't find it so pleasant" (P6). Participant who home tested noted that the sound is not as noticeable when using it outside as compared with indoors:

> *Yes, well, I can live with the sound now. Outside you don't notice it so much. Because I walk next to the streets where there is a lot of noise anyway. You don't hear it there.* [P3]

The Individual

On the level of the individual, the general attitudes toward technology, fear of falling, and individual walking capabilities, as well as the expected and perceived benefits of using the technology, were identified as barriers or facilitators.

Attitude Toward Technology

Technology acceptance by either the older adults themselves or the therapists as one important point of contact with such technologies was identified as a potential barrier by PTs. On the contrary, most older adults in this study expressed that they were open and interested in new technologies. Digital media are part of their everyday lives, and they use digital technologies to measure their daily activity, such as pedometers or fitness trackers. One participant (P3) commented, "Of course not [only] for health,…I have a laptop and do most things online."

Fear of Falling

Participants described how they are afraid of falling in everyday life. One of the participants who decided to test the technology at home has had several falls without injuries previously. She described using a walking stick in combination with the Myosuit, which made her feel safer. For some participants, donning and doffing, the weight, or the force application caused a fear of falling:

> *The backpack is bothering me. Also, because it is pulling me backwards and makes me feel insecure that I might fall over. And I do not want to fall.* [P1]

PTs also considered whether fall risk might be a potential barrier to its use:

> *I also thought about individuals with gait instability. Whether there is experience in that area [with the*

Myosuit] and whether it might even be more hindering and possibly contribute to the risk of falls. [PT3]

Individual Walking Capabilities

Most participants were capable of independent walking, with walking durations ranging between 10 minutes and 2 hours (long walks). Five participants were walking with walking sticks or hiking poles. One participant had no walking aid at all. Participants who described higher individual walking capabilities tended to be less interested in Myosuit:

I prefer to walk the stairs myself. I prefer to go for a walk or hike myself. I much prefer to exercise a little in the studio or in physiotherapy. I imagined it [a wearable robot] very differently. [P1]

Expected Benefits

Participants hoped for various immediate or long-term results from using the Myosuit, which can be summarized as expected benefits. These expected benefits were the main motivators for participants to test the Myosuit. One expected benefit was to increase mobility outdoors without depending on aids such as a wheelchair "to be able to go outside and not sit at home." One participant said:

If the walking sticks might not be sufficient anymore. Where I live, I see many people using walkers and that is not for me. And wheelchairs even less, that would be my very last option. Anything that allows me to stay mobile independently is positive for me. [P3]

PTs specialized in geriatric care similarly voiced openness toward using a wearable robot as an assistive device if it would help their patients maintain or improve independent mobility. Some older adults expected to see effects like an improved walking ability or balance: "That was the main reason, I wanted to try the technology. Whether it helps to improve my walking" (P1). One participant was under the impression that walking with the Myosuit could be more fun and therefore increase walking distance: "Possibly, maybe I would walk to [destination in town] twice more than right now. It could be that I would have more fun then, that's quite possible" (P6).

Perceptions of Benefit

Most respondents addressed the perception of benefit, reflecting the positive outcomes they experienced as a result of using the Myosuit. The range of perceived benefits spans from "more safety" and "more mobility" to "realizing one's own goals." One participant (P3) did not expect much from the technology and was then pleasantly surprised. This participant described the following: "I just felt safer than if I had gone without." Consequently, their mobility increased: "Especially to go for more walks. I was practically out every day except yesterday and the day before yesterday…. But one day, I think I even managed 2400 steps." The participant also noted that not only did the intensity of the movement increase but the quality of the movement also changed: "Well, I was able to take longer steps and I walked faster" (P3).

Others saw no personal benefit in the wearable robot for themselves or perceived a discrepancy between the benefits they had expected and their actual experiences. "…on the video on the internet, the enthusiasm was really great…. One even did a marathon…. But I don't see that at all. The support is not enough so that I could do that" (P4).

The Environment

The environmental factors identified in this study include appropriate use situations, social influences, and costs associated with the introduction of a novel technology.

Use Situations

Participants were asked to describe contexts or scenarios in which they could envision themselves using the technology. They primarily imagined using the Myosuit for walking activities outdoors, or potentially for tasks such as groceries or day activities. PTs discussed that home use would be more beneficial than using it during a therapy session, stating, "If it could be managed with home care services or with family members, and simply say, 'He wears the suit for two or three hours a day, once a day, and tries to manage everyday life." It became clear that participants also preferred to remain within the closer surroundings of the home. One participant described not wanting to use the Myosuit for activities with longer duration that would require boarding a train and take her further away from home: "So in everyday life I used it to walk more. I didn't dare to go to the city with it with the trains and trams…" (P3).

Social Influences

Family support, as an import prerequisite to putting on the Myosuit (P1) or in motivating people to try out new technologies (P4), was reported by the participants. PTs anticipated reluctance from older adults to use assistive technologies that are associated with older age:

I'm already struggling to convince some residents in the facility to use a walker because they think, 'I'm not old.' They believe that walkers are for the elderly, and we're talking about people who are over 80 years old. [PT2]

PTs also considered social desirability and were unsure whether older adults would consider wearing the Myosuit in public:

After all, you look different and if you need it in everyday life and you have this thing on, you have to be confident enough to answer questions from those around you. [PT4]

Worries about how this type of wearable robot is perceived by others were also expressed by older adults regarding the sound and looks of the Myosuit: "Of course, if I go out on the street now, someone will be looking. But I am so self-confident in my age that it doesn't bother me" (P3). Some participants were hesitant to wear the Myosuit outdoors: "I wouldn't have…the guts yet to go to a supermarket with it.… I don't think so…" (P6).

Costs

Reimbursement schemes in the health care system were discussed as a barrier for use of the technology in daily clinical practice by PTs, as usually 1 session per week is reimbursed by health care insurances and this time is often too short for PTs

to implement new technologies. It was important for participants that the benefit outweighs the costs:

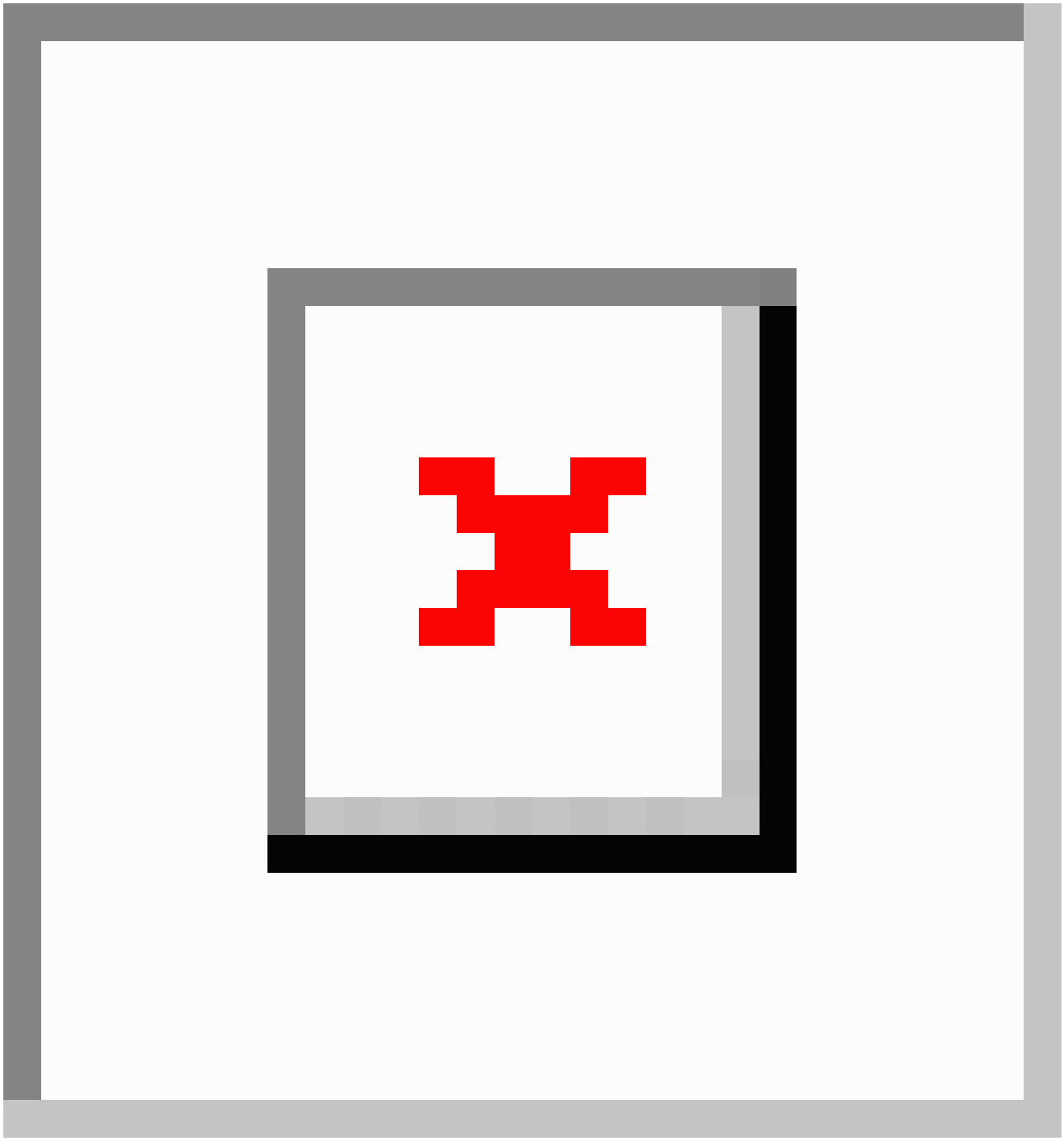
> *It's…certainly worth the price if I think I that I could walk a little better in everyday life and take a few steps with someone.* [P6]

Discussion

Principal Findings

The results demonstrate a generally favorable attitude among older adults and PTs toward the novel wearable robot. Several participants described how they experienced greater stability while standing, walking, and climbing stairs or during the sit-to-stand transfer. The technology made movement easier, and noticeable support was mentioned. Two older adults volunteered to test the Myosuit at home for an extended period and used it as a support during daily life activities. They reported an increase in walking distance and in general motivation for PA. Most other participants, however, did not see the need to use this type of technology. Main barriers to its use were factors centered around the individual (eg, the perception of "not needing it" or attitudes toward wearable robots), the technology (eg, ease of use), and the environment (eg, the support received; Figure 3). These results are in line with previous literature on factors influencing acceptance of new technologies. A systematic review [26] identified concerns regarding the technology (eg, costs), expected benefits of technology (eg, perceived usefulness), need for technology, alternatives to technology, social influence, and characteristics of older adults (eg, desire to age in place) as factors influencing the acceptance of technology in a preimplementation stage.

Figure 3. Barriers and facilitators to the use of the soft exoskeleton identified by older adults and physiotherapists.



Contrary to common beliefs, previous studies [27,28] did not find a significant association of age with acceptance or general attitude toward robots. The adoption of technologies in the older age group has indeed grown considerably in the last decade, but a substantial gap remains between younger and older adults [29]. It has been demonstrated that preconceptions of older adults about robots are ambivalent, and while they may be open to the idea, they are not prepared to actually use them [30,31]. Frennert and colleagues [30] described a tension between seeing the benefits of a robot and simultaneously having the attitude of "good for others but not themselves." Similarly, participants in this study were under the impression that they themselves do not need such technology. This may indicate that the social stigma pertaining to assistive technology of users being old or disabled also extends to these novel assistive devices. It further raises the question how best to determine who may benefit from this technology based on indicators of functional capacity rather than pathology. We composed our sample of older adults with measurable reduced walking speed. However, several participants did not feel limited in their mobility in daily life and did not benefit from using a wearable robot. A combination of functional mobility tests and self-reported mobility assessments to identify who may benefit seems like a more promising strategy.

Perceived usefulness of the technology was identified here as another central influence on acceptance (intention to use) of the technology. If a participant did not see a benefit or value when first trying the wearable robot, it was unlikely that it was given

a second chance. Previous studies of assistive technologies for older adults identified added value as a central facilitator to technology use in general [32-34]. Similarly, it is apparent in numerous studies that users' perceptions of assistive wearable robots are influenced by the experience of using the technology and that adoption of the technology is dependent on users regarding them as valuable for their own purposes [35]. By compensating for diminished mobility and enhancing exercise tolerance, wearable robots are uniquely positioned to be used by older adults for increased total PA, exercise, and social interaction [36]. Chen et al [37] have studied older adults' intention to use exoskeletons and highlight that practitioners should focus on encouraging favorable attitudes and perceptions toward robotic technologies by communicating the benefits and value that wearable robotics can provide to potential users.

Fewer studies to date have investigated the reasons behind nonuptake and uptake of technologies by PTs. Systematic reviews in the field of digital health have found that complexity, costs [38], and lack of reimbursement [39] act as barriers to the implementation of telehealth. In our study, PTs were more critical regarding the usability and expressed concerns about the complexity of the technology. They suspected that older adults would encounter difficulties with the control unit or with donning and doffing at home, which was expressed less frequently by older adults themselves. This may reflect not only a general tendency of Western societies to be more conservative with regard to technological devices than other societies [40] but also a tendency of health care providers. In addition, there is currently no reimbursement scheme that factors in the time needed to successfully implement a new technology into a therapy setting, presenting a considerable barrier for PTs to adopt new technologies [41]. This should be addressed, as PTs are in a unique position to introduce their patients to novel technologies that can foster their autonomy in daily life.

It was universal across interview and focus group participants to emphasize the importance of ease of use of the technology and an inconspicuous appearance while being comfortable. A previous qualitative study [42] similarly identified the device appearance and comfort as important, with a discreet color and materials with a comfortable feel being favored by adults with mobility impairments of different origin.

This further illustrates that while it is important to meet older adults' needs by providing the expected benefits, it is equally important that technology is easy to use, in order for these benefits to be realized [43]. Technologies that are designed without considering the specific user group's needs and preferences are less likely to be used. Future design iterations may therefore focus on comfort, the simplicity of donning and doffing, and the user interface for intuitive use.

Limitations

It should be noted that the participants most likely had a favorable attitude when approaching the study, presumably because their participation was linked to curiosity about robot-assisted training or expectations regarding the benefits of the technology. Testing the device in the home environment or therapy setting likely allowed older adults to develop a good understanding of barriers and facilitators to the use of wearable robots. Data saturation was likely not reached with the conducted interviews, as we had to base our sample on availability. This may limit the informative value of the results. However, triangulation was used by combining 2 different data collection methods and including different user groups to enhance the breadth of information. Face-to-face focus groups would have been well suited for this purpose, as they allow for personal contact between the interviewer and the PTs. Web-based focus groups, on the other hand, were less suitable but were considered necessary due to the limitations of the COVID-19 pandemic.

Conclusions

This article provides valuable insights into the barriers and facilitators influencing the use of a novel wearable robot from the perspective of older adults and PTs. The results indicate a generally positive attitude toward the technology and highlight the importance of perceived usefulness and value besides the specific characteristics of the technology to realize its benefits.

To overcome the barriers and capitalize on facilitators, the following points should be considered for future action. First, there is a need to clearly communicate the potential benefits and value of the technology, emphasizing how it can address specific challenges faced by older adults and enhance mobility. Second, ease of use should be prioritized through intuitive interfaces and straightforward controls to facilitate integration into daily life activities. Third, providing adequate support, including clear instructions and resources, is crucial to ensure successful adoption and use of the wearable robot.

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Conflicts of Interest

ESG, AK, MS, and LR declare that they have no competing interests. JED is cofounder and CEO of MyoSwiss AG.

Multimedia Appendix 1
Interview questions.

[DOCX File, 16 KB - rehab_v11i1e52676_app1.docx]

Multimedia Appendix 2
Category system.
[DOCX File, 15 KB - rehab_v11i1e52676_app2.docx]

References

1. Bechtold U, Stauder N, Fieder M. Let's walk it: mobility and the perceived quality of life in older adults. Int J Environ Res Public Health 2021 Jan;18(21):11515. [doi: 10.3390/ijerph182111515] [Medline: 34770028]
2. Webber SC, Porter MM, Menec VH. Mobility in older adults: a comprehensive framework. Gerontologist 2010 Aug;50(4):443-450. [doi: 10.1093/geront/gnq013] [Medline: 20145017]
3. Izquierdo M, Merchant RA, Morley JE, et al. International exercise recommendations in older adults (ICFSR): expert consensus guidelines. J Nutr Health Aging 2021;25(7):824-853. [doi: 10.1007/s12603-021-1665-8] [Medline: 34409961]
4. Talbot LA, Metter EJ, Fleg JL. Leisure-time physical activities and their relationship to cardiorespiratory fitness in healthy men and women 18–95 years old. Med Sci Sports Exerc 2000 Feb;32(2):417. [doi: 10.1097/00005768-200002000-00024]
5. Cunningham C, O' Sullivan R, Caserotti P, Tully MA. Consequences of physical inactivity in older adults: a systematic review of reviews and meta‐analyses. Scand J Med Sci Sports 2020 May;30(5):816-827. [doi: 10.1111/sms.13616] [Medline: 32020713]
6. Steffl M, Bohannon RW, Sontakova L, Tufano JJ, Shiells K, Holmerova I. Relationship between sarcopenia and physical activity in older people: a systematic review and meta-analysis. Clin Interv Aging 2017;12:835-845. [doi: 10.2147/CIA.S132940] [Medline: 28553092]
7. Tudor-Locke C, Schuna JM, Barreira TV, et al. Normative steps/day values for older adults: NHANES 2005-2006. J Gerontol A Biol Sci Med Sci 2013 Nov;68(11):1426-1432. [doi: 10.1093/gerona/glt116] [Medline: 23913932]
8. Bertrand K, Raymond MH, Miller WC, Martin Ginis KA, Demers L. Walking aids for enabling activity and participation: a systematic review. Am J Phys Med Rehabil 2017 Dec;96(12):894-903. [doi: 10.1097/PHM.0000000000000836] [Medline: 29176406]
9. van Dijsseldonk RB, van Nes IJW, Geurts ACH, Keijsers NLW. Exoskeleton home and community use in people with complete spinal cord injury. Sci Rep 2020 Sep 24;10(1):15600. [doi: 10.1038/s41598-020-72397-6] [Medline: 32973244]
10. Graf ES, Bauer CM, Power V, et al. Basic functionality of a prototype wearable assistive soft exoskeleton for people with gait impairments: a case study. Presented at: PETRA '18: The 11th PErvasive Technologies Related to Assistive Environments Conference; Jun 26 to 29, 2018:; Corfu, Greece p. 202-207. [doi: 10.1145/3197768.3197779]
11. Schmidt K, Riener R. MAXX: Mobility Assisting teXtile eXoskeleton that exploits neural control synergies. In: Ibáñez J, González-Vargas J, Azorín JM, Akay M, Pons JL, editors. Converging Clinical and Engineering Research on Neurorehabilitation II: Springer International Publishing; 2017:539-543. [doi: 10.1007/978-3-319-46669-9_89]
12. Kim DS, Lee HJ, Lee SH, et al. A wearable hip-assist robot reduces the cardiopulmonary metabolic energy expenditure during stair ascent in elderly adults: a pilot cross-sectional study. BMC Geriatr 2018 Sep 29;18(1):230. [doi: 10.1186/s12877-018-0921-1] [Medline: 30268096]
13. Kusuda Y. In quest of mobility—Honda to develop walking assist devices. Ind Robot 2009 Oct 16;36(6):537-539. [doi: 10.1108/01439910910994597]
14. Lee HJ, Lee S, Chang WH, et al. A wearable hip assist robot can improve gait function and cardiopulmonary metabolic efficiency in elderly adults. IEEE Trans Neural Syst Rehabil Eng 2017 Sep;25(9):1549-1557. [doi: 10.1109/TNSRE.2017.2664801] [Medline: 28186902]
15. Schmidt K, Duarte JE, Grimmer M, et al. The Myosuit: bi-articular anti-gravity exosuit that reduces hip extensor activity in sitting transfers. Front Neurorobot 2017 Oct;11:57. [doi: 10.3389/fnbot.2017.00057] [Medline: 29163120]
16. Haufe FL, Schmidt K, Duarte JE, Wolf P, Riener R, Xiloyannis M. Activity-based training with the Myosuit: a safety and feasibility study across diverse gait disorders. J Neuroeng Rehabil 2020 Oct 8;17(1):135. [doi: 10.1186/s12984-020-00765-4] [Medline: 33032627]
17. Jung MM, Ludden GDS. What do older adults and clinicians think about traditional mobility aids and exoskeleton technology? J Hum-Robot Interact 2019 Jun 30;8(2):1-17. [doi: 10.1145/3311789]
18. Shore L, Power V, De Eyto A, O'Sullivan L. Technology acceptance and user-centred design of assistive exoskeletons for older adults: a commentary. Robotics 2018 Jan 3;7(1):3. [doi: 10.3390/robotics7010003]
19. Shore L, de Eyto A, O'Sullivan L. Technology acceptance and perceptions of robotic assistive devices by older adults—implications for exoskeleton design. Disabil Rehabil Assist Technol 2022 Oct;17(7):782-790. [doi: 10.1080/17483107.2020.1817988] [Medline: 32988251]
20. Bartenbach V, Schmidt K, Naef M, Wyss D, Riener R. Concept of a soft exosuit for the support of leg function in rehabilitation. Presented at: 2015 IEEE International Conference on Rehabilitation Robotics (ICORR); Aug 11 to 14, 2015:; Singapore, Singapore p. 125-130. [doi: 10.1109/ICORR.2015.7281187]

21. Haufe FL, Kober AM, Schmidt K, et al. User-driven walking assistance: first experimental results using the Myosuit. Presented at: 2019 IEEE 16th International Conference on Rehabilitation Robotics (ICORR); Jun 24 to 28, 2019:; Toronto, ON, Canada p. 944-949. [doi: 10.1109/ICORR.2019.8779375]
22. Benighaus C, Benighaus L. Moderation, Gesprächsaufbau und Dynamik in Fokusgruppen. In: Schulz M, Mack B, Renn O, editors. Fokusgruppen in Der Empirischen Sozialwissenschaft: Von Der Konzeption Bis Zur Auswertung: VS Verlag für Sozialwissenschaften; 2012:111-132. [doi: 10.1007/978-3-531-19397-7_6]
23. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implement Sci 2012 Apr 24;7:37. [doi: 10.1186/1748-5908-7-37] [Medline: 22530986]
24. Atkins L, Francis J, Islam R, et al. A guide to using the theoretical domains framework of behaviour change to investigate implementation problems. Implement Sci 2017 Jun 21;12(1):77. [doi: 10.1186/s13012-017-0605-9] [Medline: 28637486]
25. Kuckartz U. Qualitative Text Analysis: A Guide to Methods, Practice & Using Software: SAGE Publications Ltd; 2014. [doi: 10.4135/9781446288719]
26. Peek STM, Wouters EJM, van Hoof J, Luijkx KG, Boeije HR, Vrijhoef HJM. Factors influencing acceptance of technology for aging in place: a systematic review. Int J Med Inform 2014 Apr;83(4):235-248. [doi: 10.1016/j.ijmedinf.2014.01.004] [Medline: 24529817]
27. Naneva S, Sarda Gou M, Webb TL, Prescott TJ. A systematic review of attitudes, anxiety, acceptance, and trust towards social robots. Int J Soc Robotics 2020 Dec;12(6):1179-1201. [doi: 10.1007/s12369-020-00659-4]
28. Gnambs T, Appel M. Are robots becoming unpopular? Changes in attitudes towards autonomous robotic systems in Europe. Comput Human Behav 2019 Apr;93:53-61. [doi: 10.1016/j.chb.2018.11.045]
29. Faverio M. Share of those 65 and older who are tech users has grown in the past decade. Pew Research Center. 2022 Jan 13. URL: https://www.pewresearch.org/short-reads/2022/01/13/share-of-those-65-and-older-who-are-tech-users-has-grown-in-the-past-decade/ [accessed 2023-07-06]
30. Frennert S, Eftring H, Östlund B. What older people expect of robots: a mixed methods approach. In: Herrmann G, Pearson MJ, Lenz A, Bremner P, Spiers A, Leonards U, editors. Social Robotics: 5th International Conference, ICSR 2013, Bristol, UK, October 27-29, 2013, Proceedings: Springer International Publishing; 2013:19-29. [doi: 10.1007/978-3-319-02675-6_3]
31. Wang RH, Sudhama A, Begum M, Huq R, Mihailidis A. Robots to assist daily activities: views of older adults with Alzheimer's disease and their caregivers. Int Psychogeriatr 2017 Jan;29(1):67-79. [doi: 10.1017/S1041610216001435] [Medline: 27660047]
32. Yusif S, Soar J, Hafeez-Baig A. Older people, assistive technologies, and the barriers to adoption: a systematic review. Int J Med Inform 2016 Oct;94:112-116. [doi: 10.1016/j.ijmedinf.2016.07.004] [Medline: 27573318]
33. Wu YH, Wrobel J, Cristancho-Lacroix V, et al. Designing an assistive robot for older adults: the ROBADOM project. IRBM 2013 Apr;34(2):119-123. [doi: 10.1016/j.irbm.2013.01.003]
34. Lee C, Coughlin JF. PERSPECTIVE: older adults' adoption of technology: an integrated approach to identifying determinants and barriers. J Product Innov Manag 2015 Sep;32(5):747-759. [doi: 10.1111/jpim.12176]
35. Hill D, Holloway CS, Morgado Ramirez DZ, Smitham P, Pappas Y. What are user perspectives of exoskeleton technology? A literature review. Int J Technol Assess Health Care 2017 Jan;33(2):160-167. [doi: 10.1017/S0266462317000460] [Medline: 28849760]
36. Shore L, Power V, Hartigan B, et al. Exoscore: a design tool to evaluate factors associated with technology acceptance of soft lower limb exosuits by older adults. Hum Factors 2020 May;62(3):391-410. [doi: 10.1177/0018720819868122] [Medline: 31419179]
37. Chen K, Lou VW, Cheng CYM. Intention to use robotic exoskeletons by older people: a fuzzy-set qualitative comparative analysis approach. Comput Human Behav 2023 Apr;141:107610. [doi: 10.1016/j.chb.2022.107610]
38. Ross J, Stevenson F, Lau R, Murray E. Factors that influence the implementation of e-health: a systematic review of systematic reviews (an update). Implement Sci 2016 Oct 26;11(1):146. [doi: 10.1186/s13012-016-0510-7] [Medline: 27782832]
39. Scott Kruse C, Karem P, Shifflett K, Vegi L, Ravi K, Brooks M. Evaluating barriers to adopting telemedicine worldwide: a systematic review. J Telemed Telecare 2018 Jan;24(1):4-12. [doi: 10.1177/1357633X16674087] [Medline: 29320966]
40. Kaplan F. Who is afraid of the humanoid? Investigating cultural differences in the acceptance of robots. Int J Human Robot 2004 Sep;01(3):465-480. [doi: 10.1142/S0219843604000289]
41. Rausch AK, Baur H, Reicherzer L, et al. Physiotherapists' use and perceptions of digital remote physiotherapy during COVID-19 lockdown in Switzerland: an online cross-sectional survey. Arch Physiother 2021 Jul 7;11(1):18. [doi: 10.1186/s40945-021-00112-3] [Medline: 34233763]
42. Morris L, Cramp M, Turton A. User perspectives on the future of mobility assistive devices: understanding users' assistive device experiences and needs. J Rehabil Assist Technol Eng 2022 Jan;9:20556683221114790. [doi: 10.1177/20556683221114790] [Medline: 35983071]
43. Wang A, Redington L, Steinmetz V, Lindeman D. The ADOPT model: accelerating diffusion of proven technologies for older adults. Ageing Int 2011 Mar;36(1):29-45. [doi: 10.1007/s12126-010-9072-1]

Abbreviations

PA: physical activity
PT: physiotherapist

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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

Giulio E Lancioni[1], PhD; Nirbhay N Singh[2], PhD; Mark F O'Reilly[3], PhD; Jeff Sigafoos[4], PhD; Gloria Alberti[1], MA; Isabella Orlando[1], MA; Valeria Chiariello[1], MA; Lorenzo Desideri[5], PhD

[1]Lega F D'Oro Research Center, Osimo, Italy

[2]Department of Psychiatry and Health Behavior, Augusta University, Augusta, GA, United States

[3]College of Education, University of Texas at Austin, Austin, TX, United States

[4]School of Education, Victoria University of Wellington, Wellington, New Zealand

[5]Department of Psychology, Sigmund Freud University, Milan, Italy

Corresponding Author:
Giulio E Lancioni, PhD
Lega F D'Oro Research Center
Via Linguetta 3
Osimo, 60027
Italy
Phone: 39 3408323465
Email: giulio.lancioni@uniba.it

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

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

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.

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

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

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.

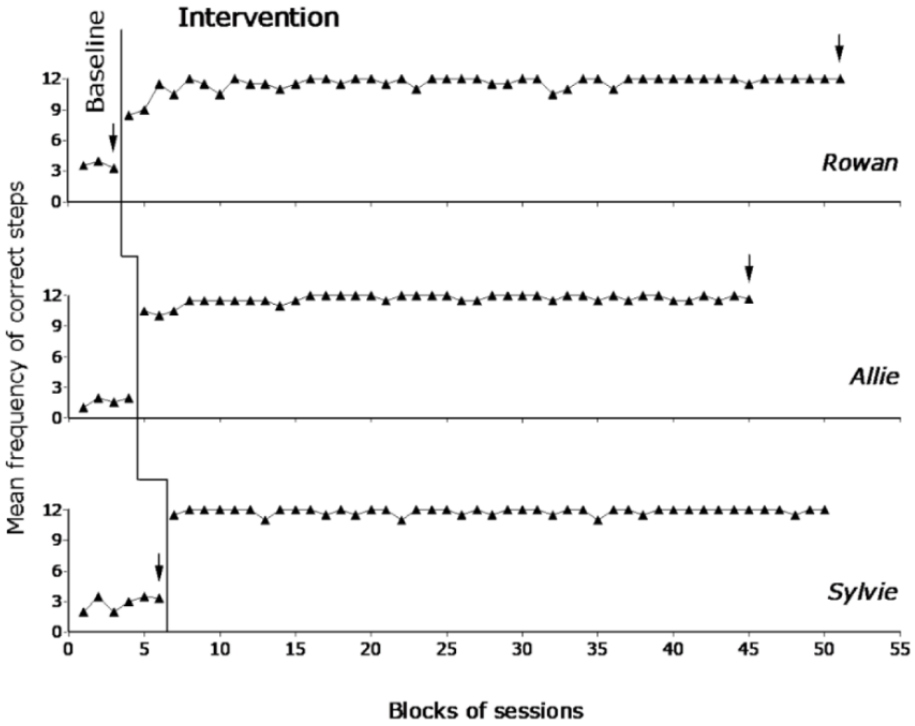
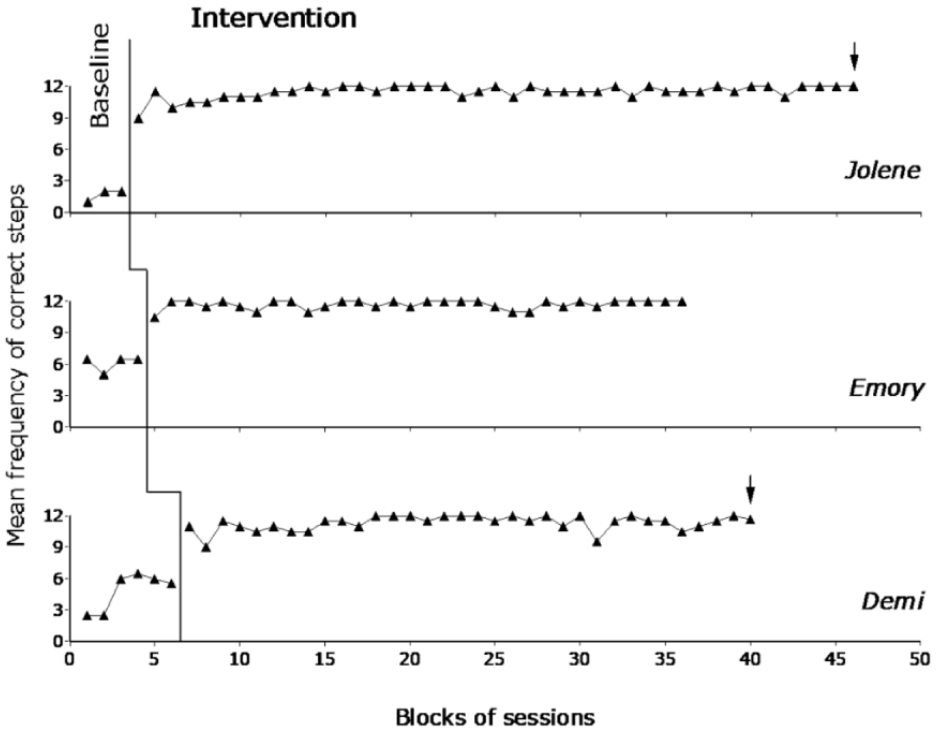


Figure 4. The 3 graphs report the baseline and intervention data for Jolene, Emory, and Demi. Data are plotted as in Figure 3.



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,

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.

References

1. Desideri L, Lancioni G, Malavasi M, Gherardini A, Cesario L. Step-instruction technology to help people with intellectual and other disabilities perform multistep tasks: a literature review. J Dev Phys Disabil 2021;33(6):857-886. [doi: 10.1007/s10882-020-09781-7]
2. Golisz K, Waldman-Levi A, Swierat RP, Toglia J. Adults with intellectual disabilities: case studies using everyday technology to support daily living skills. Br J Occup Ther 2018 Apr 08;81(9):514-524. [doi: 10.1177/0308022618764781]
3. Lin M, Chiang M, Shih C, Li M. Improving the occupational skills of students with intellectual disability by applying video prompting combined with dance pads. J Appl Res Intellect Disabil 2018 Jan 24;31(1):114-119. [doi: 10.1111/jar.12368] [Medline: 28544583]
4. Muharib R, Ledbetter-Cho K, Bross LA, Lang R, Hinson MD, Cilek RK. Handheld Technology to Support Vocational Skills of Individuals with Intellectual and Developmental Disabilities in Authentic Settings: a Systematic Review. Rev J Autism Dev Disord 2022;9(1):108-119. [doi: 10.1007/s40489-021-00247-w]
5. Randall KN, Johnson F, Adams SE, Kiss CW, Ryan JB. Use of a iPhone task analysis application to increase employment-related chores for individuals with intellectual disabilities. J Spec Educ Technol 2020;35(1):26-36. [doi: 10.1177/0162643419836410]
6. Dijkhuizen A, Hilgenkamp TI, Krijnen WP, van der Schans CP, Waninge A. The impact of visual impairment on the ability to perform activities of daily living for persons with severe/profound intellectual disability. Res Dev Disabil 2016 Jan;48:35-42. [doi: 10.1016/j.ridd.2015.10.001] [Medline: 26529065]
7. Lancioni GE, Singh NN, O'Reilly MF, Sigafoos J, Alberti G, Zimbaro C, et al. Using smartphones to help people with intellectual and sensory disabilities perform daily activities. Front Public Health 2017 Oct 24;5:282 [FREE Full text] [doi: 10.3389/fpubh.2017.00282] [Medline: 29114539]

8. Lancioni GE, O'Reilly MF, Sigafoos J, Alberti G, Tenerelli G, Ricci C, et al. Tying the delivery of activity step instructions to step performance: evaluating a basic technology system with people with special needs. Adv Neurodev Disord 2021 Oct 18;5(4):488-497. [doi: 10.1007/s41252-021-00223-9]
9. Heider AE, Cannella-Malone HI, Andzik NR. Effects of self-directed video prompting on vocational task acquisition. CDTI 2019;42(2):87-98. [doi: 10.1177/2165143417752901]
10. Johnson KR, Blaskowitz MG, Mahoney WJ. Technology for adults with intellectual disability: secondary analysis of a scoping review. Can J Occup Ther 2023 Dec 13;90(4):395-404 [FREE Full text] [doi: 10.1177/00084174231160975] [Medline: 36911970]
11. Park J, Bouck E, Duenas A. The effect of video modeling and video prompting interventions on individuals with intellectual disability: a systematic literature review. J Spec Educ Technol 2019;34(1):3-16. [doi: 10.1177/0162643418780464]
12. Resta E, Brunone L, D'Amico F, Desideri L. Evaluating a low-cost technology to enable people with intellectual disability or psychiatric disorders to initiate and perform functional daily activities. Int J Environ Res Public Health 2021 Sep 14;18(18):9659 [FREE Full text] [doi: 10.3390/ijerph18189659] [Medline: 34574584]
13. Bigby C, Beadle-Brown J. Improving quality of life outcomes in supported accommodation for people with intellectual disability: what makes a difference? J Appl Res Intellect Disabil 2018 Mar 24;31(2):e182-e200. [doi: 10.1111/jar.12291] [Medline: 27778426]
14. Cummins RA. Quality of life of adults with an intellectual disability. Curr Dev Disord Rep 2020 Jul 02;7(3):182-187. [doi: 10.1007/s40474-020-00205-x]
15. Fekete C, Siegrist J, Post MWM, Brinkhof MWG, SwiSCI Study Group. Productive activities, mental health and quality of life in disability: exploring the role enhancement and the role strain hypotheses. BMC Psychol 2019 Jan 08;7(1):1 [FREE Full text] [doi: 10.1186/s40359-018-0276-6] [Medline: 30621778]
16. Lancioni GE, Singh NN, O'Reilly MF, Sigafoos J, Alberti G, Del Gaudio V, et al. People with intellectual and sensory disabilities can independently start and perform functional daily activities with the support of simple technology. PLoS One 2022 Jun 13;17(6):e0269793 [FREE Full text] [doi: 10.1371/journal.pone.0269793] [Medline: 35696373]
17. Mechling LC, Gast DL, Seid NH. Evaluation of a personal digital assistant as a self-prompting device for increasing multi-step task completion by students with moderate intellectual disabilities. Educ Train Autism Dev Disabil 2010;45:422-439 [FREE Full text]
18. Oh A, Gan S, Boscardin WJ, Allison TA, Barnes DE, Covinsky KE, et al. Engagement in meaningful activities among older adults with disability, dementia, and depression. JAMA Intern Med 2021 Apr 01;181(4):560-562 [FREE Full text] [doi: 10.1001/jamainternmed.2020.7492] [Medline: 33492334]
19. Smith EM, Huff S, Wescott H, Daniel R, Ebuenyi ID, O'Donnell J, et al. Assistive technologies are central to the realization of the Convention on the Rights of Persons with Disabilities. Disabil Rehabil Assist Technol 2024 Feb 28;19(2):486-491. [doi: 10.1080/17483107.2022.2099987] [Medline: 35900971]
20. Fernández-Batanero JM, Montenegro-Rueda M, Fernández-Cerero J, García-Martínez I. Assistive technology for the inclusion of students with disabilities: a systematic review. Education Tech Research Dev 2022;70(5):1911-1930. [doi: 10.1007/s11423-022-10127-7]
21. Khanlou N, Khan A, Vazquez LM, Zangeneh M. Digital literacy, access to technology and inclusion for young adults with developmental disabilities. J Dev Phys Disabil 2021;33(1):1-25. [doi: 10.1007/s10882-020-09738-w]
22. Collins JC, Ryan JB, Katsiyannis A, Yell M, Barrett DE. Use of portable electronic assistive technology to improve independent job performance of young adults with intellectual disability. J Spec Educ Technol 2014 Sep 01;29(3):15-29. [doi: 10.1177/016264341402900302]
23. Cullen JM, Alber-Morgan SR, Simmons-Reed EA, Izzo MV. Effects of self-directed video prompting using iPads on the vocational task completion of young adults with intellectual and developmental disabilities. JVR 2017 Jun 02;46(3):361-375. [doi: 10.3233/jvr-170873]
24. Cullen JM, Simmons‐Reed EA, Weaver L. Using 21st century video prompting technology to facilitate the independence of individuals with intellectual and developmental disabilities. Psychology in the Schools 2017 Sep 20;54(9):965-978. [doi: 10.1002/pits.22056]
25. Lancioni G, Singh N, O'Reilly M, Sigafoos J, Alberti G, Boccasini A, et al. A Computer-aided program regulating the presentation of visual instructions to support activity performance in persons with multiple disabilities. J Dev Phys Disabil 2014 Sep 24;27(1):79-91. [doi: 10.1007/s10882-014-9402-4] [Medline: 24370112]
26. Lancioni GE, Singh NN, O'Reilly MF, Sigafoos J, Alberti G, Chiariello V, et al. Everyday technology to support leisure and daily activities in people with intellectual and other disabilities. Dev Neurorehabil 2020 Oct 02;23(7):431-438. [doi: 10.1080/17518423.2020.1737590] [Medline: 32118503]
27. Ivey AN, Mechling LC, Spencer GP. Use of a proximity sensor switch for "hands free" operation of computer-based video prompting by young adults with moderate intellectual disability. Educ Train Autism Dev Disabil 2015;50(3):278-289 [FREE Full text]
28. Mishra S, Laplante-Lévesque A, Barbareschi G, Witte LD, Abdi S, Spann A, et al. Assistive technology needs, access and coverage, and related barriers and facilitators in the WHO European region: a scoping review. Disabil Rehabil Assist Technol 2024 Feb 29;19(2):474-485. [doi: 10.1080/17483107.2022.2099021] [Medline: 35906719]

29. Mihailidis A, Melonis M, Keyfitz R, Lanning M, Van Vuuren S, Bodine C. A nonlinear contextually aware prompting system (N-CAPS) to assist workers with intellectual and developmental disabilities to perform factory assembly tasks: system overview and pilot testing. Disabil Rehabil Assist Technol 2016 Oct 24;11(7):604-612. [doi: 10.3109/17483107.2015.1063713] [Medline: 26135042]
30. Balboni G, Belacchi C, Bonichini S, Coscarelli A. Vineland-II. In: Vineland Adaptive Behavior Scales Second Edition. Standardizzazione Italiana. Florence, Italy: OS; 2016.
31. Sparrow S, Cicchetti D, Balla D. Vineland Adaptive Behavior Scales. London, UK: Pearson; 2005.
32. DEATTI. URL: https://www.deatti.com/ [accessed 2024-06-11]
33. Lancioni GE, Desideri L, Singh NN, Sigafoos J, O'Reilly MF. A commentary on standards for single-case experimental studies. Int J Dev Disabil 2022 Jan 08;68(5):781-783 [FREE Full text] [doi: 10.1080/20473869.2020.1870420] [Medline: 36210905]
34. Ledford J, Gast D. Single Case Research Methodology: Applications in Special Education and Behavioral Sciences. New York, NY: Routledge; 2018.
35. Strain P, Fox L, Barton EE. On expanding the definition and use of procedural fidelity. RPSD 2021 Aug 08;46(3):173-183. [doi: 10.1177/15407969211036911]
36. Ma H. An alternative method for quantitative synthesis of single-subject researches: percentage of data points exceeding the median. Behav Modif 2006 Sep 26;30(5):598-617. [doi: 10.1177/0145445504272974] [Medline: 16894232]
37. Parker RI, Vannest KJ, Davis JL. Effect size in single-case research: a review of nine nonoverlap techniques. Behav Modif 2011 Jul 16;35(4):303-322. [doi: 10.1177/0145445511399147] [Medline: 21411481]
38. Kocman A, Weber G. Job satisfaction, quality of work life and work motivation in employees with intellectual disability: a systematic review. J Appl Res Intellect Disabil 2018 Jan 21;31(1):1-22. [doi: 10.1111/jar.12319] [Medline: 28000421]
39. Pierce W, Cheney C. Behavior Analysis and Learning. Sixth Edition. New York, NY: Routledge; 2017.
40. Federici S, Scherer M. Assistive Technology Assessment Handbook. Second Edition. London, UK: CRC Press; 2017.
41. Lifshitz H, Kilberg E, Vakil E. Working memory studies among individuals with intellectual disability: an integrative research review. Res Dev Disabil 2016 Dec;59:147-165. [doi: 10.1016/j.ridd.2016.08.001] [Medline: 27614274]
42. Vicari S, Costanzo F, Menghini D. Memory and learning in intellectual disability. Int Rev Res Dev Disabil 2016;50:119-148. [doi: 10.1016/bs.irrdd.2016.05.003]
43. Lancioni GE, Singh NN, O'Reilly MF, Sigafoos J. Possible assistive technology solutions for people with moderate to severe/profound intellectual and multiple disabilities: considerations on their function and long-term role. Int J Dev Disabil 2024 Jan 16:1-7. [doi: 10.1080/20473869.2024.2303532]
44. Shepley SB. Self-instructing with mobile technology: considerations and applications to increase independence. Teach Except Child 2017 Aug 07;50(2):59-65. [doi: 10.1177/0040059917704971]
45. Sigafoos J, O'Reilly M, Cannella H, Edrisinha C, de la Cruz B, Upadhyaya M, et al. Evaluation of a video prompting and fading procedure for teaching dish washing skills to adults with developmental disabilities. J Behav Educ 2006 Jun 27;16(2):93-109. [doi: 10.1007/s10864-006-9004-z]
46. Wu P, Cannella-Malone HI, Wheaton JE, Tullis CA. Using video prompting with different fading procedures to teach daily living skills. Focus Autism Other Dev Disabl 2014 May 20;31(2):129-139. [doi: 10.1177/1088357614533594]
47. Boot FH, Dinsmore J, Khasnabis C, MacLachlan M. Intellectual disability and assistive technology: opening the GATE wider. Front Public Health 2017 Feb 22;5:10 [FREE Full text] [doi: 10.3389/fpubh.2017.00010] [Medline: 28275593]
48. Borg J, Winberg M, Eide AH, Calvo I, Khasnabis C, Zhang W. On the relation between assistive technology system elements and access to assistive products based on 20 country surveys. Healthcare (Basel) 2023 May 03;11(9):1313 [FREE Full text] [doi: 10.3390/healthcare11091313] [Medline: 37174855]
49. Botelho FHF. Accessibility to digital technology: virtual barriers, real opportunities. Assist Technol 2021 Dec 01;33(sup1):27-34. [doi: 10.1080/10400435.2021.1945705] [Medline: 34951832]
50. Horton S. Empathy cannot sustain action in technology accessibility. Front Comput Sci 2021 Apr 28;3:1-5. [doi: 10.3389/fcomp.2021.617044]
51. Lancioni GE, Singh NN, O'Reilly MF, Sigafoos J, Alberti G, Chiariello V, et al. Technology-aided spatial cues, instructions, and preferred stimulation for supporting people with intellectual and visual disabilities in their occupational engagement and mobility: usability study. JMIR Rehabil Assist Technol 2021 Nov 17;8(4):e33481 [FREE Full text] [doi: 10.2196/33481] [Medline: 34787588]
52. Abdi S, Kitsara I, Hawley MS, de Witte LP. Emerging technologies and their potential for generating new assistive technologies. Assist Technol 2021 Dec 01;33(sup1):17-26 [FREE Full text] [doi: 10.1080/10400435.2021.1945704] [Medline: 34951831]
53. Kazdin A. Single-Case Research Designs: Methods for Clinical and Applied Settings. Second Edition. London, UK: Oxford University Press; 2011.
54. Locey ML. The evolution of behavior analysis: toward a replication crisis? Perspect Behav Sci 2020 Dec 12;43(4):655-675 [FREE Full text] [doi: 10.1007/s40614-020-00264-w] [Medline: 33381684]
55. Walker SG, Carr JE. Generality of findings from single-case designs: it's not all about the " N". Behav Anal Pract 2021 Dec 16;14(4):991-995 [FREE Full text] [doi: 10.1007/s40617-020-00547-3] [Medline: 34868812]

56. Pennington B, Simacek J, McComas J, McMaster K, Elmquist M. Maintenance and generalization in functional behavior assessment/behavior intervention plan literature. J Behav Educ 2019;28(1):27-53. [doi: 10.1007/s10864-018-9299-6]
57. Smith KA, Ayres KA, Alexander J, Ledford JR, Shepley C, Shepley SB. Initiation and generalization of self-instructional skills in adolescents with autism and intellectual disability. J Autism Dev Disord 2016 Apr;46(4):1196-1209. [doi: 10.1007/s10803-015-2654-8] [Medline: 26572658]
58. Carney T, Then S, Bigby C, Wiesel I, Douglas J, Smith E. Realising 'will, preferences and rights': reconciling differences on best practice support for decision-making? Griffith Law Review 2019 Nov 17;28(4):357-379. [doi: 10.1080/10383441.2019.1690741]
59. Ninci J, Gerow S, Rispoli M, Boles M. Systematic review of vocational preferences on behavioral outcomes of individuals with disabilities. J Dev Phys Disabil 2017 Jul 22;29(6):875-894. [doi: 10.1007/s10882-017-9560-2]
60. Tullis C, Cannella-Malone H, Basbigill A, Yeager A, Fleming C, Payne D, et al. Review of the choice and preference assessment literature for individuals with severe to profound disabilities. Educ Train Autism Dev Disabil 2011;46(4):595 [FREE Full text]
61. Wehmeyer ML. The importance of self-determination to the quality of life of people with intellectual disability: a perspective. Int J Environ Res Public Health 2020 Sep 29;17(19):7121 [FREE Full text] [doi: 10.3390/ijerph17197121] [Medline: 33003321]
62. Stasolla F, Caffò AO, Perilli V, Albano V. Experimental examination and social validation of a microswitch intervention to improve choice-making and activity engagement for six girls with Rett syndrome. Dev Neurorehabil 2019 Nov 06;22(8):527-541. [doi: 10.1080/17518423.2019.1624655] [Medline: 31169045]
63. Worthen D, Luiselli JK. Comparative effects and social validation of support strategies to promote mindfulness practices among high school students. Child Fam Behav Ther 2019 Sep 19;41(4):221-236. [doi: 10.1080/07317107.2019.1659544]

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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

Alec Bass[1,2], PT, PhD; Suzanne N Morin[3], MSc, MD; Michael Guidea[1,2]; Jacqueline T A T Lam[1,2], MSc, PT; Antony D Karelis[4], PhD; Mylène Aubertin-Leheudre[4,5*], PhD; Dany H Gagnon[1,2*], PT, PhD; Montreal Exoskeleton Walking Program (MEWP) Group[6*]

[1]School of Rehabilitation, Faculty of Medicine, Université de Montréal, Montréal, QC, Canada

[2]Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (CRIR), Centre Intégré Universitaire de Santé et Services Sociaux (CIUSSS) du Centre-Sud-de-l'Île-de-Montréal, Montréal, QC, Canada

[3]Department of Medicine, McGill University, Montréal, QC, Canada

[4]Department of Exercise Science, Faculty of Sciences, Université du Québec à Montréal, Montréal, QC, Canada

[5]Centre de Recherche de l'Institut Universitaire de Gériatrie de Montréal (CRIUGM), Montréal, QC, Canada

[6]See Acknowledgements

[*]these authors contributed equally

Corresponding Author:
Dany H Gagnon, PT, PhD
School of Rehabilitation
Faculty of Medicine
Université de Montréal
PO Box 6128, Station Centre-Ville
Pavillon 7077 Avenue du Parc—Office U-402-32
Montréal, QC, H3C 3J7
Canada
Phone: 1 514 343 6111 ext 26382
Email: dany.gagnon.2@umontreal.ca

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.

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.

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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.

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

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.

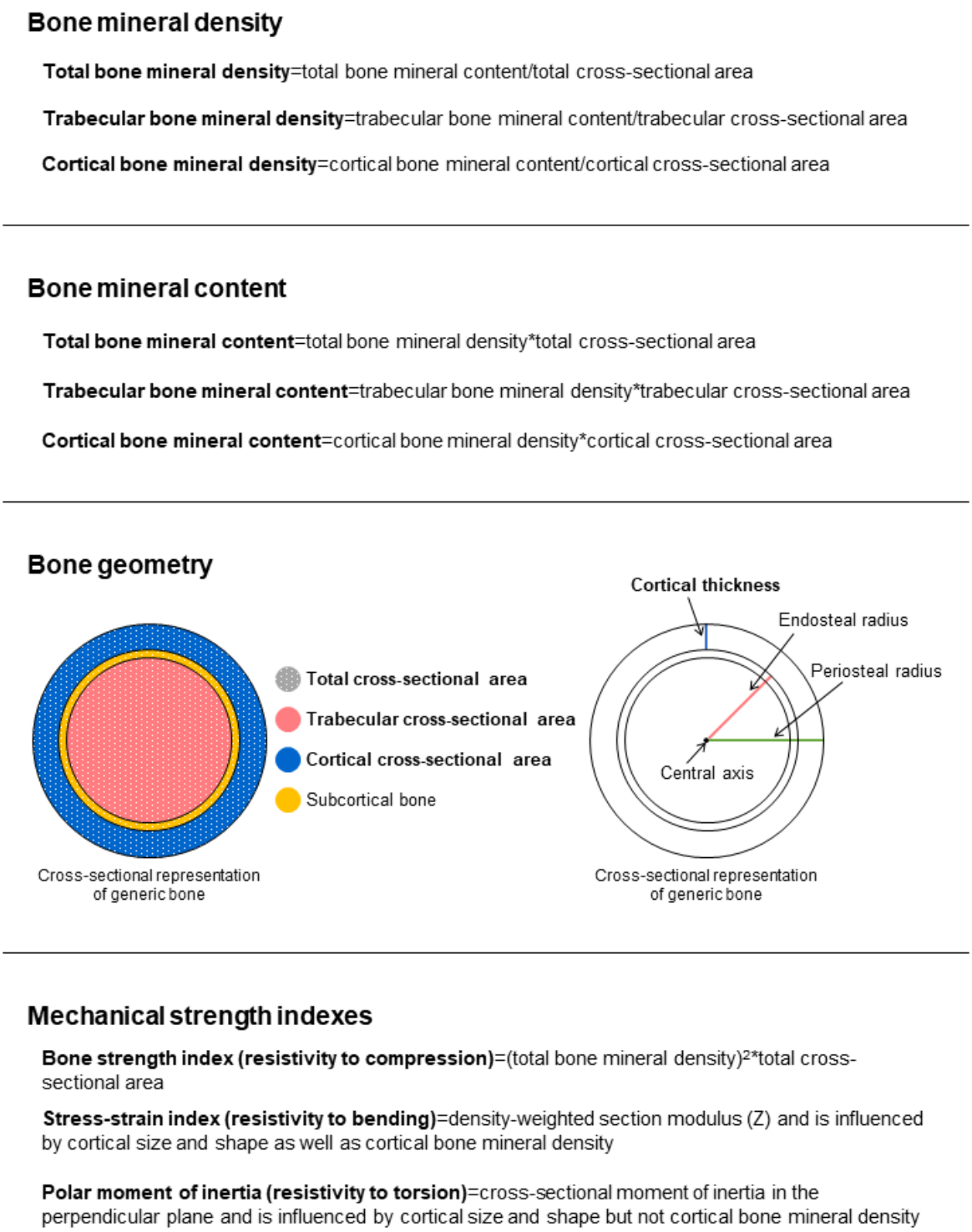
Prior to quantitative analysis, the quality of all pQCT images was independently assessed by 2 evaluators (AB and MG or JTATL) using a previously published 5-level visual inspection and quality scale, where an image score of 1 indicated high quality and an image score of 5 represented low quality [23]. 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.

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

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.

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.

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%.

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 ($P \leq .10$) 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.

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 ($P \leq .10$) 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

(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,

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]

References

1. Yavropoulou MP, Yovos JG. The molecular basis of bone mechanotransduction. J Musculoskelet Neuronal Interact 2016;16(3):221-236 [FREE Full text] [Medline: 27609037]
2. Daly RM, Ahlborg HG, Ringsberg K, Gardsell P, Sernbo I, Karlsson MK. Association between changes in habitual physical activity and changes in bone density, muscle strength, and functional performance in elderly men and women. J Am Geriatr Soc 2008;56(12):2252-2260 [FREE Full text] [doi: 10.1111/j.1532-5415.2008.02039.x] [Medline: 19016934]
3. van Middendorp JJ, Hosman AJF, Donders ART, Pouw MH, Ditunno JF, Curt A, et al. A clinical prediction rule for ambulation outcomes after traumatic spinal cord injury: a longitudinal cohort study. Lancet 2011;377(9770):1004-1010 [FREE Full text] [doi: 10.1016/S0140-6736(10)62276-3] [Medline: 21377202]
4. Clark JM, Findlay DM. Musculoskeletal health in the context of spinal cord injury. Curr Osteoporos Rep 2017;15(5):433-442 [FREE Full text] [doi: 10.1007/s11914-017-0400-1] [Medline: 28842819]
5. Craven BC, Robertson LA, McGillivray CF, Adachi JD. Detection and treatment of sublesional osteoporosis among patients with chronic spinal cord injury: proposed paradigms. Top Spinal Cord Inj Rehabil 2009;14(4):1-22 [FREE Full text] [doi: 10.1310/sci1404-1]
6. Troy KL, Morse LR. Measurement of bone: diagnosis of SCI-induced osteoporosis and fracture risk prediction. Top Spinal Cord Inj Rehabil 2015;21(4):267-274 [FREE Full text] [doi: 10.1310/sci2104-267] [Medline: 26689691]
7. Bryce T, Beck LA, Bombardier CH, Richmond MA, Gorman P, Marsolais EB, et al. Bone health and osteoporosis management in individuals with spinal cord injury. Clinical Practice Guideline Spinal Cord Medicine. 2022. URL: https://pva.org/wp-content/uploads/2022/05/CPG_Spinal-Cord-Medicine_2022_FINAL.pdf [accessed 2023-12-08]
8. Lala D, Craven BC, Thabane L, Papaioannou A, Adachi JD, Popovic MR, et al. Exploring the determinants of fracture risk among individuals with spinal cord injury. Osteoporos Int 2014;25(1):177-185 [FREE Full text] [doi: 10.1007/s00198-013-2419-1] [Medline: 23812595]
9. Choksi P, Jepsen KJ, Clines GA. The challenges of diagnosing osteoporosis and the limitations of currently available tools. Clin Diabetes Endocrinol 2018;4(1):12 [FREE Full text] [doi: 10.1186/s40842-018-0062-7] [Medline: 29862042]
10. Hart NH, Nimphius S, Rantalainen T, Ireland A, Siafarikas A, Newton RU. Mechanical basis of bone strength: influence of bone material, bone structure and muscle action. J Musculoskelet Neuronal Interact 2017;17(3):114-139 [FREE Full text] [Medline: 28860414]
11. Cervinka T, Giangregorio L, Sievanen H, Cheung AM, Craven BC. Peripheral quantitative computed tomography: review of evidence and recommendations for image acquisition, analysis, and reporting, among individuals with neurological impairment. J Clin Densitom 2018;21(4):563-582 [FREE Full text] [doi: 10.1016/j.jocd.2018.07.003] [Medline: 30196052]
12. Craven BC, Giangregorio LM, Alavinia SM, Blencowe LA, Desai N, Hitzig SL, et al. Evaluating the efficacy of functional electrical stimulation therapy assisted walking after chronic motor incomplete spinal cord injury: effects on bone biomarkers and bone strength. J Spinal Cord Med 2017;40(6):748-758 [FREE Full text] [doi: 10.1080/10790268.2017.1368961] [Medline: 28929919]
13. Xiang XN, Ding MF, Zong HY, Liu Y, Cheng H, He CQ, et al. The safety and feasibility of a new rehabilitation robotic exoskeleton for assisting individuals with lower extremity motor complete lesions following spinal cord injury (SCI): an observational study. Spinal Cord 2020;58(7):787-794 [FREE Full text] [doi: 10.1038/s41393-020-0423-9] [Medline: 32034295]
14. Gagnon DH, Vermette M, Duclos C, Aubertin-Leheudre M, Ahmed S, Kairy D. Satisfaction and perceptions of long-term manual wheelchair users with a spinal cord injury upon completion of a locomotor training program with an overground

robotic exoskeleton. Disabil Rehabil Assist Technol 2019;14(2):138-145 [FREE Full text] [doi: 10.1080/17483107.2017.1413145] [Medline: 29256640]
15. Gagnon DH, Escalona MJ, Vermette M, Carvalho LP, Karelis AD, Duclos C, et al. Locomotor training using an overground robotic exoskeleton in long-term manual wheelchair users with a chronic spinal cord injury living in the community: lessons learned from a feasibility study in terms of recruitment, attendance, learnability, performance and safety. J Neuroeng Rehabil 2018;15(1):12 [FREE Full text] [doi: 10.1186/s12984-018-0354-2] [Medline: 29490678]
16. Kozlowski AJ, Bryce TN, Dijkers MP. Time and effort required by persons with spinal cord injury to learn to use a powered exoskeleton for assisted walking. Top Spinal Cord Inj Rehabil 2015;21(2):110-121 [FREE Full text] [doi: 10.1310/sci2102-110] [Medline: 26364280]
17. Benson I, Hart K, Tussler D, van Middendorp JJ. Lower-limb exoskeletons for individuals with chronic spinal cord injury: findings from a feasibility study. Clin Rehabil 2016;30(1):73-84. [doi: 10.1177/0269215515575166] [Medline: 25761635]
18. Baunsgaard CB, Nissen UV, Brust AK, Frotzler A, Ribeill C, Kalke YB, et al. Gait training after spinal cord injury: safety, feasibility and gait function following 8 weeks of training with the exoskeletons from Ekso Bionics. Spinal Cord 2018;56(2):106-116 [FREE Full text] [doi: 10.1038/s41393-017-0013-7] [Medline: 29105657]
19. Bass A, Aubertin-Leheudre M, Morin SN, Gagnon DH. Preliminary training volume and progression algorithm to tackle fragility fracture risk during exoskeleton-assisted overground walking in individuals with a chronic spinal cord injury. Spinal Cord Ser Cases 2022;8(1):29 [FREE Full text] [doi: 10.1038/s41394-022-00498-7] [Medline: 35260550]
20. Karelis AD, Carvalho LP, Castillo MJ, Gagnon DH, Aubertin-Leheudre M. Effect on body composition and bone mineral density of walking with a robotic exoskeleton in adults with chronic spinal cord injury. J Rehabil Med 2017;49(1):84-87 [FREE Full text] [doi: 10.2340/16501977-2173] [Medline: 27973679]
21. Bass A, Aubertin-Leheudre M, Vincent C, Karelis AD, Morin SN, McKerral M, et al. Effects of an overground walking program with a robotic exoskeleton on long-term manual wheelchair users with a chronic spinal cord injury: protocol for a self-controlled interventional study. JMIR Res Protoc 2020;9(9):e19251 [FREE Full text] [doi: 10.2196/19251] [Medline: 32663160]
22. Dual energy X-ray absorptiometry (DXA) procedures manual. Centers for Disease Control and Prevention. National Health and Nutrition Examination Survey (NHANES). 2007. URL: https://www.cdc.gov/nchs/data/nhanes/nhanes_07_08/manual_dexa.pdf [accessed 2023-12-08]
23. Blew RM, Lee VR, Farr JN, Schiferl DJ, Going SB. Standardizing evaluation of pQCT image quality in the presence of subject movement: qualitative versus quantitative assessment. Calcif Tissue Int 2014;94(2):202-211 [FREE Full text] [doi: 10.1007/s00223-013-9803-x] [Medline: 24077875]
24. Kontulainen SA, Johnston JD, Liu D, Leung C, Oxland TR, McKay HA. Strength indices from pQCT imaging predict up to 85% of variance in bone failure properties at tibial epiphysis and diaphysis. J Musculoskelet Neuronal Interact 2008;8(4):401-409 [FREE Full text] [Medline: 19147978]
25. Fritz CO, Morris PE, Richler JJ. Effect size estimates: current use, calculations, and interpretation. J Exp Psychol Gen 2012;141(1):2-18. [doi: 10.1037/a0024338] [Medline: 21823805]
26. Kawalilak CE, Johnston JD, Olszynski WP, Kontulainen SA. Least significant changes and monitoring time intervals for high-resolution pQCT-derived bone outcomes in postmenopausal women. J Musculoskelet Neuronal Interact 2015;15(2):190-196 [FREE Full text] [Medline: 26032212]
27. Beck LA, Bombardier CH, Richmond M, Gorman P, Marsolais EB, Hawryluk GWJ, et al. Identification and management of cardiometabolic risk after spinal cord injury: clinical practice guideline for health care providers. Clinical Practice Guideline Spinal Cord Medicine. 2018. URL: https://pva.org/wp-content/uploads/2021/09/cpg_cardiometabolic-risk_digital.pdf [accessed 2023-12-08]
28. Wu CH, Mao HF, Hu JS, Wang TY, Tsai YJ, Hsu WL. The effects of gait training using powered lower limb exoskeleton robot on individuals with complete spinal cord injury. J Neuroeng Rehabil 2018;15(1):14 [FREE Full text] [doi: 10.1186/s12984-018-0355-1] [Medline: 29506530]
29. Shackleton C, Evans R, West S, Derman W, Albertus Y. Robotic walking to mitigate bone mineral density decline and adverse body composition in individuals with incomplete spinal cord injury: a pilot randomized clinical trial. Am J Phys Med Rehabil 2022;101(10):931-936 [FREE Full text] [doi: 10.1097/PHM.0000000000001937] [Medline: 34864766]
30. Gordon KE, Wald MJ, Schnitzer TJ. Effect of parathyroid hormone combined with gait training on bone density and bone architecture in people with chronic spinal cord injury. PM R 2013;5(8):663-671 [FREE Full text] [doi: 10.1016/j.pmrj.2013.03.032] [Medline: 23558091]
31. Giangregorio LM, Webber CE, Phillips SM, Hicks AL, Craven BC, Bugaresti JM, et al. Can body weight supported treadmill training increase bone mass and reverse muscle atrophy in individuals with chronic incomplete spinal cord injury? Appl Physiol Nutr Metab 2006;31(3):283-291 [FREE Full text] [doi: 10.1139/h05-036] [Medline: 16770357]
32. Gibbs JC, Patsakos EM, Maltais DB, Wolfe DL, Gagnon DH, Craven BC. Rehabilitation interventions to modify endocrine-metabolic disease risk in individuals with chronic spinal cord injury living in the community (RIISC): a systematic search and review of prospective cohort and case-control studies. J Spinal Cord Med 2023;46(1):6-25 [FREE Full text] [doi: 10.1080/10790268.2020.1863898] [Medline: 33596167]

33. Battaglino RA, Lazzari AA, Garshick E, Morse LR. Spinal cord injury-induced osteoporosis: pathogenesis and emerging therapies. Curr Osteoporos Rep 2012;10(4):278-285 [FREE Full text] [doi: 10.1007/s11914-012-0117-0] [Medline: 22983921]
34. Coupaud S, Jack LP, Hunt KJ, Allan DB. Muscle and bone adaptations after treadmill training in incomplete spinal cord injury: a case study using peripheral quantitative computed tomography. J Musculoskelet Neuronal Interact 2009;9(4):288-297 [FREE Full text] [Medline: 19949287]
35. Lee SJ, Hidler J. Biomechanics of overground vs. treadmill walking in healthy individuals. J Appl Physiol (1985) 2008;104(3):747-755 [FREE Full text] [doi: 10.1152/japplphysiol.01380.2006] [Medline: 18048582]
36. Al Nazer R, Lanovaz J, Kawalilak C, Johnston JD, Kontulainen S. Direct in vivo strain measurements in human bone-a systematic literature review. J Biomech 2012;45(1):27-40 [FREE Full text] [doi: 10.1016/j.jbiomech.2011.08.004] [Medline: 21889149]
37. Bass A, Morin SN, Vermette M, Aubertin-Leheudre M, Gagnon DH. Incidental bilateral calcaneal fractures following overground walking with a wearable robotic exoskeleton in a wheelchair user with a chronic spinal cord injury: is zero risk possible? Osteoporos Int 2020;31(5):1007-1011 [FREE Full text] [doi: 10.1007/s00198-020-05277-4] [Medline: 31932962]
38. Eser P, Frotzler A, Zehnder Y, Wick L, Knecht H, Denoth J, et al. Relationship between the duration of paralysis and bone structure: a pQCT study of spinal cord injured individuals. Bone 2004;34(5):869-880 [FREE Full text] [doi: 10.1016/j.bone.2004.01.001] [Medline: 15121019]
39. Fernandes MR, Barreto WDR. Association between physical activity and vitamin D: a narrative literature review. Rev Assoc Med Bras (1992) 2017;63(6):550-556 [FREE Full text] [doi: 10.1590/1806-9282.63.06.550] [Medline: 28876433]
40. Hanley DA, Cranney A, Jones G, Whiting SJ, Leslie WD, Cole DEC, et al. Vitamin D in adult health and disease: a review and guideline statement from Osteoporosis Canada. CMAJ 2010;182(12):E610-E618 [FREE Full text] [doi: 10.1503/cmaj.080663] [Medline: 20624868]
41. Schwalfenberg G. Not enough vitamin D: health consequences for Canadians. Can Fam Physician 2007;53(5):841-854 [FREE Full text] [Medline: 17872747]
42. Pearce SHS, Cheetham TD. Diagnosis and management of vitamin D deficiency. BMJ 2010;340:b5664. [doi: 10.1136/bmj.b5664] [Medline: 20064851]
43. Reid IR, Bolland MJ, Grey A. Effects of vitamin D supplements on bone mineral density: a systematic review and meta-analysis. Lancet 2014;383(9912):146-155 [FREE Full text] [doi: 10.1016/S0140-6736(13)61647-5] [Medline: 24119980]
44. Lai CH, Chang WHS, Chan WP, Peng CW, Shen LK, Chen JJJ, et al. Effects of functional electrical stimulation cycling exercise on bone mineral density loss in the early stages of spinal cord injury. J Rehabil Med 2010;42(2):150-154 [FREE Full text] [doi: 10.2340/16501977-0499] [Medline: 20140411]
45. BeDell KK, Scremin AM, Perell KL, Kunkel CF. Effects of functional electrical stimulation-induced lower extremity cycling on bone density of spinal cord-injured patients. Am J Phys Med Rehabil 1996;75(1):29-34. [doi: 10.1097/00002060-199601000-00008] [Medline: 8645435]
46. Bloomfield SA, Mysiw WJ, Jackson RD. Bone mass and endocrine adaptations to training in spinal cord injured individuals. Bone 1996;19(1):61-68 [FREE Full text] [doi: 10.1016/8756-3282(96)00109-3] [Medline: 8830990]
47. Eser P, de Bruin ED, Telley I, Lechner HE, Knecht H, Stüssi E. Effect of electrical stimulation-induced cycling on bone mineral density in spinal cord-injured patients. Eur J Clin Invest 2003;33(5):412-419 [FREE Full text] [doi: 10.1046/j.1365-2362.2003.01156.x] [Medline: 12713456]
48. Chen SC, Lai CH, Chan WP, Huang MH, Tsai HW, Chen JJJ. Increases in bone mineral density after functional electrical stimulation cycling exercises in spinal cord injured patients. Disabil Rehabil 2005;27(22):1337-1341. [doi: 10.1080/09638280500164032] [Medline: 16321917]
49. Frotzler A, Coupaud S, Perret C, Kakebeeke TH, Hunt KJ, de N Donaldson N, et al. High-volume FES-cycling partially reverses bone loss in people with chronic spinal cord injury. Bone 2008;43(1):169-176 [FREE Full text] [doi: 10.1016/j.bone.2008.03.004] [Medline: 18440891]
50. Mohr T, Podenphant J, Biering-Sorensen F, Galbo H, Thamsborg G, Kjaer M. Increased bone mineral density after prolonged electrically induced cycle training of paralyzed limbs in spinal cord injured man. Calcif Tissue Int 1997;61(1):22-25 [FREE Full text] [doi: 10.1007/s002239900286] [Medline: 9192506]

Abbreviations

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

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Original Paper

Usage, Attitudes, Facilitators, and Barriers Toward Digital Health Technologies in Musculoskeletal Care: Survey Among Primary Care Physiotherapists in Norway

Lars Martinsen[1,2], PT, MSc; Nina Østerås[1,2], PT, PhD; Tuva Moseng[1], PT, PhD; Anne Therese Tveter[1,3], PT, PhD

[1]Center for Treatment of Rheumatic and Musculoskeletal Diseases (REMEDY), Diakonhjemmet Hospital, Oslo, Norway

[2]Department for Interdisciplinary Health Sciences, Faculty of Medicine, University of Oslo, Oslo, Norway

[3]Department of Rehabilitation Science and Health Technology, Faculty of Health Sciences, Oslo Metropolitan University, Oslo, Norway

Corresponding Author:
Lars Martinsen, PT, MSc
Center for Treatment of Rheumatic and Musculoskeletal Diseases (REMEDY)
Diakonhjemmet Hospital
Diakonveien 12
Oslo, 0370
Norway
Phone: 47 22451500
Email: lars.martinsen@diakonsyk.no

Abstract

Background: Work burden increases for physiotherapists in the primary health care sector as the prevalence of musculoskeletal disorders (MSDs) increases. Digital health technologies (DHTs) are proposed as a viable solution to secure the sustainability of the health care system and have shown promising results in a range of conditions. However, little is known about use of DHTs among physiotherapists in the primary health care sector in Norway.

Objective: This study aimed to investigate the use of and attitudes toward DHTs among physiotherapists treating patients with MSDs in primary care, and potential facilitators or barriers for adopting DHTs in clinical practice.

Methods: An author-developed web-based questionnaire was distributed to physiotherapists in all Norwegian municipalities in March 2023. The questionnaire included items regarding use of technologies, attitudes, suitability, and factors influencing adoption of DHT. Suitability and agreement on statements were scored on an 11-point numeric rating scale (0=very unsuitable or strongly disagree, 10=very suitable or strongly agree). Differences across employment sites and users versus nonusers of DHT were analyzed using the χ^2 test, Fisher exact test, Student *t* test, and Mann-Whitney *U* test.

Results: Approximately 5000 physiotherapists were invited to participate, of which 6.8% (338) completed the questionnaire. A total of 46.2% (156/338) offered DHTs in their practice, of which 53.2% (83/156) used it on a weekly basis, mostly telephone consultations (105/156, 67.3%). A higher proportion of physiotherapists in private practice offered DHT compared with those employed by municipalities (95/170, 55.9% vs 61/168, 36.3%; *P*<.001). A majority (272/335, 81.2%) were positive about recommending DHTs to their patients. Suitability of DHTs in physiotherapy was rated an average of 6 (SD 2.1). Apps for smartphones or tablets were rated most suitable (mean rating 6.8, SD 2.4). The most frequently reported advantages were flexibility in how physiotherapy is offered (278/338, 82.3%) and reduced travel time for the patient (235/338, 70%). The highest rated disadvantages were limited scope for physical examination (252/338, 74.6%) and difficulty in building rapport with the patient (227/338, 67.2%). The main facilitators and barriers included a functioning (median rating 10, IQR 8-10) or lack of functioning (median rating 9, IQR 8-10) internet connection, respectively. Lack of training in DHTs was prominent regarding evaluation, diagnosing, and treatment (median rating 0, IQR 0-2), with minor, but significant, differences between nonusers and users (median rating 0, IQR 0-1 vs median rating 1, IQR 0-4); *P*<.001).

Conclusions: Physiotherapists in Norwegian primary care treating patients with MSDs are positive about using DHTs, and almost 50% (156/338) have adopted them in clinical practice. Concerns are related to lack of a physical examination and technical aspects. Training in the use of DHTs should be addressed in implementation processes.

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KEYWORDS

physiotherapy; physiotherapist; physiotherapists; mHealth; mobile health; app; apps; application; applications; digital health; smartphone; smartphones; ehealth; telemedicine; tele-medicine; family medicine; primary care; primary health care; musculoskeletal; musculoskeletal care; muscle; skeleton; musculoskeletal disorders; MSD; MSDs; internet survey; internet surveys; online survey; online surveys; web-based survey; web-based surveys; survey; surveys; mobile phone

Introduction

The burden of musculoskeletal disorders (MSDs) is high, with an estimated prevalence of 1.7 billion people worldwide [1]. In Norway, 18% of men and 27% of women report chronic MSDs lasting for more than 6 months, and there is an increasing prevalence with age [2]. MSDs account for one-third of all sickness benefits and disability pensions and 9% of all direct health care costs [3]. There is consensus that the majority of these disorders should be treated in primary care [1,4,5]. Among Norwegian patients with MSDs, about 30% have annual contact with primary health care services and 5% to 9% with a physiotherapist [2]. The aging population and expected increase in MSDs threaten the sustainability of the health care system [6,7]. To counteract this unsustainable burden on the health care system, and maintain and improve universal health coverage, increased use of digital health technologies has been suggested as a viable solution [7,8].

Digital health technologies encompass a wide range of different technologies, such as telephone or video consultations, apps, and artificial intelligence [9-11]. Various technologies have already proven to be efficient in the treatment of MSDs [12-15]. However, despite the positive effects, the implementation rate of digital health technologies in physiotherapy practice has been slow [9,16]. Studies during the COVID-19 pandemic in Finland revealed that physiotherapists were largely inexperienced with digital health technologies [17,18]. Several other studies conducted before the COVID-19 pandemic showed similar results; physiotherapists are positive to digital health technologies, but experience barriers to implementing them in clinical practice [19-22].

Despite being one of the most digitalized countries in the Western world [23], little is known about the use of digital health technologies among physiotherapists in primary care in Norway. Given that digital health technologies are highlighted as an important tool in the future of the health care service [7], it is imperative to gain knowledge on physiotherapists' use of health technologies, their attitudes, and elements relevant for implementation. The overall purpose was to (1) investigate the use of and attitudes toward digital health technologies among physiotherapists treating patients with MSDs in primary care in Norway; (2) explore the suitability, advantages, and disadvantages of digital health technologies in physiotherapy practice; (3) assess potential facilitators and barriers for adopting digital health technologies in clinical practice; and (4) investigate differences in these elements between physiotherapist sector of employment and users versus nonusers of digital health technologies.

Methods

Design, Participants, and Recruitment

We used a cross-sectional study design, using an anonymous survey featuring a web-based questionnaire as a method of data collection to answer the research questions. The target population was a convenience sample of physiotherapists actively engaged in the treatment of patients with MSDs and working in primary care in Norway. The study was conducted in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement [24] and CHERRIES (Checklist for Reporting Results of Internet E-Surveys) [25].

The survey was limited to physiotherapists treating adults with MSDs, defined as conditions sorted under chapter L in the Norwegian version of the *International Classification of Primary Care, 2nd edition* (*ICPC-2*) [26]. Participants were informed regarding the scope of the survey and limitations in participation through the information letter following the link to the survey. No stratification on specialty or rostering at the independent employment site was induced. As no distinct definition of digital health technologies exists, based on previous descriptions we defined digital health technologies as digital methods or tools used in the evaluation, diagnosis, and treatment of patients with MSDs, in in-patients, out-patients, and remote settings [8,16]. We excluded the use of electronic health records and digital communication between health care personnel from our definition, as this is ubiquitous in the Norwegian health care service.

The physiotherapy service in primary care in Norway is organized as a combination of municipality-employed physiotherapists on a fixed salary and physiotherapists in private practice. Municipality-employed physiotherapists typically work in an in-patient or home-based setting, either alone or as a part of a multidisciplinary team. Physiotherapists in private practice usually work in an out-patient physiotherapy clinic, either with an operating grant to practice within the municipality, or solely on the cost of the patient. There are no clear guidelines determining which patients should receive physiotherapy from a municipality-employed physiotherapist or a physiotherapist in private practice. However, differences in the characteristics of the patients may occur, and we therefore analyzed these sectors separately in our study.

The survey was distributed as an open survey collecting anonymous data. An email with an invitation to participate was sent on March 20, 2023, to either the head of the physiotherapy service or a shared email address for official correspondence in all the 356 Norwegian municipalities. The email contained a link to the survey through a digital solution. The email was also sent directly to physiotherapists whose email addresses were available on the municipalities' websites. This included

physiotherapists working in private practice. In addition, the link to the questionnaire was advertised on social media (Facebook [Meta] and Twitter [rebranded as X]) by the authors and in their networks. The questionnaire was open for response for 2 weeks and closed on April 3, 2023. No incentive to participate was granted to the responders.

The Questionnaire

The questionnaire was developed based on previous questionnaires covering similar topics [18,27-30], and discussion within the members of the research group. The research group included 4 physiotherapists with extensive experience with digital health technologies in musculoskeletal physiotherapy and clinical experience as physiotherapists in primary care, and 2 patient research partners.

Nettskjema, a web-based survey tool by the University of Oslo, was used to construct the questionnaire [31]. Access to the questionnaire was only possible through a unique link, leading directly to the survey. The questionnaire included 49 items, divided into 12 questions, 37 statements, and additional free-text fields (not analyzed in this study). The selection of items was guided by the Unified Theory of Acceptance and Use of Technology (UTAUT), which posits that an individual's intention to use an information system can be explained by 4 key constructs, that are performance expectancy, effort expectancy, social influence, and facilitating conditions [32]. A mandatory employment question determined access to the rest of the questionnaire, allowing only physiotherapists reporting to work in primary care to proceed. Further questions covered the demographic characteristics of the participants (sex, age, and work experience), and the use, recommendation, and suitability of digital health technologies. The type of digital health technologies and frequency of use were conditionally displayed only to those stating to be offering digital health technologies. Statements covered attitudes toward using digital health technologies, and facilitators and barriers toward adopting such technologies. Suitability and agreement on statements were scored on an 11-point numeric rating scale (0=very unsuitable or strongly disagree and 10=very suitable or strongly agree). A score of ≥7 on attitudes was considered a positive attitude [33]. Items were distributed on 8 electronic pages, with 1 to 12 items per page. Except for the question on employment in primary care, no questions were mandatory. No completeness check was therefore provided; however, the responders had the opportunity to review and check their answers before submitting the questionnaire. Nettskjema does not provide information on the number of views or the participation rate. As no cutoff for minimum completion of the questionnaire was applied in this study, the completion rate is similar to users who agreed to participate.

The questionnaire was pretested in a sample of 3 independent physiotherapists with experience in primary care and treatment of MSDs, and the members of the research group, including the patient research partners. Improvement of accuracy and clarity, including adding questions and statements regarding reimbursement and data security, was subsequently implemented in the questionnaire.

Statistical Method

Stata version 17 (StataCorp) was used for all analyses and the significance level was set at $P<.05$. Noncontinuous variables are presented as frequency counts and percentages, whereas continuous variables are presented as mean values. Differences between employment sites and users or nonusers of digital health technology in usage, recommendation, advantages, and disadvantages were analyzed using the chi-square test. Where expected values were <5, the Fisher exact test was used. Similarly, to assess differences in suitability, facilitators, barriers, and attitudes, Student *t* test was used. Data were visually inspected for normality by assessing histograms and quantile-quantile plots. If normality was not met in analyses of facilitators, barriers, and attitudes, the Mann-Whitney *U* test was conducted. Wilcoxon signed-rank test was conducted for assessing differences in attitudes regarding the evaluation, diagnosing, and treatment of acute and chronic conditions. Questionnaires with more than 50% missing items were removed. No imputation was performed for missing values. No cut-off point for atypical timestamps was induced, and neither were any corrections to adjust for nonrepresentative samples. Of the physiotherapists in private practice, 16 worked without operating grants. These 16 did not differ from the physiotherapists with operating grants on any aspects in this survey, and the 2 categories were merged to 1.

Ethical Considerations

The study was conducted in line with The Declaration of Helsinki [34]. As no health information and only anonymous data were processed in this survey, ethical approval from the National Research Ethics Committees was not required. This is in accordance with the Norwegian Health Research Act and The Personal Data Act including the General Data Protection Regulation (GDPR) [35]. However, an assessment of the privacy of the questionnaire was undertaken by the Institutional Data Protection Officer and an Institutional Board at Diakonhjemmet Hospital before the data collection. Information regarding the purpose of the study, privacy, institutional affiliation, principal investigator, and consent to publication was included in the web questionnaire and provided to all participants before answering.

Results

Demographics

An estimated 5000 physiotherapists were invited to participate in the survey, of which 338 (6.8%) completed the questionnaire. The majority were female (226/338, 66.9%), and the mean age was 43.4 (SD 11.1) years (Table 1). The responders were equally divided between municipality-employed physiotherapists (168/338, 49.7%) and physiotherapists in private practice (170/338, 50.3%). A large majority had more than 10 years of work experience. Only 1 questionnaire was removed due to more than 50% missing values.

Table 1. Characteristics of responders.

	Total group (N=338)	Employed by municipalities (n=168)	Private practice (n=170)
Age (years), mean (SD)	43.4 (11.1)	40 (10.5)	46.7 (10.7)
Sex (female), n (%)	226 (66.9)	138 (82.1)	88 (51.8)
Work experience, n (%)[a]			
Less than 1 year	9 (2.7)	9 (5.4)	0 (0)
1-5 years	38 (11.3)	28 (16.9)	10 (5.9)
6-10 years	42 (12.5)	33 (19.9)	9 (5.3)
More than 10 years	246 (73.5)	96 (57.8)	150 (88.8)

[a]Total group (n=335), employed by municipalities (n=166), private practice (n=169).

Use of Digital Health Technologies

Digital health technologies were offered by 46.2% (156/338) of the physiotherapists. A significantly higher proportion of physiotherapists in private practice (95/170, 55.9%) offered digital health technology compared with those employed by municipalities (61/168, 36.3%; χ^2_1=13, *P*<.001). More than half of those who offered digital health technologies used it on a weekly basis (Table 2), with a significantly higher frequency of use observed among physiotherapists in private practice compared with those employed by municipalities . Only 10.2% (16/156) used digital health technologies daily. No differences in the use of the various technologies were found, except from telephone and video consultations, which were significantly more frequently used among physiotherapists in private practice compared with municipality-employed physiotherapists.

A large majority of the physiotherapists (272/335, 81.2%) were positive to recommending the use of digital health technologies to patients with MSDs. Significantly higher proportions of municipality-employed physiotherapists were positive compared with physiotherapists in private practice (144/166, 86.8% vs 128/169, 75.7%; χ^2_1=6.6, *P*=.01), as well as physiotherapists offering digital health technologies compared with physiotherapists not offering (143/155, 92.3% vs 129/180, 71.7%, χ^2_1=23.1, *P*<.001).

Table 2. Use of digital health technologies.

	Total group (n=156), n (%)	Employed by municipalities (n=61), n (%)	Private practice (n=95), n (%)	Chi-square (*df*)	*P* value
Frequency of use				14.2 (4)	.005[a]
Never	5 (3.2)	3 (5)	2 (2)		
1-2 times a month	68 (43.6)	36 (59)	32 (34)		
Once a week	28 (18)	10 (16)	18 (19)		
3-5 times a week	39 (25)	10 (16)	29 (30)		
Every day	16 (10.2)	2 (4)	14 (15)		
Digital health technologies offered					
Telephone consultations	105 (67.3)	35 (57)	70 (74)	4.5 (1)	.03
Apps for smartphones or tablets	103 (66)	46 (75)	57 (60)	3.9 (1)	.047
Video consultations	63 (40.4)	17 (28)	46 (48)	6.5 (1)	.01
Activity trackers	15 (9.6)	5 (8)	10 (11)	0.2 (1)	.63
Gaming	4 (2.6)	2 (3)	2 (2)	0.2 (1)	.64[a]
Virtual reality	2 (1.3)	0 (0)	2 (2)	1.3 (1)	.52[a]
Augmented reality	1 (0.6)	0 (0)	1 (1)	0.6 (1)	.99[a]
Artificial intelligence	1 (0.6)	1 (2)	0 (0)	1.6 (1)	.39[a]
Robotics	1 (0.6)	0 (0)	1 (1)	0.6 (1)	.99[a]

[a]Fisher exact test.

Suitability of Digital Health Technologies

A mean score of 6 (SD 2.1) was reported on the overall suitability of digital health technologies in physiotherapy practice with a significant, but small difference, between municipality-employed physiotherapists and physiotherapists in private practice. Similarly, significant but small differences were found regarding the suitability of apps for smartphones or tablets, activity trackers, games, and artificial intelligence, with municipality-employed physiotherapists more positive about the suitability of all technologies, except video consultations (Table 3). Overall, the therapists already offering digital solutions rated suitability significantly higher on all solutions compared with those not offering digital solutions (results not shown).

Table 3. Suitability of digital health technologies.

Digital health technology	Suitability[a]					
	Total group, mean (SD)	Employed by municipalities, mean (SD)	Private practice, mean (SD)	Mean difference (95% CI)	*t* test (*df*)	*P* value
Overall	6 (2.1)	6.3 (1.8)	5.7 (2.3)	0.6 (0.1 to 1.0)	2.6 (331)	.01
Specific						
Apps for smartphones or tablets	6.8 (2.4)	7.2 (2.0)	6.5 (2.6)	0.7 (0.2 to 1.2)	2.8 (332)	.006
Video consultations	6.1 (2.4)	6.2 (2.2)	6.1 (2.6)	0.1 (–0.4 to 0.6)	0.3 (331)	.74
Activity trackers	5.8 (2.5)	6.2 (2.4)	5.5 (2.5)	0.7 (0.01 to 1.2)	2.3 (327)	.02
Telephone consultations	5.4 (2.6)	5.2 (2.5)	5.6 (2.7)	–0.4 (–0.1 to 0.1)	–1.5 (332)	.13
Robotics	4.9 (2.8)	5.1 (2.8)	4.6 (2.8)	0.5 (–0.1 to 1.1)	1.6 (316)	.11
Virtual reality	4.8 (2.6)	5.1 (2.5)	4.6 (2.7)	0.5 (–0.1 to 1.1)	1.7 (319)	.09
Augmented reality	4.7 (2.7)	4.9 (2.6)	4.4 (2.7)	0.5 (–0.1 to 1.1)	1.6 (316)	.10
Gaming	4.7 (2.7)	5.2 (2.7)	4.2 (2.6)	1.0 (0.4 to 1.6)	3.3 (317)	.001
Artificial intelligence	4.2 (2.7)	4.5 (2.6)	3.8 (2.8)	0.7 (0.1 to 1.2)	2.1 (310)	.04

[a]0=very unsuitable, 10=very suitable.

Advantages and Disadvantages of Digital Health Technologies

Digital health technologies' contribution to flexibility in how physiotherapy is offered was agreed upon by 82.3% (278/228) of the responders. As well, reduction in travel for patients (235/338, 69.5%) and improved access (207/338, 61.2%) were highlighted as advantages. Where significant differences were found, the municipality-employed physiotherapists consistently responded more positively to the statements compared with the physiotherapists in private practice (Table 4).

Regarding disadvantages with digital health technologies, the limited scope for physical examination (252/338, 74.6%) and difficulty in building a rapport with the patient (227/338, 67.2%) were the two most frequently reported. A significant difference was found regarding low digital competence of the patients, with a greater proportion of municipality-employed physiotherapists reporting this as a disadvantage as compared with physiotherapists in private practice (Table 5).

Table 4. Advantages of digital health technology.

Advantage	Total group, n (%)	Employed by municipalities, n (%)	Private practice, n (%)	Chi-square (*df*)	*P* value
Offers flexibility in how physiotherapy is delivered	278 (82.3)	148 (88.1)	130 (76.5)	7.8 (1)	.005
Reduction in travel for the service user	235 (69.5)	134 (79.8)	101 (59.4)	16.5 (1)	<.001
Improved access to physiotherapy	207 (61.2)	114 (67.9)	93 (54.7)	6.2 (1)	.01
Modernizes our approach to communication	179 (53)	85 (50.6)	94 (55.3)	0.7 (1)	.39
More efficient for conducting and attending meetings	169 (50)	100 (59.5)	69 (40.6)	12.1 (1)	<.001
Less time consuming than conventional interventions	153 (45.3)	100 (59.5)	53 (31.2)	27.4 (1)	<.001
Good service user's satisfaction	123 (36.4)	55 (32.7)	68 (40)	1.9 (1)	.17
Useful for continuing your professional development	80 (24)	39 (23)	41 (24)	0.04 (1)	.85
Reduces "did not attend" rate	71 (21)	38 (23)	33 (20)	0.5 (1)	.47
Good job satisfaction for the physiotherapist	54 (16)	22 (13)	32 (19)	2.1 (1)	.15
Adequate to outrule serious pathologies	18 (5)	7 (4)	11 (7)	0.9 (1)	.35
An adequate subjective and objective examination can be completed	15 (4)	7 (4)	8 (5)	0.06 (1)	.81
No advantages	13 (4)	3 (2)	10 (6)	3.8 (1)	.049

Table 5. Disadvantages of digital health technology.

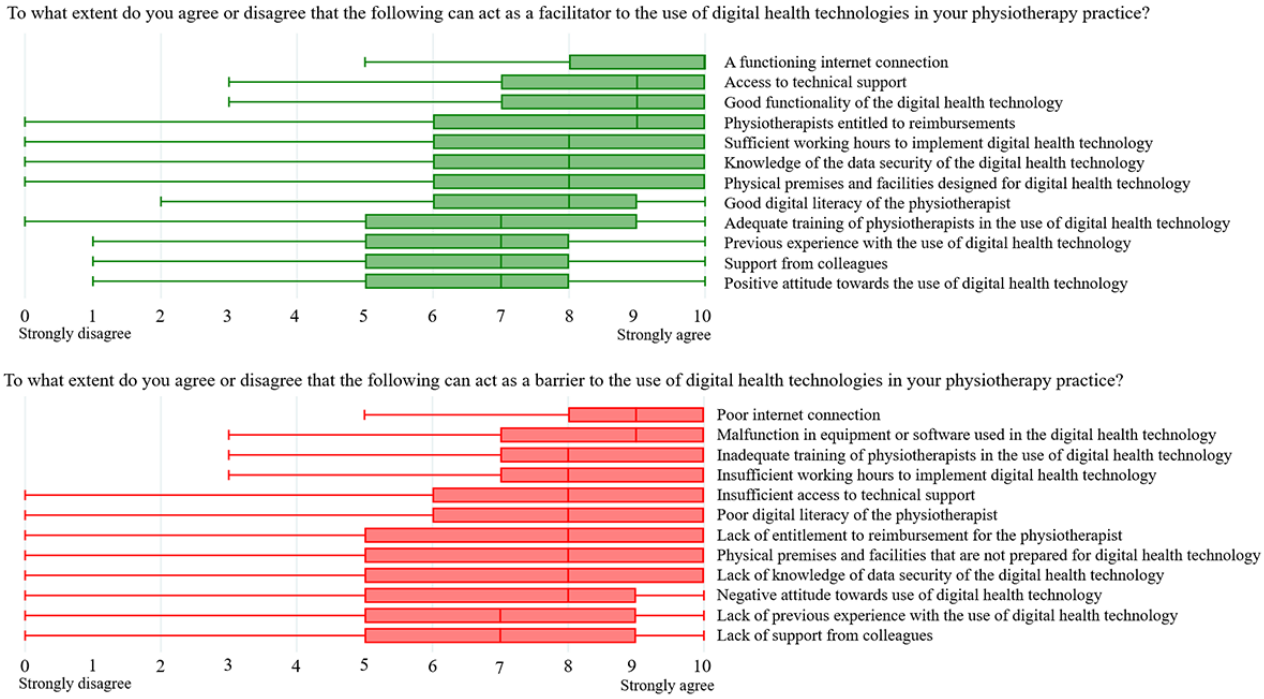
Disadvantage	Total group, n (%)	Employed by municipalities, n (%)	Private practice, n (%)	Chi-square (*df*)	*P* value
Limited scope for the physical examination	252 (74.6)	130 (77.4)	122 (71.8)	1.4 (1)	.24
Difficult to build a rapport with the service user	227 (67.2)	116 (69.1)	111 (65.3)	0.5 (1)	.46
Computer literacy of the service user is poor	211 (62.4)	133 (79.2)	78 (45.9)	39.9 (1)	<.001
Inadequate ability to rule out serious pathologies	201 (59.5)	106 (63.1)	95 (55.9)	1.8 (1)	.18
Difficult to alleviate service user's concerns regarding their health	159 (47)	83 (49.4)	76 (44.7)	0.7 (1)	.39
Difficult to communicate "bad news" to the service users	126 (37.3)	59 (35.1)	67 (39.4)	0.7 (1)	.41
Reduces service user satisfaction	89 (26)	43 (26)	46 (27)	0.1 (1)	.76
The technology will fail regularly	73 (22)	45 (27)	28 (17)	5.3 (1)	.02
Difficult to prescribe a specialized treatment plan	58 (17)	27 (16)	31 (18)	0.3 (1)	.60
Difficult to ensure privacy and confidentiality	53 (16)	31 (19)	22 (13)	1.9 (1)	.16
Reduces job satisfaction for the physiotherapist	38 (11)	14 (8)	24 (14)	2.8 (1)	.09
Difficult to obtain consent	31 (9)	23 (14)	8 (5)	8.2 (1)	.004
More time consuming that conventional interventions	20 (6)	7 (4)	13 (8)	1.8 (1)	.18
Increases "did not attend" rate	16 (5)	7 (4)	9 (5)	0.2 (1)	.63
No disadvantages	7 (2)	1 (1)	6 (4)	3.6 (1)	.06[a]

[a]Fisher exact test.

Facilitators and Barriers

Among facilitating factors, technical aspects of using digital health technologies showed high median scores, especially a functioning internet connection (median 10, IQR 8-10) and access to technical support (median 9, IQR 7-10). Similarly, lack of technical infrastructure showed high median scores as barriers to adopting digital health technologies, with a poor internet connection (median 9, IQR 8-10) and malfunction in equipment or software used in the digital solution (median 7, IQR 7-10) ranking as primary barriers (Figure 1). Minimal differences were found between municipality-employed physiotherapists and physiotherapists in private practice in their responses to factors acting as facilitators or barriers. The physiotherapists in private practice reported entitlement to reimbursement as significantly more important both as a facilitator (median 10, IQR 7.5-10 vs median 8, IQR 5-10; z=–4.3; P<.001) and a barrier (median 9, IQR 6-10 vs median 8, IQR 5-10; z=–3.2; P=.002) as compared with the municipality-employed physiotherapists. However, municipality-employed physiotherapists rated the importance of all other statements regarding facilitators and barriers higher than physiotherapists in private practice.

Figure 1. Facilitators and barriers to adopting digital health technologies.



Attitudes Toward Digital Health Technologies

The physiotherapists expressed a significantly higher confidence in treating patients using digital health technologies compared with evaluating and diagnosing, both in acute (median 4, IQR 2-6 vs median 3, IQR 2-5; z=–5.3; P<.001) and chronic conditions (median 5, IQR 3-7 vs median 4, IQR 2-6; z=–7.2; P<.001). In addition, they reported a significantly higher confidence in evaluating and diagnosing patients with chronic conditions compared with acute conditions (median 4, IQR 2-6 vs median 3, IQR 2-5; z=–2.6; P=.01), and similar for treatment (median 5, IQR 3-7 vs median 4, IQR 2-6; z=–3.9; P<.001). Physiotherapists offering digital health technologies were significantly more confident in using technologies in evaluating, diagnosing, and treating patients both regarding acute and chronic conditions compared with those not offering them. A large majority of the responders disagreed that they had received training in using digital health technologies. Although both groups disagreed with the statement, a significant difference was observed between those offering digital health technologies and those who did not; with those not offering such technologies scoring significantly lower than those who offered the technologies (Multimedia Appendix 1).

Discussion

Principal Findings

In this study, we found that the use of digital health technologies was approximately 50% among the responders, with a higher frequency of use among physiotherapists in private practice. The suitability of digital health technologies was rated as high, with the municipality-employed physiotherapists scoring suitability more positively, together with those already using digital health technologies. The advantages of digital health technologies reflected benefits for both patients and the physiotherapists, however, the lack of physical examination was a prominent disadvantage. The municipality-employed physiotherapists appeared as more positive toward the advantages of digital health technologies, and as more confident regarding its use. Technical aspects could serve as both facilitators and barriers to adopting the technology. Our study is believed to be the first study quantifying the extent of use of digital health technologies among this group of physiotherapists, and one of the first assessing facilitators and barriers in a postpandemic setting.

As waiting lists and the prevalence of MSDs increase, the health care sector will be dependent on adopting digital health technologies in the future [36]. Limitations in access to trained health care personnel, supplied by an expectation of high-quality care from the patients, will entail a shift in the provision of care in a direction of using more digital health technologies [7]. Our data demonstrate that approximately half of the physiotherapists in our study already used digital health technologies on a weekly basis. A rapid increase of technology has previously been observed during the COVID-19 pandemic [33,37,38], and it appears that the use of technology has been sustained for some of the physiotherapists. Prominent in our data was the use of telephone and video in consultations as well as the use of apps for smartphones and tablets. Our results are in line with the results in the Norwegian national eHealth survey, stating that the preferred digital contact with patients among health care personnel is telephone consultations, followed by written digital contact and video consultations [39]. Notable in our study is the very low use of other technologies—technologies that we could expect to be relevant in the treatment of patients with MSDs. Gaming and virtual reality have shown beneficial effects in other patient populations, including increasing physical performance, that potentially could have been used in musculoskeletal physiotherapy [40-42].

The large majority of physiotherapists were positive toward recommending digital health technologies to patients with MSDs. Together, with the positive view of the suitability of digital health technologies in physiotherapy, this indicates that there is a potential for increased use of such technologies within primary care physiotherapy for patients with MSDs. The most frequently reported advantages of digital health technologies contained benefits both for patients and the physiotherapists, reflecting its potential in increasing accessibility and reducing barriers to treatment for the patients. Interestingly, nearly half of the respondents (153/338, 45.3%) stated that an advantage of digital health technology is its reduced time consumption compared with conventional interventions. On the other hand, the limited scope for physical examination (252/338, 74.6%) and difficulty in building a rapport with the patient (227/338, 67.2%) were noted as disadvantages of the technology. It is assumed that this reflects the nature of physiotherapy, a profession that traditionally has relied on a hands-on approach [43]. The latter is most likely also reflected in the difference found between using digital health technology in evaluating and diagnosing, compared with treatment. The increased confidence in using technology in treatment likely reflects that the physiotherapists feel dependent on a physical meeting to perform an adequate clinical evaluation, a concern reported by physiotherapists in previous literature [30,44,45]. However, studies have found high levels of agreement between face-to-face and telehealth evaluations, somewhat in contradiction to the expressed disadvantage in our study [46,47]. Resistance toward changing practice has been found to be a barrier for implementing digital health technologies among health care professionals in previous studies, but whether this expressed dependence on a physical examination reflects such a resistance is unclear [48].

An interesting finding in our data is that the physiotherapists using digital health technologies were more positive toward its suitability. Furthermore, they reported a higher confidence in using the technology in physiotherapy practice. These findings are in line with evidence provided in other research works [21,49]. Given the notable result in our data regarding the lack of training in the use of digital health technologies, it may not come as a surprise that the physiotherapists more experienced in using the technology had a more positive attitude. Hellstén et al [50] suggest that this indicates a “learning by doing” approach by the physiotherapists and that the experience of the physiotherapist may affect their use. However, as both the users and nonusers expressed a lack of training, the latter should be an aspect of concern if increased use of digital health technology is warranted. Providing proper training is essential to overcome a range of previously expressed barriers, such as lack of digital literacy among the health care personnel, concerns regarding diminished patient safety, and issues with securing privacy and confidentiality of health information [51-53].

A magnitude of factors that could act as facilitators and barriers for implementing digital health technologies in the health care sector has been found in previous studies. From an organizational perspective, the cost of implementing digital solutions is often cited as a barrier, especially highlighting the lack of systems regarding reimbursement for digitally provided care [37,51]. This was also found in our study. The physiotherapists in private practice, who receive their payment as a combination of reimbursement and deductible from the patients, emphasized entitlement to reimbursement as a significantly more important facilitator and barrier than the municipality-employed physiotherapists. In a health care system like the Norwegian, which to a certain degree relies on a combination of health care personnel on a fixed salary and on reimbursement, this is an important aspect. It is unlikely that a further change in clinical care toward adopting digital health technologies will continue only based on the goodwill of the physiotherapists and without certain financial incentives.

The main facilitators and barriers found in our study were related to technology. Similar results have been found in other studies, with technological aspects serving as both a facilitator [50,54] and a barrier [49,55]. The degradation of physiotherapist-related aspects, and the emphasis on aspects regarding technology and infrastructure, might indicate that a further adoption of digital health technologies is affected by implemented measures on a system level. However, there is a lack of research regarding the optimal integration of technology into the health care sector on a system level [56]. To reach the full potential of digital health technologies, further research on the implementation and integration of technology in the digital ecosystem should be prioritized.

We also noted some differences between the municipality-employed physiotherapists and physiotherapists in private practice in our results. An overall finding is that the municipality-employed physiotherapists, though having less frequent use of the technology, appeared more positive about its use and suitability. In addition, the municipality-employed physiotherapists generally scored both advantages and disadvantages, and the importance of the facilitators and barriers,

higher than the physiotherapists in private practice. The frequency of use of digital health technologies was higher among physiotherapists in private practice, including significantly more frequent use of telephone and video consultations. This likely reflects a difference in clinical practice as physiotherapists in private practice predominantly practice in out-patient clinics, whereas municipality-employed physiotherapists tend to conduct home visits and provide services in nursing homes and rehabilitation facilities more frequently. Also, patient characteristics could differ as municipality-employed physiotherapists predominantly treat an older patient population, characterized by a higher proportion of diagnoses related to geriatrics, functional deterioration, and fall, rather than MSDs [57]. Previous studies have shown that age and general digital skills are closely linked [58]. In our study, the municipality-employed physiotherapists reported low digital competence of the patients as a disadvantage in relation to digital health technology to a significantly higher degree compared with the physiotherapists in private practice. This could possibly indicate that there is an age difference in the patient population between the practices.

Strengths and Limitations

There are some limitations to our study. Despite distributing the survey to all Norwegian municipalities, we only had a response rate of approximately 7%. However, the response rate is comparable with other countries [18], and our study includes more than twice as many responding physiotherapists as in the Norwegian national eHealth survey [39]. Distributing the survey to physiotherapists in all municipalities in Norway has most likely given us a nationwide representativity, covering both rural and urban areas. An almost 50/50 distribution between municipality-employed physiotherapists and physiotherapists in private practice increases the generalizability of the study. Caution should be exercised in generalizing the study findings beyond a Norwegian primary care setting and physiotherapists treating patients with MSDs. The limitation to primary care was chosen as this will be an important setting for treating patients with MSDs in the future and the limitation to MSDs was made to improve interpretability of the results. These limitations might influence the response rate and our results, as we are not certain whether we have captured all aspects of the use of digital health technologies among Norwegian physiotherapists. A volunteer bias may exist in our study, as the therapists with less positive experience and impression of digital health technologies may have refused to respond. The questionnaire was based on consensus in the research group, drawing on previous literature and questionnaires and pretesting; however, the lack of a standardized questionnaire could be a limitation. While it is recommended to include a mix of positively and negatively worded questions to avoid response bias [59], our questionnaire included only positively worded questions as we were cautious about altering the existing questionnaires. Web-based data collection secured a widespread distribution of the questionnaire. Due to the anonymous nature of the questionnaire and no option for cookies or IP checks in the Nettskjema tool, multiple entries may have been possible, although we believe that this is unlikely.

Conclusion

Almost 50% of physiotherapists in Norwegian primary care treating patients with MSDs have adapted the use of digital health technologies, particularly those in private practice. The physiotherapists expressed positive attitudes to the use of digital health technologies, and more so if they already offered it. However, challenges in adapting technologies included the need for a physical examination to exclude severe pathology and in-person meetings to establish a relationship, which appear as the greatest disadvantages. Technical aspects and an appropriate scheme for reimbursement served as both facilitators and barriers. Notably, lack of training in the use of digital health technologies was prominent and appeared as a barrier and should likely be addressed in future research and implementation.

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Authors' Contributions

All the authors (LM, NØ, TM, and ATT) have made substantial contributions to the study design, analysis, and interpretation of the paper. All the authors have drafted and critically revised the paper. All authors have approved the submitted version. LM contributed to the acquisition of data.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Attitudes toward digital health technologies.
[PDF File (Adobe PDF File), 97 KB - rehab_v11i1e54116_app1.pdf]

References

1. Cieza A, Causey K, Kamenov K, Hanson SW, Chatterji S, Vos T. Global estimates of the need for rehabilitation based on the global burden of disease study 2019: a systematic analysis for the global burden of disease study 2019. Lancet 2021;396(10267):2006-2017 [FREE Full text] [doi: 10.1016/S0140-6736(20)32340-0] [Medline: 33275908]
2. Kinge JM, Knudsen AK, Skirbekk V, Vollset SE. Musculoskeletal disorders in Norway: prevalence of chronicity and use of primary and specialist health care services. BMC Musculoskelet Disord 2015;16:75 [FREE Full text] [doi: 10.1186/s12891-015-0536-z] [Medline: 25887763]
3. Amundsen O, Moger TA, Holte JH, Haavaag SB, Bragstad LK, Hellesø R, et al. Combination of health care service use and the relation to demographic and socioeconomic factors for patients with musculoskeletal disorders: a descriptive cohort study. BMC Health Serv Res 2023;23(1):858. [doi: 10.1186/s12913-023-09852-3] [Medline: 37580723]
4. Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, et al. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. Br J Sports Med 2020;54(2):79-86. [doi: 10.1136/bjsports-2018-099878] [Medline: 30826805]
5. Report No. 47 (2008-2009). The Coordination Reform. Proper treatment - at the right place and right time. The Norwegian Ministry of Health and Care Services. 2009. URL: https://www.regjeringen.no/contentassets/d4f0e16ad32e4bbd8d8ab5c21445a5dc/en-gb/pdfs/stm200820090047000en_pdfs.pdf [accessed 2024-06-24]
6. Ackerman IN, Bohensky MA, Zomer E, Tacey M, Gorelik A, Brand CA, et al. The projected burden of primary total knee and hip replacement for osteoarthritis in Australia to the year 2030. BMC Musculoskelet Disord 2019;20(1):90 [FREE Full text] [doi: 10.1186/s12891-019-2411-9] [Medline: 30797228]
7. NOU 2023:4. Tid for handling: personellet i en bærekraftig helse- og omsorgstjeneste [Time to act]. Departementenes sikkerhets- og serviceorganisasjon, Teknisk redaksjon. 2023. URL: https://www.regjeringen.no/contentassets/337fef958f2148bebd326f0749a1213d/no/pdfs/nou202320230004000dddpdfs.pdf [accessed 2023-02-28]
8. WHO guideline: recommendations on digital interventions for health system strengthening. World Health Organization. 2019. URL: https://apps.who.int/iris/bitstream/handle/10665/311941/9789241550505-eng.pdf?ua=1 [accessed 2024-06-24]
9. Cottrell MA, Russell TG. Telehealth for musculoskeletal physiotherapy. Musculoskelet Sci Pract 2020;48:102193 [FREE Full text] [doi: 10.1016/j.msksp.2020.102193] [Medline: 32560876]
10. Merolli M, Francis JJ, Vallance P, Bennell KL, Malliaras P, Hinman RS. Evaluation of patient-facing mobile apps to support physiotherapy care: systematic review. JMIR Mhealth Uhealth 2024;12:e55003. [doi: 10.2196/55003] [Medline: 38437018]
11. Sandal LF, Bach K, Øverås CK, Svendsen MJ, Dalager T, Stejnicher Drongstrup Jensen J, et al. Effectiveness of app-delivered, tailored self-management support for adults with lower back pain-related disability: a selfBACK randomized clinical trial. JAMA Intern Med 2021;181(10):1288-1296 [FREE Full text] [doi: 10.1001/jamainternmed.2021.4097] [Medline: 34338710]
12. Seron P, Oliveros MJ, Gutierrez-Arias R, Fuentes-Aspe R, Torres-Castro RC, Merino-Osorio C, et al. Effectiveness of telerehabilitation in physical therapy: a rapid overview. Phys Ther 2021;101(6):pzab053 [FREE Full text] [doi: 10.1093/ptj/pzab053] [Medline: 33561280]
13. Agnew JMR, Hanratty CE, McVeigh JG, Nugent C, Kerr DP. An investigation into the use of mHealth in musculoskeletal physiotherapy: scoping review. JMIR Rehabil Assist Technol 2022;9(1):e33609. [doi: 10.2196/33609] [Medline: 35275089]
14. Shah N, Costello K, Mehta A, Kumar D. Applications of digital health technologies in knee osteoarthritis: narrative review. JMIR Rehabil Assist Technol 2022;9(2):e33489 [FREE Full text] [doi: 10.2196/33489] [Medline: 35675102]
15. Nagel J, Wegener F, Grim C, Hoppe MW. Effects of digital physical health exercises on musculoskeletal diseases: systematic review with best-evidence synthesis. JMIR Mhealth Uhealth 2024;12:e50616 [FREE Full text] [doi: 10.2196/50616] [Medline: 38261356]
16. Keel S, Schmid A, Keller F, Schoeb V. Investigating the use of digital health tools in physiotherapy: facilitators and barriers. Physiother Theory Pract 2023;39(7):1449-1468. [doi: 10.1080/09593985.2022.2042439] [Medline: 35293846]
17. Heiskanen T, Rinne H, Miettinen S, Salminen AL. Uptake of tele-rehabilitation in Finland amongst rehabilitation professionals during the COVID-19 pandemic. Int J Environ Res Public Health 2021;18(8):4383 [FREE Full text] [doi: 10.3390/ijerph18084383] [Medline: 33924234]
18. Hellstén T, Arokoski J, Sjögren T, Jäppinen AM, Kettunen J. The current state of remote physiotherapy in Finland: cross-sectional web-based questionnaire study. JMIR Rehabil Assist Technol 2022;9(2):e35569. [doi: 10.2196/35569]
19. Blumenthal J, Wilkinson A, Chignell M. Physiotherapists' and physiotherapy students' perspectives on the use of mobile or wearable technology in their practice. Physiother Can 2018;70(3):251-261 [FREE Full text] [doi: 10.3138/ptc.2016-100.e] [Medline: 30275650]
20. Damhus CS, Emme C, Hansen H. Barriers and enablers of COPD telerehabilitation - a frontline staff perspective. Int J Chron Obstruct Pulmon Dis 2018;13:2473-2482 [FREE Full text] [doi: 10.2147/COPD.S167501] [Medline: 30154650]
21. Lawford BJ, Bennell KL, Kasza J, Hinman RS. Physical therapists' perceptions of telephone- and Internet video-mediated service models for exercise management of people with osteoarthritis. Arthritis Care Res (Hoboken) 2018;70(3):398-408. [doi: 10.1002/acr.23260] [Medline: 28437566]
22. Lawford BJ, Delany C, Bennell KL, Hinman RS. "I Was Really Pleasantly Surprised": Firsthand experience and shifts in physical therapist perceptions of telephone-delivered exercise therapy for knee osteoarthritis-a qualitative study. Arthritis Care Res (Hoboken) 2019;71(4):545-557. [doi: 10.1002/acr.23618] [Medline: 29885026]

23. Digital economy and society index (DESI) 2022. European Commission. URL: https://digital-strategy.ec.europa.eu/en/library/digital-economy-and-society-index-desi-2022 [accessed 2024-06-24]
24. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, STROBE Initiative. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. BMJ 2007;335(7624):806-808 [FREE Full text] [doi: 10.1136/bmj.39335.541782.AD] [Medline: 17947786]
25. Eysenbach G. Improving the quality of Web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). J Med Internet Res 2004;6(3):e34 [FREE Full text] [doi: 10.2196/jmir.6.3.e34] [Medline: 15471760]
26. ICPC-2. The Norwegian Directorate of eHealth. 2023. URL: https://www.ehelse.no/kodeverk-og-terminologi/ICPC-2 [accessed 2023-09-19]
27. Rausch AK, Baur H, Reicherzer L, Wirz M, Keller F, Opsommer E, et al. Physiotherapists' use and perceptions of digital remote physiotherapy during COVID-19 lockdown in Switzerland: an online cross-sectional survey. Arch Physiother 2021;11(1):18 [FREE Full text] [doi: 10.1186/s40945-021-00112-3] [Medline: 34233763]
28. Biebl JT, Huber S, Rykala M, Kraft E, Lorenz A. Attitudes and expectations of health care professionals toward app-based therapy in patients with osteoarthritis of the hip or knee: questionnaire study. JMIR Mhealth Uhealth 2020;8(10):e21704 [FREE Full text] [doi: 10.2196/21704] [Medline: 33112255]
29. Reynolds A, Awan N, Gallagher P. Physiotherapists' perspective of telehealth during the Covid-19 pandemic. Int J Med Inform 2021;156:104613 [FREE Full text] [doi: 10.1016/j.ijmedinf.2021.104613] [Medline: 34688969]
30. Malliaras P, Merolli M, Williams CM, Caneiro JP, Haines T, Barton C. 'It's not hands-on therapy, so it's very limited': telehealth use and views among allied health clinicians during the coronavirus pandemic. Musculoskelet Sci Pract 2021;52:102340 [FREE Full text] [doi: 10.1016/j.msksp.2021.102340] [Medline: 33571900]
31. Nettskjema. University of Oslo. 2023. URL: https://nettskjema.no/?lang=en [accessed 2024-06-24]
32. Venkatesh V, Morris MG, Davis GB, Davis FD. User acceptance of information technology: toward a unified view. MIS Quarterly 2003;27(3):425. [doi: 10.2307/30036540]
33. Bennell KL, Lawford BJ, Metcalf B, Mackenzie D, Russell T, van den Berg M, et al. Physiotherapists and patients report positive experiences overall with telehealth during the COVID-19 pandemic: a mixed-methods study. J Physiother 2021;67(3):201-209 [FREE Full text] [doi: 10.1016/j.jphys.2021.06.009] [Medline: 34147399]
34. WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. World Medical Association. 2021. URL: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ [accessed 2021-05-06]
35. Lov om behandling av personopplysninger (personopplysningsloven) [The Personal Data Act]. Lovdata. URL: https://lovdata.no/dokument/NL/lov/2018-06-15-38/ [accessed 2024-06-24]
36. de Thurah A, Bosch P, Marques A, Meissner Y, Mukhtyar CB, Knitza J, et al. 2022 EULAR points to consider for remote care in rheumatic and musculoskeletal diseases. Ann Rheum Dis 2022;81(8):1065-1071. [doi: 10.1136/annrheumdis-2022-222341] [Medline: 35470160]
37. Bezuidenhout L, Joseph C, Thurston C, Rhoda A, English C, Conradsson DM. Telerehabilitation during the COVID-19 pandemic in Sweden: a survey of use and perceptions among physiotherapists treating people with neurological diseases or older adults. BMC Health Serv Res 2022;22(1):555 [FREE Full text] [doi: 10.1186/s12913-022-07968-6] [Medline: 35473602]
38. Hatef E, Wilson RF, Zhang A, Hannum SM, Kharrazi H, Davis SA, et al. Effectiveness of telehealth versus in-person care during the COVID-19 pandemic: a systematic review. NPJ Digit Med 2024;7(1):157 [FREE Full text] [doi: 10.1038/s41746-024-01152-2] [Medline: 38879682]
39. Helsepersonellundersøkelsen om e-helse 2022 [Norwegian national eHealth survey]. The Norwegian Directorate of eHealth. 2023. URL: https://www.helsedirektoratet.no/rapporter/helsepersonellundersokelsen-om-e-helse-2023/Rapport_helsepersonellunders%C3%B8kelsen%20om%20e-helse.pdf/_/attachment/inline/2314c48c-1880-4371-a2a6-ab562d91f6a0:dacf4a5d6cf42a8bb2c839979cfd258b96fdada2/Rapport_helsepersonellunders%C3%B8kelsen%20om%20e-helse.pdf [accessed 2024-06-24]
40. Karamians R, Proffitt R, Kline D, Gauthier LV. Effectiveness of virtual reality-and gaming-based interventions for upper extremity rehabilitation poststroke: a meta-analysis. Arch Phys Med Rehabil 2020;101(5):885-896. [doi: 10.1016/j.apmr.2019.10.195] [Medline: 31821799]
41. Taylor LM, Kerse N, Frakking T, Maddison R. Active video games for improving physical performance measures in older people: a meta-analysis. J Geriatr Phys Ther 2018;41(2):108-123 [FREE Full text] [doi: 10.1519/JPT.0000000000000078] [Medline: 26974212]
42. Randriambelonoro M, Perrin Franck C, Herrmann F, Carmona GA, Geissbuhler A, Graf C, et al. Gamified physical rehabilitation for older adults with musculoskeletal issues: pilot noninferiority randomized clinical trial. JMIR Rehabil Assist Technol 2023;10:e39543 [FREE Full text] [doi: 10.2196/39543] [Medline: 36877563]
43. Fornasier R. A century-long struggle towards professionalism. Key factors in the growth of the physiotherapists' role in the United States, from subordinated practitioners to autonomous professionals. Management & Organizational History 2017;12(2):142-162. [doi: 10.1080/17449359.2017.1329090]

44. Giesbrecht E, Major ME, Fricke M, Wener P, van Egmond M, Aarden JJ, et al. Telerehabilitation delivery in Canada and the Netherlands: results of a survey study. JMIR Rehabil Assist Technol 2023;10:e45448 [FREE Full text] [doi: 10.2196/45448] [Medline: 36806194]
45. Weber F, Kloek C, Arntz A, Grüneberg C, Veenhof C. Blended care in patients with knee and hip osteoarthritis in physical therapy: delphi study on needs and preconditions. JMIR Rehabil Assist Technol 2023;10:e43813 [FREE Full text] [doi: 10.2196/43813] [Medline: 37418301]
46. Cottrell MA, O'Leary SP, Swete-Kelly P, Elwell B, Hess S, Litchfield M, et al. Agreement between telehealth and in-person assessment of patients with chronic musculoskeletal conditions presenting to an advanced-practice physiotherapy screening clinic. Musculoskelet Sci Pract 2018;38:99-105. [doi: 10.1016/j.msksp.2018.09.014] [Medline: 30366292]
47. Zischke C, Simas V, Hing W, Milne N, Spittle A, Pope R. The utility of physiotherapy assessments delivered by telehealth: A systematic review. J Glob Health 2021;11:04072 [FREE Full text] [doi: 10.7189/jogh.11.04072] [Medline: 34956637]
48. Michell A, Besomi M, Seron P, Voigt M, Cubillos R, Parada-Hernández F, et al. Implementation of physiotherapy telerehabilitation before and post Covid-19 outbreak: a comparative narrative between South American countries and Australia. Salud Publica Mex 2022;64:S31-S39. [doi: 10.21149/13160] [Medline: 36130385]
49. Albahrouh SI, Buabbas AJ. Physiotherapists' perceptions of and willingness to use telerehabilitation in Kuwait during the COVID-19 pandemic. BMC Med Inform Decis Mak 2021;21(1):122 [FREE Full text] [doi: 10.1186/s12911-021-01478-x] [Medline: 33832473]
50. Hellstén T, Arokoski J, Sjögren T, Jäppinen AM, Kettunen J. Remote physiotherapy in Finland—suitability, usability and factors affecting its use. European Journal of Physiotherapy 2023;25(6):378-387. [doi: 10.1080/21679169.2023.2233560]
51. Scott Kruse C, Karem P, Shifflett K, Vegi L, Ravi K, Brooks M. Evaluating barriers to adopting telemedicine worldwide: a systematic review. J Telemed Telecare 2018;24(1):4-12 [FREE Full text] [doi: 10.1177/1357633X16674087] [Medline: 29320966]
52. Hinman RS, Lawford BJ, Bennell KL. Harnessing technology to deliver care by physical therapists for people with persistent joint pain: telephone and video ‐ conferencing service models. J Appl Behav Res 2018;24(2):e12150. [doi: 10.1111/jabr.12150]
53. Elser A, Lange M, Kopkow C, Schäfer AG. Barriers and facilitators to the implementation of virtual reality interventions for people with chronic pain: scoping review. JMIR XR Spatial Comput 2024;1:e53129. [doi: 10.2196/53129]
54. Hasani F, Malliaras P, Haines T, Munteanu SE, White J, Ridgway J, et al. Telehealth sounds a bit challenging, but it has potential: participant and physiotherapist experiences of gym-based exercise intervention for achilles tendinopathy monitored via telehealth. BMC Musculoskelet Disord 2021;22(1):138 [FREE Full text] [doi: 10.1186/s12891-020-03907-w] [Medline: 33541314]
55. Aloyuni S, Alharbi R, Kashoo F, Alqahtani M, Alanazi A, Alzhrani M, et al. Knowledge, attitude, and barriers to telerehabilitation-based physical therapy practice in Saudi Arabia. Healthcare (Basel) 2020;8(4):460 [FREE Full text] [doi: 10.3390/healthcare8040460] [Medline: 33158298]
56. Giebel GD, Speckemeier C, Abels C, Plescher F, Börchers K, Wasem J, et al. Problems and barriers related to the use of digital health applications: scoping review. J Med Internet Res 2023;25:e43808 [FREE Full text] [doi: 10.2196/43808] [Medline: 37171838]
57. Evensen KAI, Robinson HS, Meisingset I, Woodhouse A, Thielemann M, Bjorbækmo WS, et al. Characteristics, course and outcome of patients receiving physiotherapy in primary health care in Norway: design of a longitudinal observational project. BMC Health Serv Res 2018;18(1):936 [FREE Full text] [doi: 10.1186/s12913-018-3729-y] [Medline: 30514287]
58. Le C, Finbråten H, Pettersen K, Joranger P, Guttersrud Ø. Health Literacy in the Norwegian Population. The Norwegian Directorate of eHealth. 2021. URL: https://www.helsedirektoratet.no/rapporter/befolkningens-helsekompetanse/Health%20Literacy%20in%20the%20Norwegian%20Population.%20English%20summary.pdf/_/attachment/inline/a08fec5e-16c7-435e-abf8-e2f0ba05cc84:c576b33bcd3eb386c58124a817bc3b01fde33df8/Health%20Literacy%20in%20the%20Norwegian%20Population.%20English%20summary.pdf [accessed 2024-06-24]
59. Reuben DB, Lee M, Davis JW, Eslami MS, Osterweil DG, Melchiore S, et al. Development and validation of a geriatrics attitudes scale for primary care residents. J Am Geriatr Soc 1998;46(11):1425-1430. [doi: 10.1111/j.1532-5415.1998.tb06012.x] [Medline: 9809767]

Abbreviations

CHERRIES: Checklist for Reporting Results of Internet E-Surveys
GDPR: General Data Protection Regulation
ICPC-2: International Classification of Primary Care, 2nd edition
MSD: musculoskeletal disorder
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
UTAUT: Unified Theory of Acceptance and Use of Technology

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Review

An Evaluation of the Design of Multimedia Patient Education Materials in Musculoskeletal Health Care: Systematic Review

Garett Van Oirschot[1,2*], BScPT, MMskSportPhty; Amanda Pomphrey[1*], MPT; Caoimhe Dunne[1*], MPT; Kate Murphy[1*], MPT; Karina Blood[1*], MPT; Cailbhe Doherty[1,2], BSc, PhD

[1]School of Public Health, Physiotherapy & Sport Science, University College Dublin, Dublin, Ireland

[2]Insight SFI Research Centre for Data Analytics, Dublin, Ireland

[*]these authors contributed equally

Corresponding Author:
Garett Van Oirschot, BScPT, MMskSportPhty
School of Public Health, Physiotherapy & Sport Science
University College Dublin
4 Stillorgan Road
Belfield
Dublin, D04 C7X2
Ireland
Phone: 353 17166511
Email: garett.vanoirschot@ucdconnect.ie

Abstract

Background: Educational multimedia is a cost-effective and straightforward way to administer large-scale information interventions to patient populations in musculoskeletal health care. While an abundance of health research informs the content of these interventions, less guidance exists about optimizing their design.

Objective: This study aims to identify randomized controlled trials of patient populations with musculoskeletal conditions that used multimedia-based patient educational materials (PEMs) and examine how design was reported and impacted patients' knowledge and rehabilitation outcomes. Design was evaluated using principles from the cognitive theory of multimedia learning (CTML).

Methods: PubMed, CINAHL, PsycINFO, and Embase were searched from inception to September 2023 for studies examining adult patients with musculoskeletal conditions receiving multimedia PEMs compared to any other interventions. The primary outcome was knowledge retention measured via test scores. Secondary outcomes were any patient-reported measures. Retrievability was noted, and PEMs were sourced through search, purchase, and author communication.

Results: A total of 160 randomized controlled trials were eligible for inclusion: 13 (8.1%) included their educational materials and 31 (19.4%) required a web search, purchase, or direct requests for educational materials. Of these 44 (27.5%) studies, none fully optimized the design of their educational materials, particularly lacking in the CTML principles of coherence, redundancy, modality, and generative activities for the learner. Of the 160 studies, the remaining 116 (72.5%) contained interventions that could not be retrieved or appraised. Learning was evaluated in 5 (3.1%) studies.

Conclusions: Musculoskeletal studies should use open science principles and provide their PEMs wherever possible. The link between providing multimedia PEMs and patient learning is largely unexamined, but engagement potential may be maximized when considering design principles such as the CTML.

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KEYWORDS

health education; patient education; patient education materials; multimedia; musculoskeletal diseases; musculoskeletal pain; eHealth; self-management

Introduction

Rationale

The worldwide prevalence and burden of musculoskeletal conditions are exceptionally high, affecting 20% of the global population and accounting for 150 million disability-adjusted life years [1]. They are the second-greatest contributor to worldwide disability [2] and threaten healthy aging by limiting physical and mental capacities and functional ability [3]. The United States demonstrated one of the highest levels of age-standardized disability-adjusted life-years in musculoskeletal disorders worldwide, at over 3000 per 100,000 [4]. A multidisciplinary, multimodal approach is appropriate when managing musculoskeletal conditions [5], and a vital component is patient education [6], that is, teaching the patient [7] about their condition and management options, including nonpharmacological treatment strategies such as exercise or activity modification. Patient education empowers patients with knowledge to participate in and adhere to treatment [6,8-10]. Empowerment is imperative in musculoskeletal health care, underscoring efforts to reframe treatment as less about curing and more about self-management [7]. Multiple expert consensus statements [10-19] include patient education in their clinical guidelines, and further research on patient education is needed for some clinical areas [14,15,20,21].

Multimedia, by definition, is the combination of images and words and has been used to increase learning and understanding since 1657, when the first children's picture book, *Orbis Pictus*, was created, to the current day, when numerous digital multimedia platforms permeate life [22]. This is also true in health care, where multimedia patient education materials (PEMs) combine images and words in an effort to increase patient learning and understanding. It may be more advantageous to provide PEMs in multimedia format [23,24], such as leaflets, posters, infographics, or videos, than in traditional text-only format or verbal, face-to-face format, which can be burdensome in certain clinical settings [25], understaffed health care systems [26], or rural and remote locations without direct access to desired clinical care [27,28]. Traditionally, PEMs in musculoskeletal health care relied on printed or film formats, and while these materials can be effective, they lack the engagement and interactivity offered by digital educational interventions, leveraging multimedia elements such as videography, animations, interactive websites, and mobile apps to enhance patient education. The advantage of using such PEMs is that, once developed, the burden of delivery is very low when they can be disseminated cheaply, en masse [26,29,30], and without physical proximity [31,32]. Condensing the findings of health care research into these consumable formats with wide dispersal potential is particularly helpful for emerging health care systems in underresourced countries where face-to-face encounters are not always feasible [26]. A proposed disadvantage of PEMs is that they are generally not individualized to the patient [30], but this can be overcome by modern educational interventions possessing the digital capacity to tailor themselves to the user [33] or allow the addition of remote support [34]. Tracking the sharing of or engagement with such PEMs may help ensure that new, innovative metrics are used to translate research into practice as opposed to traditional citations [35].

Multimedia education research has seen a series of multimedia learning principles emerge based on empirical studies on how to maximize engagement and learning. One prominent example is the cognitive theory of multimedia learning (CTML) proposed by Mayer [22], which outlines 15 principles according to which educational multimedia should be designed to maximize learning and engagement. This theory suggests that learning is more effective when information is presented through multiple channels (eg, visual and auditory) using spoken words alongside images and in a manner that reduces cognitive overload. For example, the "segmenting principle" states that materials should be split into shorter, user-paced chunks, while the "signaling principle" recommends the use of text or symbols to highlight important information. Since its original publication in 2005 [36], a catalog of research has independently replicated and verified each of the 15 principles from the CTML [22]. This provides an opportunity to optimize the design of PEMs, given that many previous frameworks and scientific advice have focused on different aspects of optimizing the educational content [37-39]. Furthermore, the CTML framework has been applied to health research, where it has informed the design of health care education materials provided to practitioners [40-42], students [43-47], and patients with nonmusculoskeletal conditions [48-53]. It has the potential to inform studies of patients with musculoskeletal conditions as well. One study of low back pain videos found no strong correlates between user engagement and location or setting, duration, conflict of interest risk, speaker's professional designation, source of the video, or clinical recommendations but did recommend that future research should focus on more detailed analyses of audiovisual aspects that may affect engagement [54]. This demonstrates a gap in the education research of patients with musculoskeletal conditions, where the CTML could be useful in correlating design features with engagement. Given the newfound ease in rapidly creating multimedia video content, the new digital age could benefit from its theories.

The dissemination of multimedia content is more effective if it is engaging and is more likely to be watched by more people for a longer duration [55]. The engagement of people with educational content results from more than simply presenting them with scientifically rigorous findings. Patients are now digital citizens [56,57] who must ration their attention across a spectrum of multimedia information, where science competes with misinformation [58-60], especially true in musculoskeletal health care [54,61-64]. Health care researchers and providers must keep their PEMs scientifically current and accurate [65], but they cannot rely on the content alone to sell the PEMs, if they fail to optimize engagement. Such shortcomings are more likely when the research of PEMs lack sufficient description and reporting standards [25,66]. Difficulty was noted when trying to retrieve and examine PEMs used in low back pain research [66], so this should be confirmed in the wider musculoskeletal literature. This may also reiterate the need to continually promote open science so that patient education interventions are available for appraisal and replication studies.

Research often focuses on the scientific content of PEMs rather than the design characteristics that promote knowledge transfer [67], but there has been limited design advice published in the musculoskeletal field, typically narrative advice from rehabilitation-based journals or authors. These commonly include the concise use of text and images in close proximation while avoiding redundancy between them [68], limitations on the amount of color but still using color to hasten the highlighting of pertinent information [68,69], or limitations on word count [70], to name a few. This provides a starting point for ensuring that the plethora of musculoskeletal guidelines promoting patient education are delivered in the most effective manner.

With further exploration into this area of patient education, there may be optimal strategies that inform the design of multimedia PEMs and draw attention away from inaccurate musculoskeletal health care messaging. Examining how their design is reported and described could aid in future trials.

Objectives

The objectives of this review were as follows: (1) to identify randomized controlled trials (RCTs) in the area of adult musculoskeletal health care that used multimedia PEMs as a treatment or component of a treatment and compared them to any other interventions; (2) to examine how these interventions were reported with respect to their reproducibility and appraisability; and (3) to identify whether common design characteristics, such as digital versus nondigital format or adherence to CTML principles, were reported as affecting effectiveness.

Methods

This systematic review was prepared according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [71] Multimedia Appendix 1) and PERSiST (PRISMA in Exercise, Rehabilitation, Sport Medicine and Sports Science) [72] guidelines. It was prospectively registered with the PROSPERO (CRD42022292134).

Information Sources

PubMed, CINAHL, PsycINFO, and Embase were searched from inception to November 26, 2021. An updated search was carried out on August 10, 2022, and again on September 20, 2023, to identify any new potential studies.

Eligibility Criteria

The population, intervention, comparison, outcomes, and study design (PICOS) framework was used to specify the eligibility criteria for this systematic review. The review sought RCTs of those aged ≥18 years with musculoskeletal conditions, defined by the World Health Organization as any condition of the joints, bones, muscles, or multiple body areas and systems that leads to temporary or lifelong limitations in function and participation [73]. Studies were included if they used any multimedia-based education intervention and examined it against any comparator. Multimedia-based educational interventions included any combination of reusable words and images that was delivered to patients. Examples included infographics, books, pamphlets, and videos. Studies were to include a knowledge outcome (primary outcome measure) and any patient-reported outcomes, including pain, disability, or self-efficacy (secondary outcome measure). No restrictions were applied to the follow-up periods or number of time points during which each outcome measure was obtained.

Exclusion criteria consisted of populations with nonmusculoskeletal conditions and the use of educational interventions that relied on clinician-delivered education with no provision of materials.

Search Strategy

A detailed search strategy combined key concepts of the PICOS framework, such as “instruction” (including “patient education,” “information,” and “home exercise programme”), “multimedia” (including “video,” “audiovisual,” and “mobile device”), and “traditional format” (including “written,” “brochure,” and “information sheet”). Individual keywords and Medical Subject Headings terms for each concept were first combined with “OR” and then combined with the “AND” operator. No date or language restrictions were applied. Studies to be screened for inclusion were drawn from this search, and backward reference search was conducted among the included studies. Relevant gray literature was also searched. The detailed search strategy was registered on PROSPERO [74] and is available in Multimedia Appendix 2.

Selection Process

Titles and abstract screening was conducted by all 6 authors using Covidence (Veritas Health Innovation) [75], and articles were advanced to full-text review when 2 authors agreed. Disagreements were resolved through consensus between the primary (GVO) and supervising (CD) authors.

Full-text review was conducted independently by the primary (GVO) and supervising (CD) authors, and all articles upon which an agreement was reached were advanced to the data extraction phase. Finally, a screening of the reference lists of all included studies was performed by the primary author (GVO), and any studies meeting inclusion were added. Any conflicts throughout this process were resolved through consensus between the primary (GVO) and supervising (CD) authors.

Data Collection

Data extraction was conducted by the primary author (GVO), who then cross-referenced these findings with those from a second data extraction process conducted by 4 other authors (AP, CD, KM, and KB). Conflicts were resolved through consensus between the primary (GVO) and supervising (CD) authors.

In cases where an included study lacked sufficient detail about the PEMs used, a request for further information was emailed by the supervising author (CD). If no reply was received, then an additional request was sent 4 months later. If no reply was received within 1 month of this second attempt, the study was still eligible for inclusion, but the materials were coded as “irretrievable.”

Data Items

The primary outcome was the retention of knowledge from the educational intervention, which was evaluated using, for example, a short answer test or a multiple-choice questionnaire. Any patient-reported outcomes were secondary outcomes. The PEMs that could be retrieved were evaluated according to the CTML principles. Variables of studies and participants were also recorded and included title, authors, author sex, year of publication, country of origin, musculoskeletal condition and population, outcome measures, sample size, age, study design, educational intervention, comparator intervention, and inclusion or retrievability of PEMs.

No assumptions were made in cases of missing data. In cases of multiple or lengthy PEMs being provided to an intervention arm, a sample was taken among all the materials to evaluate conformity with the CTML principles, as agreed by consensus between the primary (GVO) and supervising (CD) authors.

Effect Measures

Where possible, effect sizes for sufficiently homogenous populations, interventions, and outcomes were combined so that an appropriate meta-analysis could be completed. A unitless measure of treatment effect size, such as standardized mean difference or Cohen *d*, was to be used.

Synthesis Methods and Statistical Analysis

For the narrative synthesis, data regarding the components of the PEMs were extracted by the primary author (GVO), and cross-referenced against a second extraction that was performed by 4 other authors (AP, CD, KM, and KB). Conflicts were resolved through consensus between the primary (GVO) and supervising (CD) authors. Following the CTML principles proposed by Mayer [22], interventions were coded (yes, no, or not applicable) in a similar manner and synthesized based on the 15 design principles, as shown in Table 1.

Table 1. Explanation of the design principles from the cognitive theory of multimedia learning proposed by Mayer [22].

Design principle	Explanation
1. Multimedia principle	People learn better from words and pictures than from words alone.
2. Coherence principle	People learn better when extraneous material is excluded rather than included.
3. Signaling principle	People learn better when cues are added that highlight the organization of the essential material.
4. Redundancy principle	People do not learn better when printed text is added to graphics and narration. People learn better from graphics and narration than from graphics, narration, and printed text, when the lesson is fast paced.
5. Spatial contiguity principle	People learn better when corresponding words and pictures are presented near rather than far from each other on the page or screen. For example, in an animation on lightning formation, captions are presented at the bottom of the screen (separated presentation) or are placed next to the event they describe in the animation (integrated presentation).
6. Temporal contiguity principle	People learn better when corresponding words and pictures are presented simultaneously rather than successively. For example, the learner first views an animation on lightning formation and then hears the corresponding narration or vice versa (successive group), or the learner views an animation and hears the corresponding narration at the same time (simultaneous group).
7. Segmenting principle	People learn better when a multimedia message is presented in user-paced segments rather than as a continuous unit.
8. Pretraining principle	People learn more deeply from a multimedia message when they know the names and characteristics of the main concepts.
9. Modality principle	People learn more deeply from pictures and spoken words than from pictures and printed words.
10. Personalization principle	People learn better from multimedia presentations when words are in a conversational style rather than a formal style. For example, in a narrated animation on how the human lungs work, personalization involves using “you” and “your” in the narration script, such as “your nose” rather than “the nose” and “your throat” rather than “the throat.”
11. Voice principle	People learn better from multimedia presentations when words are spoken in an appealing human voice.
12. Image principle	People do not learn better from multimedia presentations when a static image of the instructor is added to the screen.
13. Embodiment principle	People learn more deeply from multimedia presentations when an onscreen instructor displays high embodiment rather than low embodiment.
14. Immersion principle	People do not necessarily learn better in 3D immersive virtual reality than with a corresponding 2D desktop presentation.
15. Generative activity principle	People learn better when they are guided in carrying out generative learning activities during learning (eg, summarizing, mapping, drawing, imagining, self-testing, self-explaining, teaching, or enacting). For example, after each of the 6 sections in a virtual reality simulation on the human bloodstream, students are asked to verbally summarize what they have learned.

Reporting Bias Assessment

The Cochrane Risk of Bias-2 tool was used to review the bias of the included studies [76]. Two assessors independently evaluated the risk of bias in each of the included studies, and any interassessor disagreement was resolved through consensus between the primary (GVO) and supervising (CD) authors.

Certainty Assessment

The Template for Intervention Description and Replication (TIDieR) checklist [77] was used to determine the quality of the RCTs that included their PEMs by 2 independent reviewers, with any conflicts resolved through consensus between the primary (GVO) and supervising (CD) authors.

Results

Study Selection

The PRISMA flow diagram in Figure 1 demonstrates the selection process.

Of the 176 studies originally deemed eligible for inclusion, 16 (9.1%) were based on patient cohorts used in previous publications, so these were merged with their previously reported trials, leaving a data set of 160 patient cohorts (female patients: n=29,903, 56%). Patient characteristics are shown in Table 2.

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

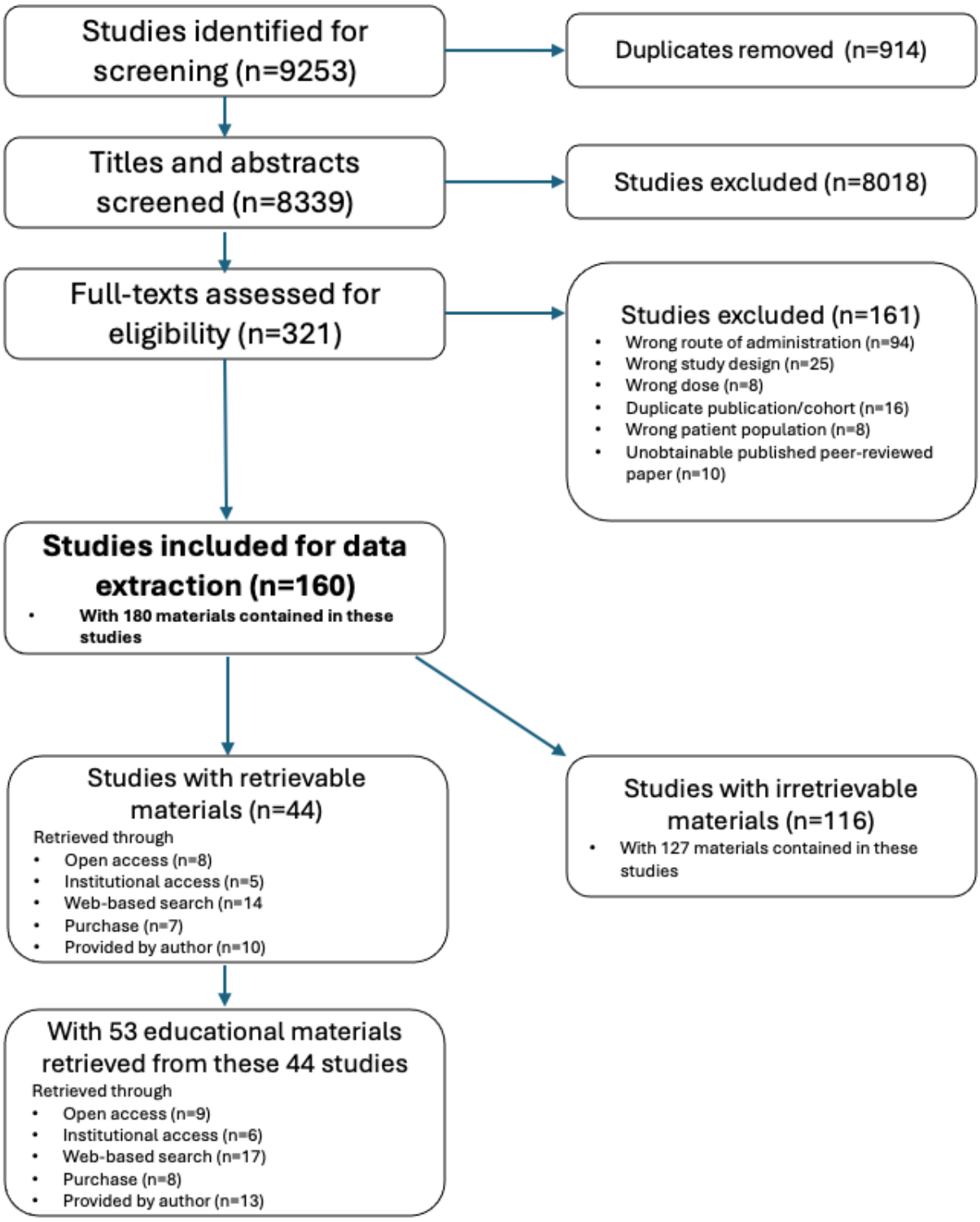


Table 2. Characteristics of participants in included studies (N=29,903).

Characteristics	Values
Sex, n (%)	
Male	12,293 (41.07)
Female	16,868 (56.36)
Other[a]	6 (0.02)
Not reported	736 (2.46)
Age (y), range[b]	18-90
Population or condition, n (%)	
Spinal pain	
LBP[c]	12,963 (43.31)
Neck pain	2099 (7.01)
Back pain	908 (3.03)
WAD[d]	765 (2.56)
Spinal pain	290 (0.97)
Radiculopathy	
LBP with or without radicular symptoms	729 (2.44)
Cervical or lumbar radiculopathy	67 (0.22)
Pain conditions	
Chronic pain	5964 (19.9)
Fibromyalgia	1272 (4.3)
General pain	95 (0.3)
All other conditions	
Osteoarthritis	1663 (5.56)
Knee pain	395 (1.32)
LE[e]	303 (1.01)
Tendinopathy	270 (0.9)
UE[f]	259 (0.86)
Sedentary	249 (0.83)
Rheumatoid arthritis	143 (0.48)
Migraine	116 (0.39)
TMJ[g]	86 (0.29)
Pelvic pain	82 (0.27)
Shoulder	38 (0.13)
Multiple conditions, injuries, or body regions	1064 (3.55)

[a]This category was not defined in the 2 studies where it emerged.

[b]Range is given due to the heterogenous reporting of age.

[c]LBP: low back pain.

[d]WAD: whiplash-associated disorder.

[e]LE: lower extremity.

[f]UE: upper extremity.

[g]TMJ: temporomandibular joint.

The 160 included studies were conducted between 1995 and 2023, with 68% (n=108) published since 2016, when >10 publications per year began occurring more regularly. Female names accounted for 72 (54%) of the 160 primary authors. Most

studies originated from the United States (38/160, 23.8%), followed by Spain (20/160, 12.5%), Germany (12/160, 7.5%), Australia (10/160, 6.3%), and European Union countries (73/160, 45.6%). According to World Bank definitions [78], of the 160 studies, 137 (85.6%) came from high-income countries, followed by 19 (11.9%) from upper middle–income countries and 4 (2.5%) from lower middle–income countries. Further data on the country of origin are available in Multimedia Appendix 3.

Risk of Bias

Appraisal of the included studies using Risk of Bias-2 found a high risk of bias in ≥2 of the 6 domains in 31 (19.4%) of the 160 studies, while the remaining 129 (80.6%) studies had a high risk of bias in none or just 1 of the domains. The full results can be found in Multimedia Appendix 3.

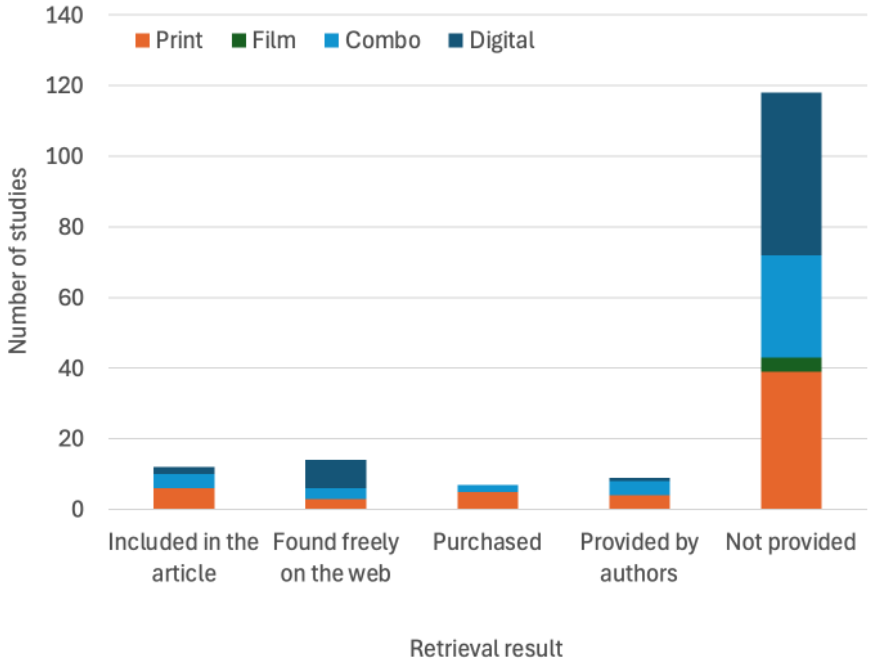
Results of Individual Studies

The full findings of the 160 included studies can be found in Multimedia Appendix 3. In summary, the 160 studies used 180 multimedia PEMs in a variety of formats. A total of 99 (61.9%) studies incorporated digital delivery, with 57 (35.6%) using digital-only delivery and 41 (25.6%) using a combined digital and nondigital delivery. Another 57 (35.6%) studies used print-only delivery, and 4 (2.5%) used film-based delivery.

Of the 180 materials used across all the studies, the most commonly used materials were leaflets or pamphlets (n=67, 37.2%), followed by videos (n=37, 20.5%, of which 33, 18.3% were digital), combinations of all types of materials (n=31, 17.2%), websites (n=27, 15%), apps (n=18, 10%), manuals or workbooks (n=18, 10%), books (n=11, 6.1%), and presentation slides (n=7, 3.9%).

Of the 160 studies, 12 (7.5%) had materials that could be retrieved via their publication, and the materials of 30 (18.8%) studies were retrieved via a web search, purchase, or by request to the authors, who were contacted initially in April 2022 and again in August 2022 and May 2024 to request their materials. Overall, 44 (27.5%) different studies [30,79-120] provided 51 different PEMs for appraisal. Figure 2 shows the retrievability of the multimedia PEMs based on the type of delivery, and Figure 3 shows the retrievability based on the year of publication. Notably, materials requiring purchase were mostly books (average cost=11.55 EUR [US $14.54] per unit) or apps (average cost=7.50 EUR [US $8.07] per unit). 116 studies [28,29,32,58,121-232] contained materials that could not be retrieved.

Figure 2. Types of materials for each retrieval method.



The 51 multimedia PEMs that were retrieved were appraised according to the CTML principles (Table 3). When applicable, nearly all interventions adhered to the principles of immersion (44/46, 96%) by avoiding virtual reality, spatial contiguity (31/51, 94%) by displaying text and graphics in close proximity, voice 93% (14/15) by using an appealing human voice, temporal contiguity (46/50, 92%) by presenting text and graphics simultaneously, and personalization (42/48, 88%) by using words in a conversational style. Most interventions adhered to the segmenting principle (41/50, 82%) by presenting educational material in shorter segments instead of continuously, the signaling principle (37/51, 73%) by using cues to organize the information, the embodiment principle (7/10, 70%) by displaying the speaker, the pretraining principle (36/51, 71%) by familiarizing participants with main concepts in advance, and the image principle (8/17, 57%) by avoiding static images of speakers on screen.

Table 3. Appraisal of the design of multimedia educational materials using the cognitive theory of multimedia learning principles proposed by Mayer [22][a].

Study	Description of the educational intervention	Type	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Bandak et al [79], 2022	Good Life with Osteoarthritis in Denmark (GLAD) education video [233]	Video (or film)	✓			✓	—[b]	✓		✓	✓	✓	✓	✓	✓	✓	
Baumeister et al [80], 2015	Video for a web psychological pain interventions	Video (or film)	✓	—		—	✓	—		✓	✓	✓	✓	✓	✓	✓	
Bennell et al [81], 2017	Website and videos [234]	Website or blog	✓	✓	✓		✓	✓	✓		✓	✓	✓	✓		✓	
Berberoğlu and Ülger [82], 2023	Multimedia instructions for motor control exercises (videos) [235]	Video (or film)	✓	✓	✓	✓	—		✓	✓	✓	✓	✓		—	✓	
Berberoğlu and Ülger [82], 2023	Face-to-face instructions for motor control exercises and handouts	Leaflet, pamphlet, or booklet	✓	✓	✓	✓	✓	✓	✓	✓	—		—	—	—	—	
Bostrøm et al [83], 2023	EPIO app	App	✓		✓		✓		✓	✓	✓	✓	✓		—	✓	✓
Chenot et al [84], 2019	German version of The Back Book (Rückenbuch)	Book	✓				✓	✓	✓			✓	—	—	—	✓	
Chimenti et al [85], 2023	PSE[c] and exercise: videos and handouts	Multiple: videos and leaflets	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Coudeyre et al [86], 2006	French version of The Back Book (Le Guide du Dos)	Book	✓				✓	✓	✓			✓	—	—	—	✓	
Coudeyre et al [87], 2007	French version of The Back Book (Le Guide du Dos)	Book	✓				✓	✓	✓			✓	—	—	—	✓	
Cramer et al [88], 2013	Written yoga instructions	Leaflet, pamphlet, or booklet	✓				✓	✓	✓	✓			—	—	—	✓	
Cramer et al [88], 2013	Self-care manual for neck pain and stiffness	Manual or workbook	✓		✓		✓	✓	✓	✓		✓	—	—	—	✓	
Dobscha et al [90], 2008	APT[d] manual and worksheet	Manual or workbook	✓		✓		✓	✓	✓	✓		✓	—	—	—	✓	✓
Gardner et al [91], 2019	Participant handbook	Manual or workbook	✓				✓	✓		✓		✓	—	—	—	✓	✓
George et al [92], 2009	The Back Book	Book	✓				✓	✓	✓			✓	—	—	—	✓	
Gibbs et al [93], 2022	Pain education TEDx video: [236]	Video (or film)	✓	✓		✓	—	✓		✓	✓	✓	✓	✓	✓	✓	
Hrkać et al [94], 2022	Pictorial and descriptive examples of the exercise	Leaflet, pamphlet, or booklet	✓				✓	✓	✓	✓	—	—	—	—	—	✓	
Ibrahim et al [95], 2023	Booklet containing key information about the program	Leaflet, pamphlet, or booklet	✓	✓	✓	✓	✓	✓	✓	✓	—		—	—	—	—	
Janevic et al [96], 2022	Positive Steps website with videos: [237]	Multiple types of media	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Study	Description of the educational intervention	Type	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Jinnouchi et al [97], 2023	Brief-See (100 minute long and therapist delivered) and material-based education	Book	✓		✓	✓	✓	✓	✓	✓	—		—	—	—	—	✓
Kohns et al [98], 2020	Pain psychology and neuroscience video: [238]	Video (or film)	✓				✓	✓	✓		✓	✓	✓		—	✓	
Kohns et al [98], 2020	Four Rules for a Healthy Lifestyle: [239]	Video (or film)	✓	✓	✓	✓	✓				✓		—		—	✓	
Lamb et al [99], 2010	The Back Book	Book	✓				✓	✓	✓			✓	—	—	—	✓	e
Meeus et al [100], 2010	Illustrations taken from “Explain Pain”	Manual or workbook	✓		✓		✓	✓	✓	✓		✓	—	—	—	✓	
Mukhtar et al [101], 2022	Standard PNE[e] and CSPNE[f]: slides, leaflet, and audio	Multiple types of media used	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
O’Keeffe et al [30], 2020	Cognitive Functional Therapy written information	Leaflet, pamphlet, or booklet	✓		✓		✓	✓	✓	✓	✓	✓	—	—	—	✓	✓
Pacella-LaBarbara et al [102], 2020	PTSD Coach app	App	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Roseen et al [103], 2023	12 weekly Hatha yoga classes with videos: [240]	Video (or film)	✓	✓		✓		✓		✓	✓	✓	✓	✓	✓	✓	✓
Roseen et al [103], 2023	Home manual	Manual or workbook	✓		✓		✓	✓	✓	✓	—	—	—	—	—	—	✓
Roseen et al [103], 2023	Education using “The Back Pain Helpbook”	Book	✓		✓		✓	✓	✓			✓	—	—	—	✓	
Sandhu et al [104], 2023	MyOpoidManager booklet	Manual or workbook	✓		✓		✓	✓	✓	✓		✓	—	—	—	✓	✓
Sandhu et al [104], 2023	MyOpoidManager app	App	✓		✓			✓	✓	✓		✓	—	—	—	—	✓
Saper et al [105], 2017	The Back Pain Helpbook	Book	✓		✓		✓	✓	✓			✓	—	—	—	✓	
Sherman et al [107], 2005	The Back Pain Helpbook	Book	✓		✓		✓	✓	✓			✓	—	—	—	✓	✓
Sherman et al [108], 2011	The Back Pain Helpbook	Book	✓		✓		✓	✓	✓			✓	—	—	—	✓	✓
Simula et al [109], 2021	Booklet [241]	Leaflet, pamphlet, or booklet	✓		✓		✓	✓		✓		✓	—				
Singh et al [110], 2018	Written instructions for opioid medication use and disposal	Leaflet, pamphlet, or booklet	✓		✓		✓	✓	—			✓	—	—	—	✓	
Skou et al [111], 2015	PowerPoint slides on exercise, education, diet, insoles and pain medication treatment presentation slides	PowerPoint (Microsoft Corporation) slides	✓	✓	✓		✓	✓	✓	✓		✓	—	—	—	✓	
Skou et al [111], 2015	Written information on knee osteoarthritis	Leaflet, pamphlet, or booklet	✓		✓		✓	✓	✓			✓	—	—	—	✓	

Study	Description of the educational intervention	Type	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Skou et al [111], 2015	Written information on treatment and healthy lifestyle	Leaflet, pamphlet, or booklet	✓		✓		✓	✓	✓			✓	—	—	—	✓	
Syed et al [112], 2018	Narrated video on risks of narcotic overuse and abuse	Video (or film)	✓		✓		✓		✓	✓	✓	✓	✓		—	✓	
Thompson et al [113], 2016	Written information on serious nerve pathology and chronic cycle of pain	Leaflet, pamphlet, or booklet	✓		✓	✓	✓	✓	✓	✓		✓	—	—	—	✓	✓
Thorn et al [114], 2018	Pain education workbook	Manual or workbook	✓		✓		✓	✓	✓	✓		✓	—	—	—	✓	✓
Traeger et al [115], 2019	Intensive patient education	Manual or workbook	✓	✓	✓	✓	✓	✓	✓	✓			—	—	—		
Valiente-Castril lo et al [116], 2021	Chronic pain video: [242]	Video (or film)	✓	✓			✓	✓		✓	✓	✓	✓		—	✓	
Vanti et al [117], 2019	User manual	Manual or workbook	✓		✓		✓	✓	✓	✓		✓	—	—	—	✓	
Vanti et al [117], 2019	Informative brochure	Leaflet, pamphlet, or booklet	✓	✓	✓	✓	✓	✓	✓	✓		✓	—	—	—	✓	
Walsh et al [118], 2020	Supporting handbook and supplementary patient booklet	Multiple (see description)	✓		✓		✓	✓		✓		✓	—	—	—	✓	✓
Westenberg et al [119], 2018	Mindfulness-based video exercise: [243]	Website or blog	✓	✓	✓	✓		✓	✓	✓		✓	—	—	—	✓	✓
Yuan et al [120], 2021	Traditional paper book consisting of 64 pages	Book	✓	—	✓	—	✓	✓	✓	✓		—	—	—	—	✓	✓

[a]Links are included where materials are found freely on the web. Relevant information included for materials requiring online search or purchase.

[b]Not applicable due to the nature of educational materials or due to the inability to translate the language of materials.

[c]PSE: patient science education.

[d]APT: assistance with patient treatment.

[e]PNE: pain neuroscience education.

[f]CSPNE: culturally sensitive pain neuroscience education.

With respect to the principles with the poorest adherence, a minority of interventions adhered to the remaining principles of generative activity (21/51, 41%) by including any generative learning activities for the learner to carry out, modality (16/46, 35%) by opting for pictures accompanied by spoken words over written words, coherence (14/49, 29%) by excluding extraneous information, and redundancy (13/49, 27%) by avoiding redundant text alongside graphics.

The interrater agreement between the authors conducting the CTML appraisal was 87% on initial scoring and then 100% after any conflicts were discussed and consensus was reached between the primary (GVO) and supervising (CD) authors.

Outcome Measures

Of the 160 included studies, 5 (3.1%) studies reported on the primary outcome for this review, knowledge translation or retention. The heterogeneity of the participants across these 5 studies precluded the planned meta-analysis of the primary outcome.

As for the secondary outcome of any patient-reported measures, the most frequently reported measure was pain intensity (89/160, 55.6%), followed by the Pain Catastrophizing Scale (42/160, 26.2%), the Roland Morris Disability Questionnaire (29/160, 18.1%), the Oswestry Disability Index (26/160, 16.2%), the Tampa Scale for Kinesiophobia (25/160, 15.6%), the Neck Disability Index (23/160, 14.4%), and patient satisfaction (26/160, 16.2%).

Certainty of the Reporting of Interventions

The TIDieR checklist is shown in Table 4 and reflects the checks performed on the 44 studies that provided at least a sample of their multimedia PEMs. The checklist items that were mostly commonly missing from the PEMs were the reporting of who delivered the intervention (16/44, 36% studies) and where the provision of the intervention took place (14/44, 32% studies).

Table 4. Template for Intervention Description and Replication (TIDieR) checklist [77].

	1	2	3 and 4		5	6	7	8	9	10	11 and 12	
Study	Brief name	Why	What		Who provided	How	Where	When and how much	Tailoring	Modifications	How well	
Bandak et al [79] 2022	✓	✓	✓	✓	✓	✓	✓	✓	✓	__[a]	—	—
Baumeister et al [80], 2015	✓	✓		✓		✓	✓			—		
Bennell et al [81], 2017	✓		✓	✓	✓	✓	✓	✓		—		✓
Chenot et al [84], 2019		✓		✓		✓	✓	✓	—	—		✓
Coudeyre et al [87], 2007	✓	✓	✓	✓		✓	✓		—	—	—	—
Coudeyre et al [86], 2006	✓	✓	✓		✓	✓	✓	✓	—	—	—	—
Cramer et al [88], 2013	✓			✓	✓	✓		✓	—	—		
Dobscha et al [90], 2008						✓	✓		—	—	✓	
Gardner et al [91], 2019	✓	✓	✓	✓	✓	✓		✓		—	—	—
George et al [92], 2009	✓	✓	✓	✓		✓	✓	✓	—	—	—	—
Gibbs et al [93], 2022	✓	✓	✓	✓	✓	✓	✓	✓	—	—	—	—
Janevic et al [96], 2022	✓	✓	✓	✓	✓	✓	✓	✓	✓	—		Y
Kohns et al [98], 2020	✓	✓	✓	✓					—	—	—	—
Lamb et al [99], 2010	✓	✓		✓		✓	✓	✓	—	—		✓
Meeus et al [100], 2010	✓	✓	✓			✓		✓	—	—	—	—
O'Keeffe et al [30], 2020	✓			✓		✓		✓	—	—	✓	
Saper et al [105], 2017	✓	✓	✓	✓		✓		✓	—	—		
Sherman et al [xx], 2011	✓	✓			✓	✓	✓	✓	—	—		✓
Sherman et al [107], 2005	✓	✓			✓	✓	✓	✓	—	—	—	—
Simula et al [109], 2021	✓	✓	✓	✓	✓	✓	✓		—	—	—	—
Singh et al [110], 2018	✓		✓	✓					—	—	—	—
Skou et al [111], 2015		✓	✓	✓		✓		✓	✓	—	—	—
Syed et al [112], 2018	✓		✓	✓		✓			—	—	—	—
Thompson et al [113], 2016	✓	✓	✓	✓	✓	✓			—	—		✓

Study	1 Brief name	2 Why	3 and 4 What		5 Who provided	6 How	7 Where	8 When and how much	9 Tailoring	10 Modifications	11 and 12 How well	
Thorn et al [114], 2018	✓	✓	✓	✓	✓	✓		✓	—	—	✓	✓
Traeger et al [115], 2019	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Valiente-Castrillo et al [116], 2021	✓	✓	✓	✓	✓	✓		✓	—	—	—	—
Vanti et al [117], 2019	✓	✓	✓	✓				✓	—	—	—	—
Walsh et al [118], 2020	✓		✓			✓	✓	✓	✓	✓	N	✓
Westenberg et al [119], 2018	✓	✓		✓		✓	✓	✓	✓	—	—	—
Pacella-LaBarbara et al [102], 2020	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Roseen et al [103], 2023	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Sandhu et al [104], 2023	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mukhtar et al [101], 2022	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Jinnouchi et al [97], 2023	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Hrkać et al [94], 2022	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Ibrahim et al [95], 2023	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Diab et al [89], 2022	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
Chimenti et al [85], 2023	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Berberoğlu and Ülger [82], 2023	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Bostrøm et al [83], 2023	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Yuan et al [120], 2021	✓	✓	✓	✓	✓	✓			—	—		

[a]Not applicable.

Discussion

Principal Findings

The aims of this systematic review were to identify all musculoskeletal-related RCTs that delivered multimedia-based educational materials to patients, to evaluate the design characteristics of these materials, and to ascertain whether a relationship exists between their design and improvements in the patients' knowledge or clinical outcomes. Unfortunately, not all of these aims could be achieved. Patient knowledge was rarely tested, and it was never tested in studies that provided their PEMs. Overall, of the 160 studies, 44 (27.5%) provided 51 PEMs that were synthesized as part of this review. Meta-analysis was not possible due to the low number of publications for which educational materials could be retrieved and due to the heterogeneity of outcomes and populations among those that were retrievable.

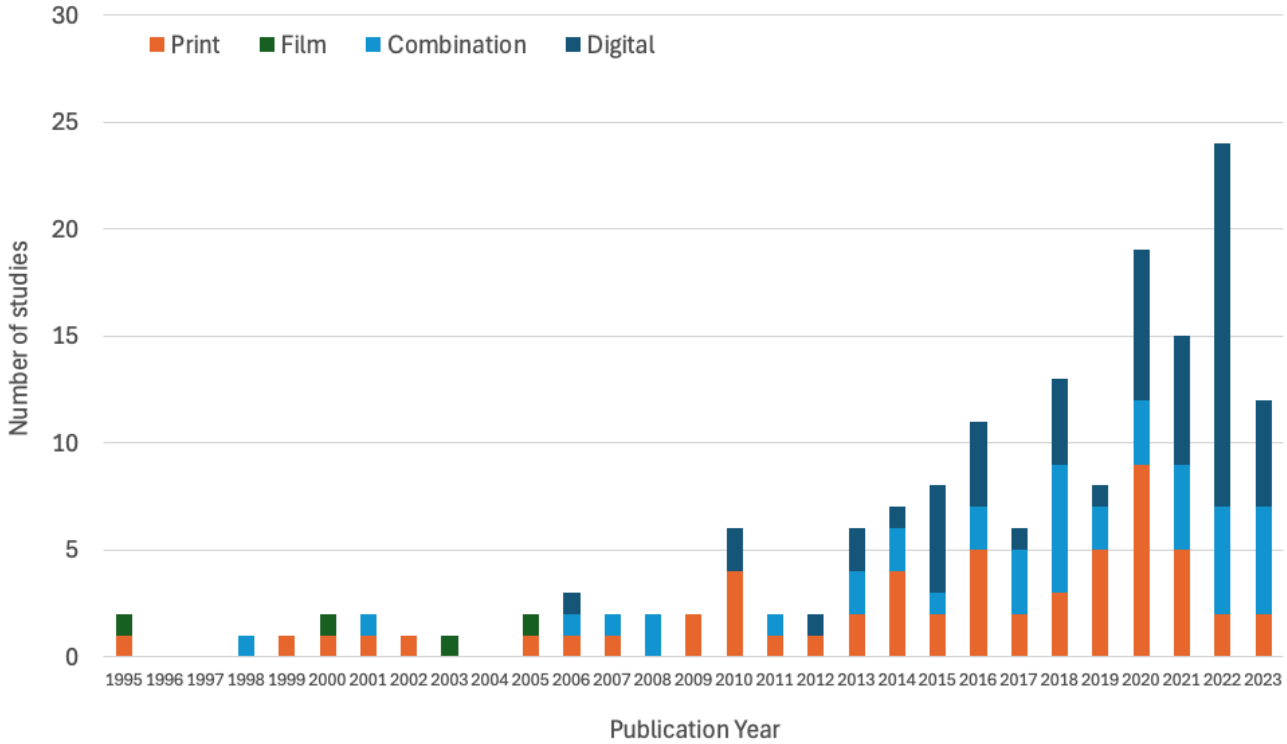
Of the 160 studies, multimedia PEMs could be initially accessed only for 26 (16.2%): 12 (7.5%) included their PEMs in the scientific report, while 14 (8.8%) used materials that were freely available on the web. Upon further efforts, materials were obtained through purchase for 7 (4.4%) studies, while the authors of 9 (5.6%) studies provided their educational materials

upon direct contact from the supervising author (CD). The fact that 118 (73.8%) of the 160 studies failed to provide their multimedia PEMs or a means to access these materials is disappointing. It undermines the replicability of the research (much of which is publicly funded) and its potential to make a real-world impact in clinical practice. If clinicians are to use patient education as recommended across a plethora of clinical guidelines in musculoskeletal health care [10-19], then clinicians must be able to see and hear what the study participants saw and heard. Having direct access to the materials used in a study's educational intervention (in the scientific article, as an appendix, or through the public domain, such as a website or social media channel) is vital to incorporating research findings into clinical practice. We noted, as shown in Figure 2, that the increasing use of digital interventions in musculoskeletal education has not improved this accessibility issue. For digital interventions to realize their full potential, it is crucial that researchers make their materials accessible, either through publication appendices or public repositories.

The inability to replicate and implement research protocols due to poor reporting has been justly criticized in prior musculoskeletal research related to exercise [244,245], biologics [246], or injury epidemiology [247]. Patient education must be held to a similar standard. Specific to the area of PEMs, it is possible that difficulties may arise due to issues around safeguarding intellectual property with potential commercial value. However, we contend that until the scientific community develops an understanding of how and why patients engage with and learn from multimedia-based educational materials and devises a series of design principles for specific PEMs (akin to the pedagogical research conducted by Mayer [22] among student populations), the pursuit of a commercial enterprise formed around a core intellectual property of PEMs is premature (Multimedia Appendix 3 [22,23,40,59,80,127,133]). Going forward, we would urge researchers in musculoskeletal health care to provide a means to access their educational content with a persistent identifier in the public domain.

Our analysis of the 160 RCTs included in this review shows that increasingly, a significant proportion of studies published since 2017 have incorporated digital formats, such as videos, websites, and mobile apps (Figure 3). This trend is quite possibly driven by advancements in technology, increased accessibility of digital devices, and potentially the remote health care solutions accelerated by the COVID-19 pandemic [28]. While printed handouts and physical materials are still present in the literature, the increasing proportion of digital formats used alone or with these physical materials underscores the importance of digital solutions in the future of musculoskeletal health care.

Figure 3. Types of educational materials used in musculoskeletal studies per year.



Indeed, because no design principles related to the design of multimedia-based educational materials exist for patient populations with musculoskeletal conditions, in this review, we evaluated the PEMs according to the 15 principles of the CTML proposed by Mayer [22]. While the CTML is not a framework explicitly designed for PEMs, the 15 principles described therein provided a mechanism to examine the design characteristics, having been used in nonmusculoskeletal [49-62] research and a previous musculoskeletal [121] study. All but 1 of the 51 sets of multimedia PEMs from the 44 appraised studies used at least half of the CTML principles in the design of their materials, and a third of the materials were found to use ≥75% of the principles. The CTML design principles that were mostly not adhered to were the coherence principle of excluding extraneous information, the redundancy principle of avoiding similar information conveyed via words and images, the modality principle of combining different senses (ie, visual and auditory), and the generative activity principle of participants engaging

in an activity that recaps their learning. The practical upshot for researchers and clinicians seeking to design and develop engaging educational materials is that the design of these materials can easily be improved over the interventions examined in this review by including words and images that do not repeat each other, cutting as much extraneous information as possible, combining auditory information with visual information wherever possible, and including some form of interactive activity to recapitulate the material. These modifications can be made to many of the multimedia PEMs that are designed for patients with musculoskeletal conditions, whether in the form of websites, apps, or social media posts, and should form the basis for design recommendations of multimedia PEMs for patients with musculoskeletal conditions.

However, it is important to note that further research is required to validate these recommendations among patient cohorts, as the CTML was developed in third-level educational settings, and not in health care. Literature that has contributed to the discussion of PEMs to date has mainly focused on aspects surrounding content [248], delivery methods [77], and understandability [39] rather than design. While it may not be possible to standardize all educational resources according to their target population or demographic, large research bodies, including reputable academic journals, professional organizations, government bodies, and charitable organizations, are key stakeholders in maintaining scientific integrity in the design and reproducibility of their content. This is especially true as self-management and widespread remote delivery of PEMs to underresourced areas become increasingly important in the delivery of musculoskeletal care [7] and for increasing public knowledge.

Then, it was surprising that very few (5/160, 3.1%) of the studies included in this review evaluated knowledge transfer or knowledge retention, as the primary purpose of an educational intervention is a change in postintervention knowledge (ie, learning). This may undermine the validity of the 96.9% (155/160) of studies using other outcomes, as the relationship is not well understood between such outcomes and the outcome of knowledge transfer or retention, which should be used to evaluate patient education. If clinical guidelines are consistently recommending educating patients, then research practices should consistently evaluate the effectiveness of this education by examining an outcome related to learning. It has been noted in low back pain PEMs that knowledge is being underassessed [66], and our review found similar results. Disability, function, pain, or any other outcome is usually favored over knowledge when multimedia PEMs are used, as in 96.9% (155/160) of the included studies in this review. However, it can also be argued that testing knowledge retention or knowledge transfer may not matter, as some types of educational materials may be effective for reasons other than learning in the target cohort, but this can only be better explored if knowledge is routinely measured. Unlike the American College of Sports Medicine guidelines [249] that recommend various exercise interventions to different populations with musculoskeletal conditions, there is no equivalent framework for educational interventions in musculoskeletal health care. This can lead to significant variety among educational interventions in terms of their content, format, length, and method of delivery. The 160 studies included in this review demonstrated that variety even when the target population was the same, such as our finding of 41 low back pain studies using a huge variety of interventions and outcomes (Multimedia Appendix 3).

Even the best research can be distorted by poor design or thwarted by the superior design of misinformation. Put bluntly, science must be designed to be as appealing as pseudoscience and other competing interests when it comes to patient education [58,59]. Scientific information does not need to debate with or debunk misinformation, as has been shown in nonmultimedia PEMs for low back pain [250]. Scientific information simply needs to be presented in the most engaging way possible [55], and health care research can find that advice exists on how to maximize engagement with videos [251,252], especially in the era of highly influential social media platforms [253]. Such cross-disciplinary fertilization with public health research and social media engagement research would allow musculoskeletal researchers and clinicians to provide more effective education to patients by using basic strategies such as segmenting into shorter portions [251] or personalizing the narration and experience [253] as much as possible, as has been noted in the CTML principles [22].

Limitations

There are several limitations to the articles included in this review. First, the increased number of studies on educational resources in the past decade, especially the last 5 years, reflects the broader surge in digital health care resources available to the public. It could be argued that studies of younger age groups, who are accustomed to more information resources being at their fingertips, may have different results from those of the studies included this review, which contained many middle-aged and older adults and did not separate younger age brackets.

Second and as previously mentioned, jurisdictions with underresourced or very remote health care systems may have a special interest in the design of multimedia PEMs, as they may be used as a frontline intervention when one-to-one clinical care is impossible at the population or community level. However, among the 160 studies in our review, only 4 (2.5%) studies were from lower middle–income countries, comprising only 1% (277/29,903) of the participants in this review, so most of this research appears to be biased toward populations from more resourced countries and not toward countries that may glean the most benefit.

In terms of methodological considerations, we were able to retrieve educational materials from only 44 (23.1%) of the 160 studies, so our findings about the commonly overlooked principles of coherence, redundancy, and generative learning may not be generalizable to the wider array of musculoskeletal research when more materials can be examined. In addition, the CTML has provided guidance for designing materials in various areas of health care education in the past [40-53], but this is an extrapolation of its original use for research into undergraduate university education. Patient education research lacks any comparable framework, and despite our best search efforts, most research on patient education resources focused on optimizing the educational content in terms of understandability and

actionability [39] or in terms of literacy [38] but failed to capture an expansive number of potential design features. While the CTML was the most obvious guideline used in the literature to date, that does not prevent better frameworks developing in the future. Multimedia interventions pertaining specifically to health care require far more research to determine whether other frameworks could be more suitable, and we hope this review using the CTML serves as a launching point for such discussions.

Implications and Future Recommendations

There is a significant gap between what social media companies and what health care researchers and practitioners know about engagement with their respective clientele, with the latter group not necessarily able to prioritize obtaining and using this skill set. Liaising with content creators to scientifically evaluate engagement holds huge potential in musculoskeletal health care. Harnessing even a portion of the engagement knowledge possessed by those involved in social media advertising, educating, or campaigning could prove very effective in disseminating musculoskeletal knowledge to patients. This requires liaising with a new discipline. In addition, research should focus on the impact of digital interventions on various patient outcomes and the mechanisms through which they influence learning and behavior change.

Another priority should be to achieve a higher standard of reporting in studies using educational interventions and to ensure that such studies always specify the medium of the interventions, such as graphic, video, or leaflet, and some form of quantifiable length, such as word count, length of time, or number of pages, especially in what should be rare instances when the actual materials cannot be provided to the reader. Research publication guidelines should reflect the obvious need for patient education interventions to be accurately and consistently described, as has been recommended for other interventions in musculoskeletal research, and publication guidelines should be influenced by the open science movement by providing the PEM interventions wherever possible. These recommendations also pertain to the appraisal and replication of such research, as supplying sufficient information is vital to accurate appraisal and replication. Notably, of the 160 studies included in this review, the 116 (72.5%) studies that failed to provide their educational materials would fail to fulfill the third item on the TIDieR checklist: “Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers” [77]. Such items need to be accurately reported in systematic reviews.

Studies should also ascertain whether patient knowledge was affected by measuring it as an outcome. As multimedia PEMs become increasingly digital and more accessible, this review provides a timely reminder that knowledge transfer and implementation science must be intertwined with musculoskeletal research to put research findings into practice.

Determining whether the research is different for a younger, more tech-savvy population is worthwhile. We intend to repeat this review in the pediatric population to determine whether differences exist [74].

Conclusions

Multimedia PEMs are widely used in musculoskeletal health care but are not supplied or sufficiently described, as is expected of reporting in other musculoskeletal assessments or interventions in terms of appraisability or reproducibility. The expansion of digital PEMs has not addressed this issue. Patient education requires higher reporting standards so that its prescription can be better replicated, which means that multimedia PEMs must be retrievable for evaluation. While no studies in our small sample appear to fully optimize the design of their multimedia PEMs, there was a particular gap in trying to design materials that conform to the generative activity, modality, coherence, and redundancy principles of the CTML, but this could change if 27.5% (44/160) of studies on multimedia PEMs could provide their actual materials. Knowledge transfer and retention must be better assessed to better explore the mechanisms of patient education. These findings must be heeded to improve the delivery of education for patients musculoskeletal and create both better research and better clinical adoption in the face of competing interests from misinformation that exists within musculoskeletal health care.

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Authors' Contributions

GVO and CD contributed to conceptualization and methodology. GVO, AP, CD, KM, and KB contributed to investigation, data curation, and visualization. Formal analysis was performed by all authors. The original draft was written by GVO, AP, CD, KM, and KB, and review and editing were performed by GVO and CD. Project administration was handled by GV, and project supervision was done by CD.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[PDF File (Adobe PDF File), 58 KB - rehab_v11i1e48154_app1.pdf]

Multimedia Appendix 2
Search strategy.
[PDF File (Adobe PDF File), 53 KB - rehab_v11i1e48154_app2.pdf]

Multimedia Appendix 3
Participants' country of origin, summary results, Risk of Bias-2 appraisal, and full reference list of the included studies.
[DOCX File , 130 KB - rehab_v11i1e48154_app3.docx]

References

1. GBD results. Institute for Health Metrics and Evaluation. URL: https://vizhub.healthdata.org/gbd-results/ [accessed 2024-06-29]
2. Cieza A, Causey K, Kamenov K, Hanson SW, Chatterji S, Vos T. Global estimates of the need for rehabilitation based on the Global Burden of Disease study 2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet 2021 Dec 19;396(10267):2006-2017 [FREE Full text] [doi: 10.1016/S0140-6736(20)32340-0] [Medline: 33275908]
3. Briggs AM, Woolf AD, Dreinhöfer K, Homb N, Hoy DG, Kopansky-Giles D, et al. Reducing the global burden of musculoskeletal conditions. Bull World Health Organ 2018 May 01;96(5):366-368 [FREE Full text] [doi: 10.2471/BLT.17.204891] [Medline: 29875522]
4. Liu S, Wang B, Fan S, Wang Y, Zhan Y, Ye D. Global burden of musculoskeletal disorders and attributable factors in 204 countries and territories: a secondary analysis of the Global Burden of Disease 2019 study. BMJ Open 2022 Jun 29;12(6):e062183 [FREE Full text] [doi: 10.1136/bmjopen-2022-062183] [Medline: 35768100]
5. Ernstzen DV, Louw QA, Hillier SL. Clinical practice guidelines for the management of chronic musculoskeletal pain in primary healthcare: a systematic review. Implement Sci 2017 Jan 05;12(1):1 [FREE Full text] [doi: 10.1186/s13012-016-0533-0] [Medline: 28057027]
6. Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, et al. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. Br J Sports Med 2020 Jan;54(2):79-86. [doi: 10.1136/bjsports-2018-099878] [Medline: 30826805]
7. Lewis JS, Stokes EK, Gojanovic B, Gellatly P, Mbada C, Sharma S, et al. Reframing how we care for people with persistent non-traumatic musculoskeletal pain. Suggestions for the rehabilitation community. Physiotherapy 2021 Sep;112:143-149. [doi: 10.1016/j.physio.2021.04.002] [Medline: 34102533]
8. Gruman J, Rovner MH, French ME, Jeffress D, Sofaer S, Shaller D, et al. From patient education to patient engagement: implications for the field of patient education. Patient Educ Couns 2010 Mar;78(3):350-356. [doi: 10.1016/j.pec.2010.02.002] [Medline: 20202780]
9. Hoving C, Visser A, Mullen PD, van den Borne B. A history of patient education by health professionals in Europe and North America: from authority to shared decision making education. Patient Educ Couns 2010 Mar;78(3):275-281. [doi: 10.1016/j.pec.2010.01.015] [Medline: 20189746]
10. Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, et al. OARSI recommendations for the management of hip and knee osteoarthritis, part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage 2008 Feb;16(2):137-162 [FREE Full text] [doi: 10.1016/j.joca.2007.12.013] [Medline: 18279766]
11. Bannuru RR, Osani MC, Vaysbrot EE, Arden NK, Bennell K, Bierma-Zeinstra SM, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. Osteoarthritis Cartilage 2019 Nov;27(11):1578-1589 [FREE Full text] [doi: 10.1016/j.joca.2019.06.011] [Medline: 31278997]
12. Fernandes L, Storheim K, Sandvik L, Nordsletten L, Risberg MA. Efficacy of patient education and supervised exercise vs patient education alone in patients with hip osteoarthritis: a single blind randomized clinical trial. Osteoarthritis Cartilage 2010 Oct;18(10):1237-1243 [FREE Full text] [doi: 10.1016/j.joca.2010.05.015] [Medline: 20633669]
13. Morrissey D, Cotchett M, Said J'Bari A, Prior T, Griffiths IB, Rathleff MS, et al. Management of plantar heel pain: a best practice guide informed by a systematic review, expert clinical reasoning and patient values. Br J Sports Med 2021 Oct;55(19):1106-1118 [FREE Full text] [doi: 10.1136/bjsports-2019-101970] [Medline: 33785535]
14. Collins NJ, Barton CJ, van Middelkoop M, Callaghan MJ, Rathleff MS, Vicenzino BT, et al. 2018 Consensus statement on exercise therapy and physical interventions (orthoses, taping and manual therapy) to treat patellofemoral pain: recommendations from the 5th International Patellofemoral Pain Research Retreat, Gold Coast, Australia, 2017. Br J Sports Med 2018 Sep;52(18):1170-1178 [FREE Full text] [doi: 10.1136/bjsports-2018-099397] [Medline: 29925502]

15. Willy RW, Hoglund LT, Barton CJ, Bolgla LA, Scalzitti DA, Logerstedt DS, et al. Patellofemoral pain. J Orthop Sports Phys Ther 2019 Sep;49(9):CPG1-CP95. [doi: 10.2519/jospt.2019.0302] [Medline: 31475628]
16. Barrett E, Larkin L, Caulfield S, de Burca N, Flanagan A, Gilsenan C, et al. Physical therapy management of nontraumatic shoulder problems lacks high-quality clinical practice guidelines: a systematic review with quality assessment using the AGREE II checklist. J Orthop Sports Phys Ther 2021 Feb;51(2):63-71. [doi: 10.2519/jospt.2021.9397] [Medline: 33356772]
17. Doiron-Cadrin P, Lafrance S, Saulnier M, Cournoyer É, Roy JS, Dyer JO, et al. Shoulder rotator cuff disorders: a systematic review of clinical practice guidelines and semantic analyses of recommendations. Arch Phys Med Rehabil 2020 Jul;101(7):1233-1242. [doi: 10.1016/j.apmr.2019.12.017] [Medline: 32007452]
18. Coombes BK, Bisset L, Vicenzino B. Management of lateral elbow tendinopathy: one size does not fit all. J Orthop Sports Phys Ther 2015 Nov;45(11):938-949. [doi: 10.2519/jospt.2015.5841] [Medline: 26381484]
19. Day JM, Lucado AM, Uhl TL. A comprehensive rehabilitation program for treating lateral elbow tendinopathy. Int J Sports Phys Ther 2019 Sep;14(5):818-829 [FREE Full text] [Medline: 31598419]
20. Martin RL, Cibulka MT, Bolgla LA, Koc TAJ, Loudon JK, Manske RC, et al. Hamstring strain injury in athletes. J Orthop Sports Phys Ther 2022 Mar;52(3):CPG1-CP44. [doi: 10.2519/jospt.2022.0301] [Medline: 35164536]
21. Weir A, Brukner P, Delahunt E, Ekstrand J, Griffin D, Khan KM, et al. Doha agreement meeting on terminology and definitions in groin pain in athletes. Br J Sports Med 2015 Jun;49(12):768-774 [FREE Full text] [doi: 10.1136/bjsports-2015-094869] [Medline: 26031643]
22. Mayer RE. Multimedia Learning, Third Edition. Cambridge, UK: Cambridge University Press; 2020.
23. Nijs J, Meeus M, Cagnie B, Roussel NA, Dolphens M, Van Oosterwijck J, et al. A modern neuroscience approach to chronic spinal pain: combining pain neuroscience education with cognition-targeted motor control training. Phys Ther 2014 May;94(5):730-738. [doi: 10.2522/ptj.20130258] [Medline: 24481595]
24. Enzenhofer M, Bludau HB, Komm N, Wild B, Mueller K, Herzog W, et al. Improvement of the educational process by computer-based visualization of procedures: randomized controlled trial. J Med Internet Res 2004 Jun 02;6(2):e16 [FREE Full text] [doi: 10.2196/jmir.6.2.e16] [Medline: 15249265]
25. Tom K, Phang PT. Effectiveness of the video medium to supplement preoperative patient education: a systematic review of the literature. Patient Educ Couns 2022 Jul;105(7):1878-1887. [doi: 10.1016/j.pec.2022.01.013] [Medline: 35101307]
26. Sharma S, Traeger AC, Mishra SR, Sharma S, Maher CG. Delivering the right care to people with low back pain in low- and middle-income countries: the case of Nepal. J Glob Health 2019 Jun;9(1):010304 [FREE Full text] [doi: 10.7189/jogh.09.010304] [Medline: 30774940]
27. Sharma S, Blyth FM, Mishra SR, Briggs AM. Health system strengthening is needed to respond to the burden of pain in low- and middle-income countries and to support healthy ageing. J Glob Health 2019 Dec;9(2):020317 [FREE Full text] [doi: 10.7189/jogh.09.020317] [Medline: 33274068]
28. Deegan O, Fullen BM, Casey MB, Segurado R, Hearty C, Doody C. Mindfulness combined with exercise online (MOVE) compared with a self-management guide for adults with chronic pain: a feasibility randomized controlled trial. Clin J Pain 2023 Aug 01;39(8):394-407. [doi: 10.1097/AJP.0000000000001126] [Medline: 37140219]
29. Hauser-Ulrich S, Künzli H, Meier-Peterhans D, Kowatsch T. A smartphone-based health care chatbot to promote self-management of chronic pain (SELMA): pilot randomized controlled trial. JMIR Mhealth Uhealth 2020 Apr 03;8(4):e15806 [FREE Full text] [doi: 10.2196/15806] [Medline: 32242820]
30. O'Keeffe M, O'Sullivan P, Purtill H, Bargary N, O'Sullivan K. Cognitive functional therapy compared with a group-based exercise and education intervention for chronic low back pain: a multicentre randomised controlled trial (RCT). Br J Sports Med 2020 Jul;54(13):782-789 [FREE Full text] [doi: 10.1136/bjsports-2019-100780] [Medline: 31630089]
31. Eccleston C, Blyth FM, Dear BF, Fisher EA, Keefe FJ, Lynch ME, et al. Managing patients with chronic pain during the COVID-19 outbreak: considerations for the rapid introduction of remotely supported (eHealth) pain management services. Pain 2020 May;161(5):889-893 [FREE Full text] [doi: 10.1097/j.pain.0000000000001885] [Medline: 32251203]
32. Garcia LM, Birckhead BJ, Krishnamurthy P, Sackman J, Mackey IG, Louis RG, et al. An 8-week self-administered at-home behavioral skills-based virtual reality program for chronic low back pain: double-blind, randomized, placebo-controlled trial conducted during COVID-19. J Med Internet Res 2021 Feb 22;23(2):e26292 [FREE Full text] [doi: 10.2196/26292] [Medline: 33484240]
33. Martorella G, Boitor M, Berube M, Fredericks S, Le May S, Gélinas C. Tailored web-based interventions for pain: systematic review and meta-analysis. J Med Internet Res 2017 Nov 10;19(11):e385 [FREE Full text] [doi: 10.2196/jmir.8826] [Medline: 29127076]
34. Lin J, Faust B, Ebert DD, Krämer L, Baumeister H. A web-based acceptance-facilitating intervention for identifying patients' acceptance, uptake, and adherence of internet- and mobile-based pain interventions: randomized controlled trial. J Med Internet Res 2018 Aug 21;20(8):e244 [FREE Full text] [doi: 10.2196/jmir.9925] [Medline: 30131313]
35. Büttner F, Ardern CL, Blazey P, Dastouri S, McKay HA, Moher D, et al. Counting publications and citations is not just irrelevant: it is an incentive that subverts the impact of clinical research. Br J Sports Med 2021 Jun;55(12):647-648 [FREE Full text] [doi: 10.1136/bjsports-2020-103146] [Medline: 33361277]
36. Mayer RE. The Cambridge Handbook of Multimedia Learning. Cambridge, MA: Cambridge University Press; 2005.

37. Ahmadzadeh K, Bahrami M, Zare-Farashbandi F, Adibi P, Boroumand MA, Rahimi A. Patient education information material assessment criteria: a scoping review. Health Info Libr J 2023 Mar;40(1):3-28. [doi: 10.1111/hir.12467] [Medline: 36637218]
38. Mbanda N, Dada S, Bastable K, Ingalill GB, Ralf WS. A scoping review of the use of visual aids in health education materials for persons with low-literacy levels. Patient Educ Couns 2021 May;104(5):998-1017. [doi: 10.1016/j.pec.2020.11.034] [Medline: 33339657]
39. Shoemaker SJ, Wolf MS, Brach C. Development of the Patient Education Materials Assessment Tool (PEMAT): a new measure of understandability and actionability for print and audiovisual patient information. Patient Educ Couns 2014 Sep;96(3):395-403 [FREE Full text] [doi: 10.1016/j.pec.2014.05.027] [Medline: 24973195]
40. Ferguson I, Phillips AW, Lin M. Continuing medical education speakers with high evaluation scores use more image-based slides. West J Emerg Med 2017 Jan;18(1):152-158 [FREE Full text] [doi: 10.5811/westjem.2016.10.31484] [Medline: 28116029]
41. Grech V. The application of the Mayer multimedia learning theory to medical PowerPoint slide show presentations. J Vis Commun Med 2018 Jan 30;41(1):36-41. [doi: 10.1080/17453054.2017.1408400] [Medline: 29381105]
42. Iorio-Morin C, Brisebois S, Becotte A, Mior F. Improving the pedagogical effectiveness of medical videos. J Vis Commun Med 2017 Jul;40(3):96-100. [doi: 10.1080/17453054.2017.1366826] [Medline: 28925762]
43. Wyatt TH, Krauskopf PB, Gaylord NM, Ward A, Huffstutler-Hawkins S, Goodwin L. Cooperative m-learning with nurse practitioner students. Nurs Educ Perspect 2010;31(2):109-113. [Medline: 20455369]
44. Sait S, Tombs M. Teaching medical students how to interpret chest X-rays: the design and development of an e-learning resource. Adv Med Educ Pract 2021 Feb 5;12:123-132 [FREE Full text] [doi: 10.2147/AMEP.S280941] [Medline: 33574725]
45. Nagmoti JM. Departing from PowerPoint default mode: applying Mayer's multimedia principles for enhanced learning of parasitology. Indian J Med Microbiol 2017;35(2):199-203 [FREE Full text] [doi: 10.4103/ijmm.IJMM_16_251] [Medline: 28681806]
46. Issa N, Mayer RE, Schuller M, Wang E, Shapiro MB, DaRosa DA. Teaching for understanding in medical classrooms using multimedia design principles. Med Educ 2013 Apr;47(4):388-396. [doi: 10.1111/medu.12127] [Medline: 23488758]
47. Dash S, Kamath U, Rao G, Prakash J, Mishra S. Audio-visual aid in teaching "fatty liver". Biochem Mol Biol Educ 2016 May 06;44(3):241-245 [FREE Full text] [doi: 10.1002/bmb.20935] [Medline: 26625860]
48. Kayler LK, Dolph B, Seibert R, Keller M, Cadzow R, Feeley TH. Development of the living donation and kidney transplantation information made easy (KidneyTIME) educational animations. Clin Transplant 2020 Apr;34(4):e13830. [doi: 10.1111/ctr.13830] [Medline: 32072670]
49. Javaid MA, Schellekens H, Cryan JF, Toulouse A. eNEUROANAT-CF: a conceptual instructional design framework for neuroanatomy e-learning tools. Med Sci Educ 2021 Apr;31(2):777-785 [FREE Full text] [doi: 10.1007/s40670-020-01149-y] [Medline: 34457925]
50. Issa N, Schuller M, Santacaterina S, Shapiro M, Wang E, Mayer RE, et al. Applying multimedia design principles enhances learning in medical education. Med Educ 2011 Aug;45(8):818-826. [doi: 10.1111/j.1365-2923.2011.03988.x] [Medline: 21752078]
51. Abujarad F, Peduzzi P, Mun S, Carlson K, Edwards C, Dziura J, et al. Comparing a multimedia digital informed consent tool with traditional paper-based methods: randomized controlled trial. JMIR Form Res 2021 Oct 19;5(10):e20458 [FREE Full text] [doi: 10.2196/20458] [Medline: 34665142]
52. Athilingam P, Osorio RE, Kaplan H, Oliver D, O'neachtain T, Rogal PJ. Embedding patient education in mobile platform for patients with heart failure: theory-based development and beta testing. Comput Inform Nurs 2016 Feb;34(2):92-98. [doi: 10.1097/CIN.0000000000000216] [Medline: 26765655]
53. Choi J. Development and pilot test of pictograph-enhanced breast health-care instructions for community-residing immigrant women. Int J Nurs Pract 2012 Aug;18(4):373-378. [doi: 10.1111/j.1440-172X.2012.02051.x] [Medline: 22845637]
54. Maia LB, Silva JP, Souza MB, Henschke N, Oliveira VC. Popular videos related to low back pain on YouTube™ do not reflect current clinical guidelines: a cross-sectional study. Braz J Phys Ther 2021;25(6):803-810 [FREE Full text] [doi: 10.1016/j.bjpt.2021.06.009] [Medline: 34332887]
55. Guo PJ, Kim J, Rubin R. How video production affects student engagement: an empirical study of MOOC videos. In: Proceedings of the First ACM Conference on Learning @ Scale Conference. 2014 Presented at: L@S '14; March 4-5, 2014; Atlanta, GA. [doi: 10.1145/2556325.2566239]
56. Lynch AD, Bove AM, Ammendolia C, Schneider M. Individuals with lumbar spinal stenosis seek education and care focused on self-management-results of focus groups among participants enrolled in a randomized controlled trial. Spine J 2018 Aug;18(8):1303-1312. [doi: 10.1016/j.spinee.2017.11.019] [Medline: 29246847]
57. Gavali MY, Khismatrao DS, Gavali YV, Patil KB. Smartphone, the new learning aid amongst medical students. J Clin Diagn Res 2017 May;11(5):JC05-JC08 [FREE Full text] [doi: 10.7860/JCDR/2017/20948.9826] [Medline: 28658804]
58. Hochlehnert A, Richter A, Bludau HB, Bieber C, Blumenstiel K, Mueller K, et al. A computer-based information-tool for chronic pain patients. Computerized information to support the process of shared decision-making. Patient Educ Couns 2006 Apr;61(1):92-98. [doi: 10.1016/j.pec.2005.02.014] [Medline: 16533681]

59. Larsen ME, Huckvale K, Nicholas J, Torous J, Birrell L, Li E, et al. Using science to sell apps: evaluation of mental health app store quality claims. NPJ Digit Med 2019 Mar 22;2(1):18 [FREE Full text] [doi: 10.1038/s41746-019-0093-1] [Medline: 31304366]
60. Chou WY, Oh A, Klein WM. Addressing health-related misinformation on social media. JAMA 2018 Dec 18;320(23):2417-2418. [doi: 10.1001/jama.2018.16865] [Medline: 30428002]
61. Haidar LA, Kortlever JT, Ring D. Misinformation in news coverage of professional and college athlete musculoskeletal ailments. Arch Bone Jt Surg 2020 Jan;8(1):33-37 [FREE Full text] [doi: 10.22038/abjs.2019.34844.1916] [Medline: 32090143]
62. Kingery MT, Schoof L, Strauss EJ, Bosco JA, Halbrecht J. Online direct-to-consumer advertising of stem cell therapy for musculoskeletal injury and disease: misinformation and violation of ethical and legal advertising parameters. J Bone Joint Surg Am 2020 Jan 02;102(1):2-9. [doi: 10.2106/JBJS.19.00714] [Medline: 31770294]
63. Smith C, Martin-Lillie C, Higano JD, Turner L, Phu S, Arthurs J, et al. Challenging misinformation and engaging patients: characterizing a regenerative medicine consult service. Regen Med 2020 Mar;15(3):1427-1440 [FREE Full text] [doi: 10.2217/rme-2020-0018] [Medline: 32319855]
64. Zheluk A, Anderson J, Dineen-Griffin S. Analysis of acute non-specific back pain content on TikTok: an exploratory study. Cureus 2022 Jan;14(1):e21404 [FREE Full text] [doi: 10.7759/cureus.21404] [Medline: 35198311]
65. Barton CJ, Holden S, Rathleff MS. Patient education on patellofemoral pain. JAMA 2018 Jun 12;319(22):2338. [doi: 10.1001/jama.2018.4458] [Medline: 29896622]
66. Furlong B, Etchegary H, Aubrey-Bassler K, Swab M, Pike A, Hall A. Patient education materials for non-specific low back pain and sciatica: a systematic review and meta-analysis. PLoS One 2022;17(10):e0274527 [FREE Full text] [doi: 10.1371/journal.pone.0274527] [Medline: 36223377]
67. Gordon WJ, Landman A, Zhang H, Bates DW. Beyond validation: getting health apps into clinical practice. NPJ Digit Med 2020;3:14 [FREE Full text] [doi: 10.1038/s41746-019-0212-z] [Medline: 32047860]
68. Hernandez-Sanchez S, Moreno-Perez V, Garcia-Campos J, Marco-Lledó J, Navarrete-Muñoz EM, Lozano-Quijada C. Twelve tips to make successful medical infographics. Med Teach 2020 Dec 20;43(12):1353-1359. [doi: 10.1080/0142159x.2020.1855323]
69. Scott H, Fawkner S, Oliver CW, Murray A. How to make an engaging infographic? Br J Sports Med 2017 Aug 30;51(16):1183-1184. [doi: 10.1136/bjsports-2016-097023] [Medline: 28039124]
70. Scott H, Fawkner S, Oliver C, Murray A. Why healthcare professionals should know a little about infographics. Br J Sports Med 2016 Sep 17;50(18):1104-1105. [doi: 10.1136/bjsports-2016-096133] [Medline: 27317791]
71. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021 Mar 29;372:n71 [FREE Full text] [doi: 10.1136/bmj.n71] [Medline: 33782057]
72. Ardern CL, Büttner F, Andrade R, Weir A, Ashe MC, Holden S, et al. Implementing the 27 PRISMA 2020 statement items for systematic reviews in the sport and exercise medicine, musculoskeletal rehabilitation and sports science fields: the PERSiST (implementing Prisma in Exercise, Rehabilitation, Sport medicine and SporTs science) guidance. Br J Sports Med 2022 Feb;56(4):175-195 [FREE Full text] [doi: 10.1136/bjsports-2021-103987] [Medline: 34625401]
73. Musculoskeletal health. World Health Organisation. 2022 Jul 14. URL: https://www.who.int/news-room/fact-sheets/detail/musculoskeletal-conditions [accessed 2024-08-27]
74. Van Oirschot G, Pomphrey A, Dunne C, Murphy K, Blood K, Doherty C. An evaluation of patient educational multimedia design in musculoskeletal healthcare: a systematic review. JMIR Rehabil Assist Technol 2024 Aug 20 (forthcoming) [FREE Full text] [doi: 10.2196/48154] [Medline: 39162239]
75. Covidence systematic review software. Veritas Health Innovation. URL: https://www.covidence.org/ [accessed 2024-08-27]
76. Sterne JA, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ 2019 Aug 28;366:l4898 [FREE Full text] [doi: 10.1136/bmj.l4898] [Medline: 31462531]
77. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014 Mar 07;348:g1687 [FREE Full text] [doi: 10.1136/bmj.g1687] [Medline: 24609605]
78. World Bank country and lending groups. The World Bank. URL: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups [accessed 2022-08-08]
79. Bandak E, Christensen R, Overgaard A, Kristensen LE, Ellegaard K, Guldberg-Møller J, et al. Exercise and education versus saline injections for knee osteoarthritis: a randomised controlled equivalence trial. Ann Rheum Dis 2022 Apr;81(4):537-543. [doi: 10.1136/annrheumdis-2021-221129] [Medline: 34844929]
80. Baumeister H, Seifferth H, Lin J, Nowoczin L, Lüking M, Ebert D. Impact of an acceptance facilitating intervention on patients' acceptance of internet-based pain interventions: a randomized controlled trial. Clin J Pain 2015 Jun;31(6):528-535. [doi: 10.1097/AJP.0000000000000118] [Medline: 24866854]
81. Bennell KL, Nelligan R, Dobson F, Rini C, Keefe F, Kasza J, et al. Effectiveness of an internet-delivered exercise and pain-coping skills training intervention for persons with chronic knee pain: a randomized trial. Ann Intern Med 2017 Apr 04;166(7):453-462. [doi: 10.7326/M16-1714] [Medline: 28241215]

82. Berberoğlu U, Ülger Ö. Multimedia instructions for motor control exercises in patients with chronic nonspecific low back pain. J Sport Rehabil 2023 May 01;32(4):424-432. [doi: 10.1123/jsr.2022-0158] [Medline: 36848900]
83. Bostrøm K, Børøsund E, Eide H, Varsi C, Kristjansdottir Ó, Schreurs KM, et al. Short-term findings from testing EPIO, a digital self-management program for people living with chronic pain: randomized controlled trial. J Med Internet Res 2023 Aug 25;25:e47284 [FREE Full text] [doi: 10.2196/47284] [Medline: 37624622]
84. Chenot JF, Pfingsten M, Marnitz U, Pfeifer K, Kohlmann T, Lindena G, et al. [Effectiveness of a risk-tailored short intervention to prevent chronic low back pain: a cluster-randomized study in general practice]. Schmerz 2019 Jun;33(3):226-235. [doi: 10.1007/s00482-019-0362-6] [Medline: 30796580]
85. Chimenti RL, Post AA, Rio EK, Moseley GL, Dao M, Mosby H, et al. The effects of pain science education plus exercise on pain and function in chronic Achilles tendinopathy: a blinded, placebo-controlled, explanatory, randomized trial. Pain 2023 Jan 01;164(1):e47-e65 [FREE Full text] [doi: 10.1097/j.pain.0000000000002720] [Medline: 36095045]
86. Coudeyre E, Givron P, Vanbiervliet W, Benaïm C, Hérisson C, Pelissier J, et al. [The role of an information booklet or oral information about back pain in reducing disability and fear-avoidance beliefs among patients with subacute and chronic low back pain. A randomized controlled trial in a rehabilitation unit]. Ann Readapt Med Phys 2006 Nov;49(8):600-608. [doi: 10.1016/j.annrmp.2006.05.003] [Medline: 16793163]
87. Coudeyre E, Tubach F, Rannou F, Baron G, Coriat F, Brin S, et al. Effect of a simple information booklet on pain persistence after an acute episode of low back pain: a non-randomized trial in a primary care setting. PLoS One 2007 Aug 08;2(8):e706 [FREE Full text] [doi: 10.1371/journal.pone.0000706] [Medline: 17684553]
88. Cramer H, Lauche R, Hohmann C, Lüdtke R, Haller H, Michalsen A, et al. Randomized-controlled trial comparing yoga and home-based exercise for chronic neck pain. Clin J Pain 2013 Mar;29(3):216-223. [doi: 10.1097/AJP.0b013e318251026c] [Medline: 23249655]
89. Diab R, Bomar R, Slaven J, Kaplan S, Ang D. Nurse-supported web-based cognitive behavioral therapy for chronic musculoskeletal pain: a randomized controlled trial. Pain Physician 2022 Oct;25(7):E959-E968 [FREE Full text] [Medline: 36288581]
90. Dobscha SK, Corson K, Leibowitz RQ, Sullivan MD, Gerrity MS. Rationale, design, and baseline findings from a randomized trial of collaborative care for chronic musculoskeletal pain in primary care. Pain Med 2008 Nov;9(8):1050-1064. [doi: 10.1111/j.1526-4637.2008.00457.x] [Medline: 18565008]
91. Gardner T, Refshauge K, McAuley J, Hübscher M, Goodall S, Smith L. Combined education and patient-led goal setting intervention reduced chronic low back pain disability and intensity at 12 months: a randomised controlled trial. Br J Sports Med 2019 Nov;53(22):1424-1431. [doi: 10.1136/bjsports-2018-100080] [Medline: 30808666]
92. George SZ, Teyhen DS, Wu SS, Wright AC, Dugan JL, Yang G, et al. Psychosocial education improves low back pain beliefs: results from a cluster randomized clinical trial (NCT00373009) in a primary prevention setting. Eur Spine J 2009 Jul;18(7):1050-1058 [FREE Full text] [doi: 10.1007/s00586-009-1016-7] [Medline: 19418075]
93. Gibbs MT, Morrison NM, Raftry S, Jones MD, Marshall PW. Does a powerlifting inspired exercise programme better compliment pain education compared to bodyweight exercise for people with chronic low back pain? A multicentre, single-blind, randomised controlled trial. Clin Rehabil 2022 Sep;36(9):1199-1213. [doi: 10.1177/02692155221095484] [Medline: 35466696]
94. Hrkać A, Bilić D, Černy-Obrdalj E, Baketarić I, Puljak L. Comparison of supervised exercise therapy with or without biopsychosocial approach for chronic nonspecific low back pain: a randomized controlled trial. BMC Musculoskelet Disord 2022 Nov 08;23(1):966 [FREE Full text] [doi: 10.1186/s12891-022-05908-3] [Medline: 36348309]
95. Ibrahim AA, Akindele MO, Ganiyu SO. Effectiveness of patient education plus motor control exercise versus patient education alone versus motor control exercise alone for rural community-dwelling adults with chronic low back pain: a randomised clinical trial. BMC Musculoskelet Disord 2023 Feb 23;24(1):142. [doi: 10.1186/s12891-022-06108-9] [Medline: 36823567]
96. Janevic M, Robinson-Lane SG, Courser R, Brines E, Hassett AL. A community health worker-led positive psychology intervention for African American older adults with chronic pain. Gerontologist 2022 Oct 19;62(9):1369-1380 [FREE Full text] [doi: 10.1093/geront/gnac010] [Medline: 35394525]
97. Jinnouchi H, Kitamura A, Matsudaira K, Kakihana H, Oka H, Yamagishi K, et al. Brief self-exercise education for adults with chronic knee pain: a randomized controlled trial. Mod Rheumatol 2023 Mar 02;33(2):408-415. [doi: 10.1093/mr/roac009] [Medline: 35134993]
98. Kohns DJ, Urbanik CP, Geisser ME, Schubiner H, Lumley MA. The effects of a pain psychology and neuroscience self-evaluation internet intervention: a randomized controlled trial. Clin J Pain 2020 Sep;36(9):683-692. [doi: 10.1097/AJP.0000000000000857] [Medline: 32520816]
99. Lamb SE, Hansen Z, Lall R, Castelnuovo E, Withers EJ, Nichols V, et al. Group cognitive behavioural treatment for low-back pain in primary care: a randomised controlled trial and cost-effectiveness analysis. Lancet 2010 Mar 13;375(9718):916-923. [doi: 10.1016/S0140-6736(09)62164-4] [Medline: 20189241]
100. Meeus M, Nijs J, Van Oosterwijck J, Van Alsenoy V, Truijen S. Pain physiology education improves pain beliefs in patients with chronic fatigue syndrome compared with pacing and self-management education: a double-blind randomized controlled trial. Arch Phys Med Rehabil 2010 Aug;91(8):1153-1159. [doi: 10.1016/j.apmr.2010.04.020] [Medline: 20684894]

101. Mukhtar NB, Meeus M, Gursen C, Mohammed J, De Pauw R, Cagnie B. Pilot study on the effects of a culturally-sensitive and standard pain neuroscience education for Hausa-speaking patients with chronic neck pain. Disabil Rehabil 2022 Nov;44(23):7226-7236. [doi: 10.1080/09638288.2021.1988155] [Medline: 34663135]
102. Pacella-LaBarbara ML, Suffoletto BP, Kuhn E, Germain A, Jaramillo S, Repine M, et al. A pilot randomized controlled trial of the PTSD coach app following motor vehicle crash-related injury. Acad Emerg Med 2020 Nov;27(11):1126-1139 [FREE Full text] [doi: 10.1111/acem.14000] [Medline: 32339359]
103. Roseen EJ, Pinheiro A, Lemaster CM, Plumb D, Wang S, Elwy AR, et al. Yoga versus education for veterans with chronic low back pain: a randomized controlled trial. J Gen Intern Med 2023 Jul;38(9):2113-2122 [FREE Full text] [doi: 10.1007/s11606-023-08037-2] [Medline: 36650329]
104. Sandhu HK, Booth K, Furlan AD, Shaw J, Carnes D, Taylor SJ, et al. Reducing opioid use for chronic pain with a group-based intervention: a randomized clinical trial. JAMA 2023 May 23;329(20):1745-1756 [FREE Full text] [doi: 10.1001/jama.2023.6454] [Medline: 37219554]
105. Saper RB, Lemaster C, Delitto A, Sherman KJ, Herman PM, Sadikova E, et al. Yoga, physical therapy, or education for chronic low back pain: a randomized noninferiority trial. Ann Intern Med 2017 Jul 18;167(2):85-94 [FREE Full text] [doi: 10.7326/M16-2579] [Medline: 28631003]
106. Sharpe L, Jones EB, Pradhan P, Todd J, Colagiuri B. A double-blind phase II randomized controlled trial of an online cognitive bias modification for interpretation program with and without psychoeducation for people with chronic pain. Pain 2023 Apr 01;164(4):e217-e227. [doi: 10.1097/j.pain.0000000000002784] [Medline: 36607275]
107. Sherman KJ, Cherkin DC, Erro J, Miglioretti DL, Deyo RA. Comparing yoga, exercise, and a self-care book for chronic low back pain: a randomized, controlled trial. Ann Intern Med 2005 Dec 20;143(12):849-856 [FREE Full text] [doi: 10.7326/0003-4819-143-12-200512200-00003] [Medline: 16365466]
108. Sherman KJ, Cherkin DC, Wellman RD, Cook AJ, Hawkes RJ, Delaney K, et al. A randomized trial comparing yoga, stretching, and a self-care book for chronic low back pain. Arch Intern Med 2011 Dec 12;171(22):2019-2026 [FREE Full text] [doi: 10.1001/archinternmed.2011.524] [Medline: 22025101]
109. Simula AS, Jenkins HJ, Hancock MJ, Malmivaara A, Booth N, Karppinen J. Patient education booklet to support evidence-based low back pain care in primary care - a cluster randomized controlled trial. BMC Fam Pract 2021 Sep 07;22(1):178 [FREE Full text] [doi: 10.1186/s12875-021-01529-2] [Medline: 34493219]
110. Singh S, Clarke C, Lawendy AR, Macleod M, Sanders D, Tieszer C. First Place: a prospective, randomized controlled trial of the impact of written discharge instructions for postoperative opioids on patient pain satisfaction and on minimizing opioid risk exposure in orthopaedic surgery. Curr Orthop Pract 2018 Aug;29(4):292-296. [doi: 10.1097/BCO.0000000000000632]
111. Skou ST, Rasmussen S, Laursen MB, Rathleff MS, Arendt-Nielsen L, Simonsen O, et al. The efficacy of 12 weeks non-surgical treatment for patients not eligible for total knee replacement: a randomized controlled trial with 1-year follow-up. Osteoarthritis Cartilage 2015 Sep;23(9):1465-1475 [FREE Full text] [doi: 10.1016/j.joca.2015.04.021] [Medline: 25937024]
112. Syed UA, Aleem AW, Wowkanech C, Weekes D, Freedman M, Tjoumakaris F, et al. Neer Award 2018: the effect of preoperative education on opioid consumption in patients undergoing arthroscopic rotator cuff repair: a prospective, randomized clinical trial. J Shoulder Elbow Surg 2018 Jun;27(6):962-967. [doi: 10.1016/j.jse.2018.02.039] [Medline: 29599038]
113. Thompson DP, Oldham JA, Woby SR. Does adding cognitive-behavioural physiotherapy to exercise improve outcome in patients with chronic neck pain? A randomised controlled trial. Physiotherapy 2016 Jun;102(2):170-177. [doi: 10.1016/j.physio.2015.04.008] [Medline: 26383695]
114. Thorn BE, Eyer JC, Van Dyke BP, Torres CA, Burns JW, Kim M, et al. Literacy-adapted cognitive behavioral therapy versus education for chronic pain at low-income clinics: a randomized controlled trial. Ann Intern Med 2018 Apr 03;168(7):471-480. [doi: 10.7326/M17-0972] [Medline: 29482213]
115. Traeger AC, Lee H, Hübscher M, Skinner IW, Moseley GL, Nicholas MK, et al. Effect of intensive patient education vs placebo patient education on outcomes in patients with acute low back pain: a randomized clinical trial. JAMA Neurol 2019 Feb 01;76(2):161-169 [FREE Full text] [doi: 10.1001/jamaneurol.2018.3376] [Medline: 30398542]
116. Valiente-Castrillo P, Martín-Pintado-Zugasti A, Calvo-Lobo C, Beltran-Alacreu H, Fernández-Carnero J. Effects of pain neuroscience education and dry needling for the management of patients with chronic myofascial neck pain: a randomized clinical trial. Acupunct Med 2021 Apr;39(2):91-105. [doi: 10.1177/0964528420920300] [Medline: 32370545]
117. Vanti C, Banchelli F, Marino C, Puccetti A, Guccione AA, Pillastrini P. Effectiveness of a "spring pillow" versus education in chronic nonspecific neck pain: a randomized controlled trial. Phys Ther 2019 Sep 01;99(9):1177-1188 [FREE Full text] [doi: 10.1093/ptj/pzz056] [Medline: 30939188]
118. Walsh N, Jones L, Phillips S, Thomas R, Odondi L, Palmer S, et al. Facilitating activity and self-management for people with arthritic knee, hip or lower back pain (FASA): a cluster randomised controlled trial. Musculoskelet Sci Pract 2020 Dec;50:102271. [doi: 10.1016/j.msksp.2020.102271] [Medline: 33068901]
119. Westenberg RF, Zale EL, Heinhuis TJ, Özkan S, Nazzal A, Lee SG, et al. Does a brief mindfulness exercise improve outcomes in upper extremity patients? A randomized controlled trial. Clin Orthop Relat Res 2018 Apr;476(4):790-798 [FREE Full text] [doi: 10.1007/s11999.0000000000000086] [Medline: 29480886]

120. Yuan SL, Couto LA, Marques AP. Effects of a six-week mobile app versus paper book intervention on quality of life, symptoms, and self-care in patients with fibromyalgia: a randomized parallel trial. Braz J Phys Ther 2021 Jul;25(4):428-436 [FREE Full text] [doi: 10.1016/j.bjpt.2020.10.003] [Medline: 33248904]
121. Rini C, Porter LS, Somers TJ, McKee DC, DeVellis RF, Smith M, et al. Automated internet-based pain coping skills training to manage osteoarthritis pain: a randomized controlled trial. Pain 2015 May;156(5):837-848 [FREE Full text] [doi: 10.1097/j.pain.0000000000000121] [Medline: 25734997]
122. Aguirrezabal I, Pérez de San Román MS, Cobos-Campos R, Orruño E, Goicoechea A, Martínez de la Eranueva R, et al. Effectiveness of a primary care-based group educational intervention in the management of patients with migraine: a randomized controlled trial. Prim Health Care Res Dev 2019 Dec 13;20:e155 [FREE Full text] [doi: 10.1017/S1463423619000720] [Medline: 31833464]
123. Alasfour M, Almarwani M. The effect of innovative smartphone application on adherence to a home-based exercise programs for female older adults with knee osteoarthritis in Saudi Arabia: a randomized controlled trial. Disabil Rehabil 2022 Jun 25;44(11):2420-2427. [doi: 10.1080/09638288.2020.1836268] [Medline: 33103499]
124. Albaladejo C, Kovacs FM, Royuela A, del Pino R, Zamora J, Spanish Back Pain Research Network. The efficacy of a short education program and a short physiotherapy program for treating low back pain in primary care: a cluster randomized trial. Spine (Phila Pa 1976) 2010 Mar 01;35(5):483-496. [doi: 10.1097/BRS.0b013e3181b9c9a7] [Medline: 20147875]
125. Almhdawi KA, Obeidat DS, Kanaan SF, Oteir AO, Mansour ZM, Alrabbaei H. Efficacy of an innovative smartphone application for office workers with chronic non-specific low back pain: a pilot randomized controlled trial. Clin Rehabil 2020 Oct;34(10):1282-1291. [doi: 10.1177/0269215520937757] [Medline: 32602362]
126. Amaral DD, Miyamoto GC, Franco KF, Dos Santos Franco YR, Bastos De Oliveira NT, Hancock MJ, et al. Examination of a subgroup of patients with chronic low back pain likely to benefit more from pilates-based exercises compared to an educational booklet. J Orthop Sports Phys Ther 2020 Apr;50(4):189-197. [doi: 10.2519/jospt.2019.8839] [Medline: 31443627]
127. Amer-Cuenca JJ, Pecos-Martín D, Martínez-Merinero P, Lluch Girbés E, Nijs J, Meeus M, et al. How much is needed? Comparison of the effectiveness of different pain education dosages in patients with fibromyalgia. Pain Med 2020 Apr 01;21(4):782-793. [doi: 10.1093/pm/pnz069] [Medline: 31216027]
128. Archer KR, Devin CJ, Vanston SW, Koyama T, Phillips SE, Mathis SL, et al. Cognitive-behavioral-based physical therapy for patients with chronic pain undergoing lumbar spine surgery: a randomized controlled trial. J Pain 2016 Jan;17(1):76-89 [FREE Full text] [doi: 10.1016/j.jpain.2015.09.013] [Medline: 26476267]
129. Areeudomwong P, Wongrat W, Neammesri N, Thongsakul T. A randomized controlled trial on the long-term effects of proprioceptive neuromuscular facilitation training, on pain-related outcomes and back muscle activity, in patients with chronic low back pain. Musculoskeletal Care 2017 Sep;15(3):218-229. [doi: 10.1002/msc.1165] [Medline: 27791345]
130. Ariza-Mateos MJ, Cabrera-Martos I, López-López L, Rodríguez-Torres J, Torres-Sánchez I, Valenza MC. Effects of a patient-centered program including the cumulative-complexity model in women with chronic pelvic pain: a randomized controlled trial. Maturitas 2020 Jul;137:18-23. [doi: 10.1016/j.maturitas.2020.04.005] [Medline: 32498932]
131. Barrenengoa-Cuadra MJ, Muñoa-Capron-Manieux M, Fernández-Luco M, Angón-Puras L, Romón-Gómez AJ, Azkuenaga M, et al. Effectiveness of a structured group intervention based on pain neuroscience education for patients with fibromyalgia in primary care: a multicentre randomized open-label controlled trial. Eur J Pain 2021 May;25(5):1137-1149 [FREE Full text] [doi: 10.1002/ejp.1738] [Medline: 33512028]
132. Baumeister H, Paganini S, Sander LB, Lin J, Schlicker S, Terhorst Y, et al. Effectiveness of a guided internet- and mobile-based intervention for patients with chronic back pain and depression (WARD-BP): a multicenter, pragmatic randomized controlled trial. Psychother Psychosom 2021;90(4):255-268. [doi: 10.1159/000511881] [Medline: 33321501]
133. Beltran-Alacreu H, López-de-Uralde-Villanueva I, Fernández-Carnero J, La Touche R. Manual therapy, therapeutic patient education, and therapeutic exercise, an effective multimodal treatment of nonspecific chronic neck pain: a randomized controlled trial. Am J Phys Med Rehabil 2015 Oct;94(10 Suppl 1):887-897. [doi: 10.1097/PHM.0000000000000293] [Medline: 25888653]
134. Bérubé M, Gélinas C, Feeley N, Martorella G, Côté J, Laflamme GY, et al. Feasibility of a hybrid web-based and in-person self-management intervention aimed at preventing acute to chronic pain transition after major lower extremity trauma (iPACT-E-trauma): a pilot randomized controlled trial. Pain Med 2019 Oct 01;20(10):2018-2032 [FREE Full text] [doi: 10.1093/pm/pnz008] [Medline: 30840085]
135. Bodes Pardo G, Lluch Girbés E, Roussel NA, Gallego Izquierdo T, Jiménez Penick V, Pecos Martín D. Pain neurophysiology education and therapeutic exercise for patients with chronic low back pain: a single-blind randomized controlled trial. Arch Phys Med Rehabil 2018 Feb;99(2):338-347. [doi: 10.1016/j.apmr.2017.10.016] [Medline: 29138049]
136. Bossen D, Veenhof C, Van Beek KE, Spreeuwenberg PM, Dekker J, De Bakker DH. Effectiveness of a web-based physical activity intervention in patients with knee and/or hip osteoarthritis: randomized controlled trial. J Med Internet Res 2013 Nov 22;15(11):e257 [FREE Full text] [doi: 10.2196/jmir.2662] [Medline: 24269911]
137. Braun L, Terhorst Y, Titzler I, Freund J, Thielecke J, Ebert DD, et al. Lessons learned from an attempted pragmatic randomized controlled trial for improvement of chronic pain-associated disability in green professions: long-term effectiveness

of a guided online-based acceptance and commitment therapy (PACT-A). Int J Environ Res Public Health 2022 Oct 25;19(21):13858 [FREE Full text] [doi: 10.3390/ijerph192113858] [Medline: 36360738]
138. Brison RJ, Hartling L, Dostaler S, Leger A, Rowe BH, Stiell I, et al. A randomized controlled trial of an educational intervention to prevent the chronic pain of whiplash associated disorders following rear-end motor vehicle collisions. Spine (Phila Pa 1976) 2005 Aug 15;30(16):1799-1807. [doi: 10.1097/01.brs.0000174115.58954.17] [Medline: 16103847]
139. Burton AK, Waddell G, Tillotson KM, Summerton N. Information and advice to patients with back pain can have a positive effect. A randomized controlled trial of a novel educational booklet in primary care. Spine (Phila Pa 1976) 1999 Dec 01;24(23):2484-2491. [doi: 10.1097/00007632-199912010-00010] [Medline: 10626311]
140. Cherkin DC, Eisenberg D, Sherman KJ, Barlow W, Kaptchuk TJ, Street J, et al. Randomized trial comparing traditional Chinese medical acupuncture, therapeutic massage, and self-care education for chronic low back pain. Arch Intern Med 2001 Apr 23;161(8):1081-1088. [doi: 10.1001/archinte.161.8.1081] [Medline: 11322842]
141. Cuesta-Vargas AI, García-Romero JC, Arroyo-Morales M, Diego-Acosta AM, Daly DJ. Exercise, manual therapy, and education with or without high-intensity deep-water running for nonspecific chronic low back pain: a pragmatic randomized controlled trial. Am J Phys Med Rehabil 2011 Jul;90(7):526-34; quiz 535. [doi: 10.1097/PHM.0b013e31821a71d0] [Medline: 21765272]
142. da Silva FS, de Melo FE, do Amaral MM, Caldas VV, Pinheiro Í, Abreu BJ, et al. Efficacy of simple integrated group rehabilitation program for patients with knee osteoarthritis: single-blind randomized controlled trial. J Rehabil Res Dev 2015;52(3):309-322. [doi: 10.1682/jrrd.2014.08.0199]
143. Darnall BD, Krishnamurthy P, Tsuei J, Minor JD. Self-administered skills-based virtual reality intervention for chronic pain: randomized controlled pilot study. JMIR Form Res 2020 Jul 07;4(7):e17293 [FREE Full text] [doi: 10.2196/17293] [Medline: 32374272]
144. Davis MC, Zautra AJ. An online mindfulness intervention targeting socioemotional regulation in fibromyalgia: results of a randomized controlled trial. Ann Behav Med 2013 Dec;46(3):273-284. [doi: 10.1007/s12160-013-9513-7] [Medline: 23670111]
145. de Boer MJ, Versteegen GJ, Vermeulen KM, Sanderman R, Struys MM. A randomized controlled trial of an Internet-based cognitive-behavioural intervention for non-specific chronic pain: an effectiveness and cost-effectiveness study. Eur J Pain 2014 Nov;18(10):1440-1451. [doi: 10.1002/ejp.509] [Medline: 24777973]
146. Derebery J, Giang GM, Gatchel RJ, Erickson K, Fogarty TW. Efficacy of a patient-educational booklet for neck-pain patients with workers' compensation: a randomized controlled trial. Spine (Phila Pa 1976) 2009 Jan 15;34(2):206-213. [doi: 10.1097/BRS.0b013e318193c9eb] [Medline: 19139673]
147. DiGiovanni BF, Nawoczenski DA, Lintal ME, Moore EA, Murray JC, Wilding GE, et al. Tissue-specific plantar fascia-stretching exercise enhances outcomes in patients with chronic heel pain. A prospective, randomized study. J Bone Joint Surg Am 2003 Jul;85(7):1270-1277. [doi: 10.2106/00004623-200307000-00013] [Medline: 12851352]
148. Doering S, Katzlberger F, Rumpold G, Roessler S, Hofstoetter B, Schatz DS, et al. Videotape preparation of patients before hip replacement surgery reduces stress. Psychosom Med 2000;62(3):365-373. [doi: 10.1097/00006842-200005000-00010] [Medline: 10845350]
149. Dowd H, Hogan MJ, McGuire BE, Davis MC, Sarma KM, Fish RA, et al. Comparison of an online mindfulness-based cognitive therapy intervention with online pain management psychoeducation: a randomized controlled study. Clin J Pain 2015 Jun;31(6):517-527. [doi: 10.1097/AJP.0000000000000201] [Medline: 25565584]
150. Fioratti I, Miyamoto GC, Fandim JV, Ribeiro CP, Batista GD, Freitas GE, et al. Feasibility, usability, and implementation context of an internet-based pain education and exercise program for chronic musculoskeletal pain: pilot trial of the ReabilitaDOR program. JMIR Form Res 2022 Aug 30;6(8):e35743 [FREE Full text] [doi: 10.2196/35743] [Medline: 35776863]
151. Frost H, Klaber Moffett JA, Moser JS, Fairbank JC. Randomised controlled trial for evaluation of fitness programme for patients with chronic low back pain. BMJ 1995 Jan 21;310(6973):151-154 [FREE Full text] [doi: 10.1136/bmj.310.6973.151] [Medline: 7833752]
152. Galan-Martin MA, Montero-Cuadrado F, Lluch-Girbes E, Coca-López MC, Mayo-Iscar A, Cuesta-Vargas A. Pain neuroscience education and physical therapeutic exercise for patients with chronic spinal pain in Spanish physiotherapy primary care: a pragmatic randomized controlled trial. J Clin Med 2020 Apr 22;9(4):1201 [FREE Full text] [doi: 10.3390/jcm9041201] [Medline: 32331323]
153. Garcia-Palacios A, Herrero R, Vizcaíno Y, Belmonte MA, Castilla D, Molinari G, et al. Integrating virtual reality with activity management for the treatment of fibromyalgia: acceptability and preliminary efficacy. Clin J Pain 2015 Jun;31(6):564-572. [doi: 10.1097/AJP.0000000000000196] [Medline: 25551475]
154. Gasslander N, Andersson G, Boström F, Brandelius L, Pelling L, Hamrin L, et al. Tailored internet-based cognitive behavioral therapy for individuals with chronic pain and comorbid psychological distress: a randomized controlled trial. Cogn Behav Ther 2022 Sep;51(5):408-434 [FREE Full text] [doi: 10.1080/16506073.2022.2065528] [Medline: 35533363]
155. Giro G, Policastro VB, Scavassin PM, Leite AR, Mendoza Marin DO, de Godoi Gonçalves DA, et al. Mandibular kinesiographic pattern of women with chronic TMD after management with educational and self-care therapies: a

double-blind, randomized clinical trial. J Prosthet Dent 2016 Nov;116(5):749-755. [doi: 10.1016/j.prosdent.2016.03.021] [Medline: 27236596]
156. Grande-Alonso M, Suso-Martí L, Cuenca-Martínez F, Pardo-Montero J, Gil-Martínez A, La Touche R. Physiotherapy based on a biobehavioral approach with or without orthopedic manual physical therapy in the treatment of nonspecific chronic low back pain: a randomized controlled trial. Pain Med 2019 Dec 01;20(12):2571-2587. [doi: 10.1093/pm/pnz093] [Medline: 31074484]
157. Groenveld TD, Smits ML, Knoop J, Kallewaard JW, Staal JB, de Vries M, et al. Effect of a behavioral therapy-based virtual reality application on quality of life in chronic low back pain. Clin J Pain 2023 Jun 01;39(6):278-285 [FREE Full text] [doi: 10.1097/AJP.0000000000001110] [Medline: 37002877]
158. Heapy AA, Higgins DM, Goulet JL, LaChappelle KM, Driscoll MA, Czlapinski RA, et al. Interactive voice response-based self-management for chronic back pain: the COPES noninferiority randomized trial. JAMA Intern Med 2017 Jun 01;177(6):765-773 [FREE Full text] [doi: 10.1001/jamainternmed.2017.0223] [Medline: 28384682]
159. Ibrahim AA, Akindele MO, Ganiyu SO. Motor control exercise and patient education program for low resource rural community dwelling adults with chronic low back pain: a pilot randomized clinical trial. J Exerc Rehabil 2018 Oct 31;14(5):851-863 [FREE Full text] [doi: 10.12965/jer.1836348.174] [Medline: 30443533]
160. Jassi FJ, Del Antônio TT, Azevedo BO, Moraes R, George SZ, Chaves TC. Star-shape kinesio taping is not better than a minimal intervention or sham kinesio taping for pain intensity and postural control in chronic low back pain: a randomized controlled trial. Arch Phys Med Rehabil 2021 Jul;102(7):1352-60.e3. [doi: 10.1016/j.apmr.2021.03.007] [Medline: 33819489]
161. Javdaneh N, Saeterbakken AH, Shams A, Barati AH. Pain neuroscience education combined with therapeutic exercises provides added benefit in the treatment of chronic neck pain. Int J Environ Res Public Health 2021 Aug 22;18(16):8848 [FREE Full text] [doi: 10.3390/ijerph18168848] [Medline: 34444594]
162. Jay K, Schraefel MC, Brandt M, Andersen LL. Effect of video-based versus personalized instruction on errors during elastic tubing exercises for musculoskeletal pain: a randomized controlled trial. Biomed Res Int 2014;2014:790937 [FREE Full text] [doi: 10.1155/2014/790937] [Medline: 24734244]
163. Khosrokiani Z, Letafatkar A, Gladin A. Lumbar motor control training as a complementary treatment for chronic neck pain: a randomized controlled trial. Clin Rehabil 2022 Jan;36(1):99-112. [doi: 10.1177/02692155211038099] [Medline: 34474578]
164. Kim SK, Kim HS, Chung SS. Effects of an individualized educational program for Korean patients with chronic low back pain: a randomized controlled trial. J Nurs Res 2021 Dec 01;29(6):e177. [doi: 10.1097/jnr.0000000000000455] [Medline: 34593721]
165. Kisaalita N, Staud R, Hurley R, Robinson M. Educational intervention about placebo mechanisms makes placebo use more acceptable for patients with chronic musculoskeletal pain. J Pain 2014 Apr;15(4):S118. [doi: 10.1016/j.jpain.2014.01.481]
166. Ko V, Naylor J, Harris I, Crosbie J, Yeo A, Mittal R. One-to-one therapy is not superior to group or home-based therapy after total knee arthroplasty: a randomized, superiority trial. J Bone Joint Surg Am 2013 Nov 06;95(21):1942-1949. [doi: 10.2106/JBJS.L.00964] [Medline: 24196464]
167. Kuvačić G, Fratini P, Padulo J, Antonio DI, De Giorgio A. Effectiveness of yoga and educational intervention on disability, anxiety, depression, and pain in people with CLBP: a randomized controlled trial. Complement Ther Clin Pract 2018 May;31:262-267. [doi: 10.1016/j.ctcp.2018.03.008] [Medline: 29705466]
168. Kwok EY, Au RK, Li-Tsang CW. The effect of a self-management program on the quality-of-life of community-dwelling older adults with chronic musculoskeletal knee pain: a pilot randomized controlled trial. Clin Gerontol 2016;39(5):428-448. [doi: 10.1080/07317115.2016.1171818] [Medline: 29471771]
169. LeFort SM, Gray-Donald K, Rowat KM, Jeans ME. Randomized controlled trial of a community-based psychoeducation program for the self-management of chronic pain. Pain 1998 Feb;74(2-3):297-306. [doi: 10.1016/s0304-3959(97)00190-5] [Medline: 9520244]
170. Li Y, Tse MY. An online pain education program for working adults: pilot randomized controlled trial. J Med Internet Res 2020 Jan 14;22(1):e15071 [FREE Full text] [doi: 10.2196/15071] [Medline: 31934865]
171. Li Z, Tse M, Tang A. The effectiveness of a dyadic pain management program for community-dwelling older adults with chronic pain: a pilot randomized controlled trial. Int J Environ Res Public Health 2020 Jul 09;17(14):4966 [FREE Full text] [doi: 10.3390/ijerph17144966] [Medline: 32660159]
172. Linton SJ, Andersson T. Can chronic disability be prevented? A randomized trial of a cognitive-behavior intervention and two forms of information for patients with spinal pain. Spine (Phila Pa 1976) 2000 Nov 01;25(21):2825-31; discussion 2824. [doi: 10.1097/00007632-200011010-00017] [Medline: 11064530]
173. Little P, Roberts L, Blowers H, Garwood J, Cantrell T, Langridge J, et al. Should we give detailed advice and information booklets to patients with back pain? A randomized controlled factorial trial of a self-management booklet and doctor advice to take exercise for back pain. Spine (Phila Pa 1976) 2001 Oct 01;26(19):2065-2072. [doi: 10.1097/00007632-200110010-00003] [Medline: 11698879]
174. Lorig KR, Ritter PL, Laurent DD, Plant K. The internet-based arthritis self-management program: a one-year randomized trial for patients with arthritis or fibromyalgia. Arthritis Rheum 2008 Jul 15;59(7):1009-1017 [FREE Full text] [doi: 10.1002/art.23817] [Medline: 18576310]

175. Louw A, Diener I, Landers MR, Puentedura EJ. Preoperative pain neuroscience education for lumbar radiculopathy: a multicenter randomized controlled trial with 1-year follow-up. Spine (Phila Pa 1976) 2014 Aug 15;39(18):1449-1457. [doi: 10.1097/BRS.0000000000000444] [Medline: 24875964]
176. Malfliet A, Kregel J, Coppieters I, De Pauw R, Meeus M, Roussel N, et al. Effect of pain neuroscience education combined with cognition-targeted motor control training on chronic spinal pain: a randomized clinical trial. JAMA Neurol 2018 Jul 01;75(7):808-817 [FREE Full text] [doi: 10.1001/jamaneurol.2018.0492] [Medline: 29710099]
177. Marcus BH, Lewis BA, Williams DM, Dunsiger S, Jakicic JM, Whiteley JA, et al. A comparison of internet and print-based physical activity interventions. Arch Intern Med 2007 May 14;167(9):944-949. [doi: 10.1001/archinte.167.9.944] [Medline: 17502536]
178. Mecklenburg G, Smittenaar P, Erhart-Hledik JC, Perez DA, Hunter S. Effects of a 12-week digital care program for chronic knee pain on pain, mobility, and surgery risk: randomized controlled trial. J Med Internet Res 2018 Apr 25;20(4):e156 [FREE Full text] [doi: 10.2196/jmir.9667] [Medline: 29695370]
179. Mellor R, Bennell K, Grimaldi A, Nicolson P, Kasza J, Hodges P, et al. Education plus exercise versus corticosteroid injection use versus a wait and see approach on global outcome and pain from gluteal tendinopathy: prospective, single blinded, randomised clinical trial. BMJ 2018 May 02;361:k1662 [FREE Full text] [doi: 10.1136/bmj.k1662] [Medline: 29720374]
180. Michaleff ZA, Maher CG, Lin CW, Rebbeck T, Jull G, Latimer J, et al. Comprehensive physiotherapy exercise programme or advice for chronic whiplash (PROMISE): a pragmatic randomised controlled trial. Lancet 2014 Jul 12;384(9938):133-141. [doi: 10.1016/S0140-6736(14)60457-8] [Medline: 24703832]
181. Michelotti A, Iodice G, Vollaro S, Steenks MH, Farella M. Evaluation of the short-term effectiveness of education versus an occlusal splint for the treatment of myofascial pain of the jaw muscles. J Am Dent Assoc 2012 Jan;143(1):47-53. [doi: 10.14219/jada.archive.2012.0018] [Medline: 22207667]
182. Michou L, Julien AS, Witteman HO, Légaré J, Ratelle L, Godbout A, et al. Measuring the impact of an educational intervention in rheumatoid arthritis: an open-label, randomized trial. Arch Rheumatol 2021 Dec 24;37(2):169-179 [FREE Full text] [doi: 10.46497/ArchRheumatol.2022.8965] [Medline: 36017212]
183. Miyamoto GC, Franco KF, van Dongen JM, Franco YR, de Oliveira NT, Amaral DD, et al. Different doses of Pilates-based exercise therapy for chronic low back pain: a randomised controlled trial with economic evaluation. Br J Sports Med 2018 Jul;52(13):859-868. [doi: 10.1136/bjsports-2017-098825] [Medline: 29525763]
184. Morcillo-Muñoz Y, Sánchez-Guarnido AJ, Calzón-Fernández S, Baena-Parejo I. Multimodal chronic pain therapy for adults via smartphone: randomized controlled clinical trial. J Med Internet Res 2022 May 11;24(5):e36114 [FREE Full text] [doi: 10.2196/36114] [Medline: 35373776]
185. Moseley L. Combined physiotherapy and education is efficacious for chronic low back pain. Aust J Physiother 2002;48(4):297-302. [doi: 10.1016/s0004-9514(14)60169-0] [Medline: 12443524]
186. Nambi G, Abdelbasset WK, Alrawaili SM, Alsubaie SF, Abodonya AM, Saleh AK. Virtual reality or isokinetic training; its effect on pain, kinesiophobia and serum stress hormones in chronic low back pain: a randomized controlled trial. Technol Health Care 2021;29(1):155-166. [doi: 10.3233/THC-202301] [Medline: 32831210]
187. Nambi G, Abdelbasset WK, Elsayed SH, Alrawaili SM, Abodonya AM, Saleh AK, et al. Comparative effects of isokinetic training and virtual reality training on sports performances in university football players with chronic low back pain-randomized controlled study. Evid Based Complement Alternat Med 2020 Jun 16;2020:2981273 [FREE Full text] [doi: 10.1155/2020/2981273] [Medline: 32617104]
188. Nicholas MK, Asghari A, Blyth FM, Wood BM, Murray R, McCabe R, et al. Long-term outcomes from training in self-management of chronic pain in an elderly population: a randomized controlled trial. Pain 2017 Jan;158(1):86-95. [doi: 10.1097/j.pain.0000000000000729] [Medline: 27682207]
189. Nordin CA, Michaelson P, Gard G, Eriksson MK. Effects of the web behavior change program for activity and multimodal pain rehabilitation: randomized controlled trial. J Med Internet Res 2016 Oct 05;18(10):e265 [FREE Full text] [doi: 10.2196/jmir.5634] [Medline: 27707686]
190. O'Connor MI, Brennan K, Kazmerchak S, Pratt J. YouTube videos to create a "virtual hospital experience" for hip and knee replacement patients to decrease preoperative anxiety: a randomized trial. Interact J Med Res 2016 Apr 18;5(2):e10 [FREE Full text] [doi: 10.2196/ijmr.4295] [Medline: 27091674]
191. Oliveira A, Gevirtz R, Hubbard D. A psycho-educational video used in the emergency department provides effective treatment for whiplash injuries. Spine (Phila Pa 1976) 2006 Jul 01;31(15):1652-1657. [doi: 10.1097/01.brs.0000224172.45828.e3] [Medline: 16816758]
192. Pach D, Blödt S, Wang J, Keller T, Bergmann B, Rogge AA, et al. App-based relaxation exercises for patients with chronic neck pain: pragmatic randomized trial. JMIR Mhealth Uhealth 2022 Jan 07;10(1):e31482 [FREE Full text] [doi: 10.2196/31482] [Medline: 34994708]
193. Peters ML, Smeets E, Feijge M, van Breukelen G, Andersson G, Buhrman M, et al. Happy despite pain: a randomized controlled trial of an 8-week internet-delivered positive psychology intervention for enhancing well-being in patients with chronic pain. Clin J Pain 2017 Nov;33(11):962-975 [FREE Full text] [doi: 10.1097/AJP.0000000000000494] [Medline: 28379873]

194. Rabiei P, Sheikhi B, Letafatkar A. Comparing pain neuroscience education followed by motor control exercises with group-based exercises for chronic low back pain: a randomized controlled trial. Pain Pract 2021 Mar;21(3):333-342. [doi: 10.1111/papr.12963] [Medline: 33135286]
195. Rafiq MT, Hamid MS, Hafiz E. Short-term effects of strengthening exercises of the lower limb rehabilitation protocol on pain, stiffness, physical function, and body mass index among knee osteoarthritis participants who were overweight or obese: a clinical trial. ScientificWorldJournal 2021 Dec 22;2021:6672274 [FREE Full text] [doi: 10.1155/2021/6672274] [Medline: 34975349]
196. Riva S, Camerini AL, Allam A, Schulz PJ. Interactive sections of an internet-based intervention increase empowerment of chronic back pain patients: randomized controlled trial. J Med Internet Res 2014 Aug 13;16(8):e180 [FREE Full text] [doi: 10.2196/jmir.3474] [Medline: 25119374]
197. Rodríguez Sánchez-Laulhé P, Luque-Romero LG, Barrero-García FJ, Biscarri-Carbonero Á, Blanquero J, Suero-Pineda A, et al. An exercise and educational and self-management program delivered with a smartphone app (CareHand) in adults with rheumatoid arthritis of the hands: randomized controlled trial. JMIR Mhealth Uhealth 2022 Apr 07;10(4):e35462 [FREE Full text] [doi: 10.2196/35462] [Medline: 35389367]
198. Rodríguez-Torres J, López-López L, Cabrera-Martos I, Prados-Román E, Granados-Santiago M, Valenza MC. Effects of an individualized comprehensive rehabilitation program on impaired postural control in women with chronic pelvic pain: a randomized controlled trial. Arch Phys Med Rehabil 2020 Aug;101(8):1304-1312. [doi: 10.1016/j.apmr.2020.02.019] [Medline: 32325162]
199. Ruehlman LS, Karoly P, Enders C. A randomized controlled evaluation of an online chronic pain self management program. Pain 2012 Feb;153(2):319-330 [FREE Full text] [doi: 10.1016/j.pain.2011.10.025] [Medline: 22133450]
200. Ryan CG, Gray HG, Newton M, Granat MH. Pain biology education and exercise classes compared to pain biology education alone for individuals with chronic low back pain: a pilot randomised controlled trial. Man Ther 2010 Aug;15(4):382-387. [doi: 10.1016/j.math.2010.03.003] [Medline: 20359937]
201. Sandal LF, Bach K, Øverås CK, Svendsen MJ, Dalager T, Stejnicher Drongstrup Jensen J, et al. Effectiveness of app-delivered, tailored self-management support for adults with lower back pain-related disability: a selfBACK randomized clinical trial. JAMA Intern Med 2021 Oct 01;181(10):1288-1296 [FREE Full text] [doi: 10.1001/jamainternmed.2021.4097] [Medline: 34338710]
202. Sander LB, Paganini S, Terhorst Y, Schlicker S, Lin J, Spanhel K, et al. Effectiveness of a guided web-based self-help intervention to prevent depression in patients with persistent back pain: the PROD-BP randomized clinical trial. JAMA Psychiatry 2020 Oct 01;77(10):1001-1011 [FREE Full text] [doi: 10.1001/jamapsychiatry.2020.1021] [Medline: 32459348]
203. Saw MM, Kruger-Jakins T, Edries N, Parker R. Significant improvements in pain after a six-week physiotherapist-led exercise and education intervention, in patients with osteoarthritis awaiting arthroplasty, in South Africa: a randomised controlled trial. BMC Musculoskelet Disord 2016 May 27;17:236 [FREE Full text] [doi: 10.1186/s12891-016-1088-6] [Medline: 27233479]
204. Schaller A, Dintsios CM, Icks A, Reibling N, Froboese I. Promoting physical activity in low back pain patients: six months follow-up of a randomised controlled trial comparing a multicomponent intervention with a low intensity intervention. Clin Rehabil 2016 Sep;30(9):865-877 [FREE Full text] [doi: 10.1177/0269215515618730] [Medline: 27496696]
205. Schmidt S, Wölfle N, Schultz C, Sielmann D, Huber R, Walach H. Assessment of a taping method combined with manual therapy as a treatment of non-specific chronic low back pain - a randomized controlled trial. BMC Musculoskelet Disord 2021 May 04;22(1):410 [FREE Full text] [doi: 10.1186/s12891-021-04236-2] [Medline: 33947367]
206. Serrat M, Albajes K, Navarrete J, Almirall M, Lluch Girbés E, Neblett R, et al. Effectiveness of two video-based multicomponent treatments for fibromyalgia: the added value of cognitive restructuring and mindfulness in a three-arm randomised controlled trial. Behav Res Ther 2022 Nov;158:104188 [FREE Full text] [doi: 10.1016/j.brat.2022.104188] [Medline: 36116229]
207. Serrat M, Coll-Omaña M, Albajes K, Solé S, Almirall M, Luciano JV, et al. Efficacy of the FIBROWALK multicomponent program moved to a virtual setting for patients with fibromyalgia during the COVID-19 pandemic: a proof-of-concept RCT performed alongside the state of alarm in Spain. Int J Environ Res Public Health 2021 Sep 30;18(19):10300 [FREE Full text] [doi: 10.3390/ijerph181910300] [Medline: 34639600]
208. Shaygan M, Jaberi A, Firozian R, Yazdani Z. Comparing the effects of multimedia and face-to-face pain management education on pain intensity and pain catastrophizing among patients with chronic low back pain: a randomized clinical trial. PLoS One 2022 Jun 16;17(6):e0269785 [FREE Full text] [doi: 10.1371/journal.pone.0269785] [Medline: 35709207]
209. Shaygan M, Jaberi A, Firozian R, Yazdani Z, Zarifsanaiey N. Effect of a multimedia training programme for pain management on pain intensity and depression in patients with non-specific chronic back pain. Invest Educ Enferm 2022 Mar;40(1):e13 [FREE Full text] [doi: 10.17533/udea.iee.v40n1e13] [Medline: 35485626]
210. Shpaner M, Kelly C, Lieberman G, Perelman H, Davis M, Keefe FJ, et al. Unlearning chronic pain: a randomized controlled trial to investigate changes in intrinsic brain connectivity following cognitive behavioral therapy. Neuroimage Clin 2014 Jul 23;5:365-376 [FREE Full text] [doi: 10.1016/j.nicl.2014.07.008] [Medline: 26958466]

211. Simister HD, Tkachuk GA, Shay BL, Vincent N, Pear JJ, Skrabek RQ. Randomized controlled trial of online acceptance and commitment therapy for fibromyalgia. J Pain 2018 Jul;19(7):741-753 [FREE Full text] [doi: 10.1016/j.jpain.2018.02.004] [Medline: 29481976]
212. Skillgate E, Pico-Espinosa OJ, Côté P, Jensen I, Viklund P, Bottai M, et al. Effectiveness of deep tissue massage therapy, and supervised strengthening and stretching exercises for subacute or persistent disabling neck pain. The Stockholm Neck (STONE) randomized controlled trial. Musculoskelet Sci Pract 2020 Feb;45:102070 [FREE Full text] [doi: 10.1016/j.msksp.2019.102070] [Medline: 31655314]
213. Skou ST, Roos EM, Laursen MB, Rathleff MS, Arendt-Nielsen L, Simonsen O, et al. A randomized, controlled trial of total knee replacement. N Engl J Med 2015 Oct 22;373(17):1597-1606. [doi: 10.1056/NEJMoa1505467] [Medline: 26488691]
214. Sorensen PH, Bendix T, Manniche C, Korsholm L, Lemvigh D, Indahl A. An educational approach based on a non-injury model compared with individual symptom-based physical training in chronic LBP. A pragmatic, randomised trial with a one-year follow-up. BMC Musculoskelet Disord 2010 Sep 17;11:212 [FREE Full text] [doi: 10.1186/1471-2474-11-212] [Medline: 20849601]
215. Tejera DM, Beltran-Alacreu H, Cano-de-la-Cuerda R, Leon Hernández JV, Martín-Pintado-Zugasti A, Calvo-Lobo C, et al. Effects of virtual reality versus exercise on pain, functional, somatosensory and psychosocial outcomes in patients with non-specific chronic neck pain: a randomized clinical trial. Int J Environ Res Public Health 2020 Aug 16;17(16):5950 [FREE Full text] [doi: 10.3390/ijerph17165950] [Medline: 32824394]
216. Timmerman L, Stronks DL, Groeneweg G, Huygen FJ. The value of medication-specific education on medication adherence and treatment outcome in patients with chronic pain: a randomized clinical trial. Pain Med 2016 Oct;17(10):1829-1837. [doi: 10.1093/pm/pnw013] [Medline: 26921890]
217. Triano JJ, McGregor M, Hondras MA, Brennan PC. Manipulative therapy versus education programs in chronic low back pain. Spine (Phila Pa 1976) 1995 Apr 15;20(8):948-955. [doi: 10.1097/00007632-199504150-00013] [Medline: 7644961]
218. Tse MM, Tang SK, Wan VT, Vong SK. The effectiveness of physical exercise training in pain, mobility, and psychological well-being of older persons living in nursing homes. Pain Manag Nurs 2014 Dec;15(4):778-788. [doi: 10.1016/j.pmn.2013.08.003] [Medline: 24361207]
219. Tse MM, Yan E, Tang AS, Cheung D, Ng S. A music-with-movement exercise programme for community-dwelling older adults suffering from chronic pain: a pilot randomized controlled trial. Nurs Open 2023 Sep;10(9):6566-6574 [FREE Full text] [doi: 10.1002/nop2.1915] [Medline: 37415289]
220. Ünal M, Evci KE, Kocatürk M, Algun ZC. Investigating the effects of myofascial induction therapy techniques on pain, function and quality of life in patients with chronic low back pain. J Bodyw Mov Ther 2020 Oct;24(4):188-195. [doi: 10.1016/j.jbmt.2020.07.014] [Medline: 33218510]
221. Valenza MC, Rodríguez-Torres J, Cabrera-Martos I, Díaz-Pelegrina A, Aguilar-Ferrándiz ME, Castellote-Caballero Y. Results of a Pilates exercise program in patients with chronic non-specific low back pain: a randomized controlled trial. Clin Rehabil 2017 Jun;31(6):753-760. [doi: 10.1177/0269215516651978] [Medline: 27260764]
222. van Ittersum MW, van Wilgen CP, van der Schans CP, Lambrecht L, Groothoff JW, Nijs J. Written pain neuroscience education in fibromyalgia: a multicenter randomized controlled trial. Pain Pract 2014 Nov;14(8):689-700. [doi: 10.1111/papr.12137] [Medline: 24251724]
223. Van Oosterwijck J, Meeus M, Paul L, De Schryver M, Pascal A, Lambrecht L, et al. Pain physiology education improves health status and endogenous pain inhibition in fibromyalgia: a double-blind randomized controlled trial. Clin J Pain 2013 Oct;29(10):873-882. [doi: 10.1097/AJP.0b013e31827c7a7d] [Medline: 23370076]
224. Vicente-Mampel J, Gargallo P, Bautista IJ, Blanco-Gímenez P, de Bernardo Tejedor N, Alonso-Martín M, et al. Impact of pain neuroscience education program in community physiotherapy context on pain perception and psychosocial variables associated with it in elderly persons: a ranzomized controlled trial. Int J Environ Res Public Health 2022 Sep 20;19(19):11855 [FREE Full text] [doi: 10.3390/ijerph191911855] [Medline: 36231171]
225. Wegwarth O, Ludwig WD, Spies C, Schulte E, Hertwig R. The role of simulated-experience and descriptive formats on perceiving risks of strong opioids: a randomized controlled trial with chronic noncancer pain patients. Patient Educ Couns 2022 Jun;105(6):1571-1580. [doi: 10.1016/j.pec.2021.10.002] [Medline: 34696941]
226. Wiklund T, Molander P, Lindner P, Andersson G, Gerdle B, Dragioti E. Internet-delivered cognitive behavioral therapy for insomnia comorbid with chronic pain: randomized controlled trial. J Med Internet Res 2022 Apr 29;24(4):e29258 [FREE Full text] [doi: 10.2196/29258] [Medline: 35486418]
227. Williams DA, Kuper D, Segar M, Mohan N, Sheth M, Clauw DJ. Internet-enhanced management of fibromyalgia: a randomized controlled trial. Pain 2010 Dec;151(3):694-702 [FREE Full text] [doi: 10.1016/j.pain.2010.08.034] [Medline: 20855168]
228. Williams RM, Day MA, Ehde DM, Turner AP, Ciol MA, Gertz KJ, et al. Effects of hypnosis vs mindfulness meditation vs education on chronic pain intensity and secondary outcomes in veterans: a randomized clinical trial. Pain 2022 Oct 01;163(10):1905-1918 [FREE Full text] [doi: 10.1097/j.pain.0000000000002586] [Medline: 35082248]
229. Wilson M, Dolor RJ, Lewis D, Regan SL, Vonder Meulen MB, Winhusen TJ. Opioid dose and pain effects of an online pain self-management program to augment usual care in adults with chronic pain: a multisite randomized clinical trial. Pain 2023 Apr 01;164(4):877-885 [FREE Full text] [doi: 10.1097/j.pain.0000000000002785] [Medline: 36525381]

230. Yeh CH, Kawi J, Grant L, Huang X, Wu H, Hardwicke RL, et al. Self-guided smartphone application to manage chronic musculoskeletal pain: a randomized, controlled pilot trial. Int J Environ Res Public Health 2022 Nov 11;19(22):14875 [FREE Full text] [doi: 10.3390/ijerph192214875] [Medline: 36429591]
231. Zheng F, Liu S, Zhang S, Yu Q, Lo WL, Li T, et al. Does m-health-based exercise (guidance plus education) improve efficacy in patients with chronic low-back pain? A preliminary report on the intervention's significance. Trials 2022 Mar 03;23(1):190 [FREE Full text] [doi: 10.1186/s13063-022-06116-z] [Medline: 35241140]
232. Ziadni MS, Gonzalez-Castro L, Anderson S, Krishnamurthy P, Darnall BD. Efficacy of a single-session "empowered relief" zoom-delivered group intervention for chronic pain: randomized controlled trial conducted during the COVID-19 pandemic. J Med Internet Res 2021 Sep 10;23(9):e29672 [FREE Full text] [doi: 10.2196/29672] [Medline: 34505832]
233. GLA:D resultater. GLA:D. URL: https://www.glaid.dk/results.html [accessed 2024-09-13]
234. Arthritis Australia homepage. Arthritis Australia. URL: https://arthritisaustralia.com.au/ [accessed 2024-09-13]
235. Multimedia instructions for motor control exercises. YouTube. URL: https://youtube.com/playlist?list=PLgwiXgaKtc0ZXOUXe68g6z7OT5gvV6SAS [accessed 2024-09-13]
236. TEDxAdelaide - Lorimer Moseley - why things hurt. YouTube. URL: https://www.youtube.com/watch?v=gwd-wLdIHjs [accessed 2024-09-13]
237. Welcome to Positive STEPS. Positive STEPS. URL: https://sites.google.com/umich.edu/positivesteps/home [accessed 2024-09-13]
238. Neural pathways. YouTube. URL: https://www.youtube.com/watch?v=D36yy63CHq4 [accessed 2024-09-13]
239. Four rules for a healthy lifestyle, animated for Harvard medical school. YouTube. URL: https://www.youtube.com/watch?v=jKikTtcqqzs [accessed 2024-09-13]
240. Saper RB, Lemaster CM, Elwy AR, Paris R, Herman PM, Plumb DN, et al. Yoga versus education for veterans with chronic low back pain: study protocol for a randomized controlled trial. Trials 2016 Apr 29;17(1):224 [FREE Full text] [doi: 10.1186/s13063-016-1321-5] [Medline: 27129472]
241. Hazel Jnkins. Understanding my low back pain and whether I need imaging. https://www.mq.edu.au/research/research-centres-groups-and-facilities/groups/spinal-pain-research-group/our-resources/understanding-low-back-pain-booklet. 2022. URL: https://www.mq.edu.au/research/research-centres-groups-and-facilities/groups/spinal-pain-research-group/low-back-pain-management-booklet [accessed 2000-09-13]
242. Vídeo explicativo sobre Dolor Crónico. YouTube. URL: https://www.youtube.com/watch?v=JYA_mrNuLz0 [accessed 2024-09-13]
243. Pixel thoughts home page. Pixel Thoughts. URL: https://www.pixelthoughts.co/ [accessed 2024-09-13]
244. Hansford HJ, Wewege MA, Cashin AG, Hagstrom AD, Clifford BK, McAuley JH, et al. If exercise is medicine, why don't we know the dose? An overview of systematic reviews assessing reporting quality of exercise interventions in health and disease. Br J Sports Med 2022 Jun 15;56(12):692-700. [doi: 10.1136/bjsports-2021-104977] [Medline: 35168956]
245. Holden S, Barton CJ. 'What should I prescribe?': time to improve reporting of resistance training programmes to ensure accurate translation and implementation. Br J Sports Med 2019 Mar 23;53(5):264-265. [doi: 10.1136/bjsports-2017-098664] [Medline: 29936430]
246. Murray IR, Murray AD, Geeslin AG, Goudie EB, White TO, Petrigliano FA, et al. Infographic: we need minimum reporting standards for biologics. Br J Sports Med 2019 Aug 22;53(15):974-975. [doi: 10.1136/bjsports-2017-098122] [Medline: 28831016]
247. Bahr R, Clarsen B, Derman W, Dvorak J, Emery CA, Finch CF, et al. International Olympic Committee consensus statement: methods for recording and reporting of epidemiological data on injury and illness in sport 2020 (including STROBE Extension for Sport Injury and Illness Surveillance (STROBE-SIIS)). Br J Sports Med 2020 Apr 18;54(7):372-389 [FREE Full text] [doi: 10.1136/bjsports-2019-101969] [Medline: 32071062]
248. Zadro JR, Ferreira GE, O'Keeffe M, Stahl-Timmins W, Elkins MR, Maher CG. How do people use and view infographics that summarise health and medical research? A cross-sectional survey. BMC Med Educ 2022 Sep 14;22(1):677 [FREE Full text] [doi: 10.1186/s12909-022-03744-6] [Medline: 36104815]
249. American College of Sports Medicine. ACSM's Guidelines for Exercise Testing and Prescription, Eleventh Edition. Philadelphia, PA: Wolters Kluwer Health; 2021.
250. Viana da Silva P, Kamper SJ, Robson E, Davidson SR, Gleadhill C, Donald B, et al. "Myths and facts" education is comparable to "facts only" for recall of back pain information but may improve fear-avoidance beliefs: an embedded randomized trial. J Orthop Sports Phys Ther 2022 Sep;52(9):586-594. [doi: 10.2519/jospt.2022.10989] [Medline: 35802818]
251. Yang S, Brossard D, Scheufele DA, Xenos MA. The science of YouTube: what factors influence user engagement with online science videos? PLoS One 2022;17(5):e0267697 [FREE Full text] [doi: 10.1371/journal.pone.0267697] [Medline: 35613095]
252. Desai T, Shariff A, Dhingra V, Minhas D, Eure M, Kats M. Is content really king? An objective analysis of the public's response to medical videos on YouTube. PLoS One 2013;8(12):e82469 [FREE Full text] [doi: 10.1371/journal.pone.0082469] [Medline: 24367517]
253. Montag C, Yang H, Elhai JD. On the psychology of TikTok use: a first glimpse from empirical findings. Front Public Health 2021;9:641673 [FREE Full text] [doi: 10.3389/fpubh.2021.641673] [Medline: 33816425]

Abbreviations

CTML: cognitive theory of multimedia learning
PEM: patient education material
PERSiST: PRISMA in Exercise, Rehabilitation, Sport Medicine and Sports Science
PICOS: population, intervention, comparison, outcomes, and study design
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
TIDieR: Template for Intervention Description and Replication

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Revolutionizing Care: Unleashing the Potential of Digital Health Technology in Physiotherapy Management for People With Cystic Fibrosis

Lisa Morrison[1,2], BSc; Zoe Louise Saynor[3,4], BSc, MSc, PhD; Alison Kirk[5], BSc (Hons), MSc, PhD; Lisa McCann[2], BSc (Hons), MSc, PhD

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Corresponding Author:
Lisa Morrison, BSc

Abstract

This viewpoint paper explores the dynamic intersection of physiotherapy and digital health technologies (DHTs) in enhancing the care of people with cystic fibrosis (CF), in the context of advancements such as highly effective modulator therapies that are enhancing life expectancy and altering physiotherapy needs. The role of DHTs, including telehealth, surveillance, home monitoring, and activity promotion, has expanded, becoming crucial in overcoming geographical barriers and accelerated by the recent pandemic. Physiotherapy, integral to CF care since 1946, has shifted toward patient-centered approaches, emphasizing exercise training and a physically active lifestyle. The reduction in inpatient admissions due to highly effective modulator therapies has led to increased home care and online or electronic consultations, and DHTs have revolutionized service delivery, offering flexibility, self-management, and personalized care options; however, there is a need to comprehensively understand user experiences from both people with CF and physiotherapists. This paper highlights the essential exploration of user experiences to facilitate clinician adaptation to the digital requirements of modern clinical management, ensuring equitable care in the "future hospitals" arena. Identifying research gaps, this paper emphasizes the need for a thorough evaluation of DHT use in CF physiotherapy education, training, and self-monitoring, as well as the experiences of people with CF with online or electronic consultations, self-monitoring, and remote interventions. Online group exercise platforms address historical challenges relating to infection control but necessitate comprehensive evaluations of user experiences and preferences. Future-proofing DHTs within the physiotherapy management of CF demands a shift toward full integration, considering stakeholder opinions and addressing barriers. While DHTs have the potential to extend physiotherapy beyond the hospital, this paper stresses the importance of understanding user experiences, addressing digital poverty, and working toward more equitable health care access. A flexible approach in the "future hospital" is advocated, emphasizing the need for a nuanced understanding of user preferences and experiences to optimize the integration of DHTs in CF care.

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KEYWORDS

cystic fibrosis; physiotherapy; digital technology; telehealth; cystic fibrosis transmembrane regulator modulators; telemedicine; digital health technology; DHTs; digital health; physical therapy; physical activity; exercise; monitoring; physiotherapists; user; experience; remote; virtual care; consultation; consultations; eConsultations; preferences; digital divide; access; accessible; accessibility; attitude; perception; attitudes; opinion; perceptions; perspectives; eHealth; online health; therapy

Introduction

Cystic fibrosis (CF) is a chronic, autosomal recessive, life-limiting, multisystem disease, historically leading to respiratory failure and premature death [1]. Chest physiotherapy (airway clearance techniques) to enhance secretion clearance has been a cornerstone of CF physiotherapy, with self-management and guided management being the focus of care as people with CF develop and their disease dictates different approaches. Advancements in the clinical management of CF, including the introduction of highly effective modulator therapies (HEMTs), have positively impacted life expectancy [1,2]. Consequently, physiotherapy management of CF and the specialist CF physiotherapist must adapt [3].

There is a growing body of evidence supporting examples where physiotherapy has benefited from digital health technologies

(DHTs), primarily existing in the management of musculoskeletal [4] or neurological issues [5,6]. Here, specific exercise, virtual reality, and gaming have positively influenced rehabilitation; however, this new innovative technology currently does not exist in CF physiotherapy management. DHTs have been used in CF for some time, particularly in areas of geographical diversity, with online or electronic consultation and monitoring therapies becoming increasingly commonplace [7]. DHTs have been used in chipped nebulizers monitoring adherence to therapeutic regimes [8] and home spirometers, alongside other wearables and mobile apps (eg, the Project Breathe patient-driven symptom reporting [9]). There has, however, been limited research into the evaluation of online or electronic physiotherapy interventions in CF, the implementation of DHTs, and their effectiveness within the physiotherapy management for CF.

Online or electronic physiotherapy in CF could facilitate more than symptom monitoring, extending to simple exercise testing, remote physical activity, and exercise opportunities, as well as implementing measures to influence adherence and the prompt management of symptoms. While online or electronic consultations may be more convenient for some people with CF and reduce the risk of cross infection, not all people with CF will benefit from reducing the frequency of in-person consultations.

The Changing Role of Physiotherapy Within CF Care

Physiotherapists, originally involved in CF care for chest clearance in 1946, now participate in a global clinical and research network, developing national and international clinical guidance and standards of care [3,10-12]. While global standards of clinical care exist, there will be variations in the implementation of these and DHTs due to socioeconomic factors, availability of infrastructure, and accessibility in health care settings and beyond [13,14]. Irrespective of these challenges, an awareness of data storage, accessibility, and safety of data is essential, and the physiotherapist must be mindful of these factors.

CF physiotherapy has progressed to a more active, patient-centered approach to clinical care [11,12]. This still includes airway clearance techniques and assessment of respiratory and nonrespiratory manifestations (eg, musculoskeletal and sinuses) and, with a rising prevalence of increase in weight leading to obesity [15] and cardiovascular diseases [16], an ever-increasing involvement in the promotion of exercise testing, training, and physical active promotion. The reduction in inpatient admissions following HEMT has enabled an increase in home care and online or electronic consultations, reducing reliance on hospital services, mitigating cross infection risks, and reducing travel to hospital.

Online or electronic consultations assess people with CF remotely, with mobile devices monitoring symptoms, assessing pulmonary function, and patient-reported outcomes, as well as promotion of physical activity [17,18]. These have been well received, but with variable compliance due to competing demands impacting overall uptake [17]. Several online or electronic platforms, some led by physiotherapists, offered education and training to people with CF and health care professionals, enabling widespread delivery of information and resources, with the potential for standardized data collection and optimized quality care [17,19-22].

Self-monitoring, particularly spirometry, has been explored, with physiological data and symptom recognition proposing earlier identification of pulmonary exacerbation [9,23-25]. Self-monitoring, however, may be less accurate, leading to undetected worsening of health status [23,24]. Despite suggestions that self-monitoring is well used [24,26], uploading of digital data is poorly adhered to, and collecting data should be optimized based upon clinical usefulness [23]. Cox et al [27] highlighted in a systematic review that >50% of participants were noncompliant with data entry, with data upload considered burdensome, potentially intrusive, and a barrier to maintainability. Exploration of opportunities for continuous monitoring or passive uploading of data (as occurs with some wearables [9]) may reduce the burden on people with CF and positively influence their use of devices. Improving the accuracy of self-monitoring and symptom monitoring using DHTs may facilitate swifter directed access to relevant professionals providing individually tailored treatments, facilitating personalized discussion and, ultimately, leading to more user-driven outcomes (NCT04798014) [28,29].

Following the introduction of HEMT, many clinical outcomes observed in people with CF with access have improved, such as fewer pulmonary exacerbations, improved lung function, and exercise tolerance [30]. The physiotherapists' role in exercise testing, training, and promoting a physically active lifestyle is well researched [31-34] and remains central to the maintenance and optimization of health in people with CF [12]; however, there are no specific CF-related physical activity guidelines [35]. Uptake and adherence to physical activity programs in people with CF is poor [19], and this occurs irrespective of remote delivery [36]. Physical activity is central to the CF physiotherapist's role; however, segregation requirements historically rendered group activities unachievable. Physical activity platforms have enabled physiotherapists to deliver online group exercise [23], both live and on demand [20], and have been shown in other chronic illnesses to provide solutions to remotely support physical activity and emotional well-being, and improve quality of life [37]. Online group activities allow people with CF to experience peer support [17,20,27], physiotherapy supervision, and education pertinent to their health [20,38]. Despite the anticipated positives of this, significant dropout and discontinuation in some centers have occurred. It is important to evaluate reasons for this and engage with people with CF to identify user opinions for future online physical activity provision.

The Use of DHTs in the Physiotherapy Management of CF

The benefits of DHTs in CF care include reducing cross infection [39] and enabling interprofessional team management in areas with diverse geographic distances [7]. People with CF

have responded positively to remote consultation, online exercise provision, and monitoring [8,12,13].

Airway clearance quality has been shown to have a greater impact on respiratory function than quantity and frequency [40,41]. The integration of DHT using pressure sensors embedded in devices may influence physiotherapy assessment and treatment delivery. Using DHTs to guide, counsel, and facilitate goal attainment may enable individualized physiotherapy care for people with CF, offering a flexible approach to modern management, enhancing adherence, and impacting clinical outcomes important to people with CF. For example, the use of wearables and supportive messaging from physiotherapists demonstrated a prolonged and positive change in step count and exercise capacity in adults with CF [42]. Assessment of data derived from online or electronic consultation and self-monitoring can guide assessment of what has worked well and what should perhaps be discontinued. This will include the evaluation of digital literacy skills and acceptance by people with CF in using DHT to access their health care teams effectively and appropriately.

The role of telehealth for exercise testing has been shown in other diseases to offer a viable alternative to some in-person testing [43] and requires further exploration in CF. To date exercise testing in people with CF has not been researched in a online or electronic capacity but could support centers with limited or no access to in-house exercise testing facilities.

Can We Future-Proof and Optimize the Use of DHTs Within the Physiotherapy Management of CF?

DHTs are not yet fully integrated into CF management locally or globally [44] and are often considered an "add-on." Electronic patient records are widely used but have not fully replaced conventional written records for all consultations. Opinions of health care teams and people with CF are essential to strengthen the implementation and maintainability of any future DHTs in routine care [24]. Further research into barriers and facilitators for maintained use of DHTs will support long-term digital plans [45,46]. The optimization of current data uploading applications and platforms to ensure that they are clinically useful for both the user and the stakeholders must occur, including support for training and education when using DHT [44].

There are numerous frameworks (eg, RE-AIM [Reach, Effectiveness, Adoption, Implementation, and Maintenance] [47] and NASSS [nonadoption, abandonment, scale-up, spread, sustainability] [48]) developed specifically for identifying interacting influences dictating the success or failure of a system [46,49-51]. The recent analysis of the physical activity in people with CF [19] recognized that frameworks offer reasons for nonengagement, with respect to relevance and user satisfaction with interventions and associated technology. Future research should apply these frameworks, exploring how to improve the uptake and use of DHT [52].

Implications of DHT should be considered, as changing one aspect may influence (positively or negatively) other areas of care [53], and the introduction of DHTs in managing children and adolescents with CF will be significantly different to adults and those with multimorbidities. Some people with CF are digital natives, growing up with an appreciation of DHTs; others have lower levels of digital literacy and trust in digital services and, consequently, the uptake of opportunities to influence their health using this technology may be lower [54,55]. DHTs could negatively impact the "personal" feel of a consultation, leaving people with CF feeling that they are no longer "known" to their clinical care team with respect to their wider societal issues [56].

Conclusions

DHTs present exciting potential for physiotherapy management in CF. Online or electronic consultations, online physiotherapy (including physical activity and exercise training), and remote monitoring may, however, not be desirable, available, or appropriate for everybody. We urgently need to understand the experience of early implementers, the enablers of success, and the needs of the CF community to better inform equitable use. We must ensure this does not create a digital divide, as digital poverty continues to exist, impacting digital and health literacy, use, and practical application of DHT. We must ensure online or electronic consultations meet the requirements of those accessing them. To ensure "no one is left behind" and optimize care for people with CF, we need to challenge the unsupportable "one-size-fits-all" approach. This involves a flexible infrastructure supporting the future physiotherapy management of people with CF, based on patient experience–related reported outcomes allowing refinement and delivery of an optimal and individualized service.

Conflicts of Interest

None declared.

References

1. Bell SC, Mall MA, Gutierrez H, et al. The future of cystic fibrosis care: a global perspective. Lancet Respir Med 2020 Jan;8(1):65-124. [doi: 10.1016/S2213-2600(19)30337-6] [Medline: 31570318]
2. Balfour-Lynn IM, King JA. CFTR modulator therapies - effect on life expectancy in people with cystic fibrosis. Paediatr Respir Rev 2022 Jun;42:3-8. [doi: 10.1016/j.prrv.2020.05.002] [Medline: 32565113]
3. Stanford G, Daniels T, Brown C, et al. The role of the physical therapist in cystic fibrosis care. Phys Ther 2022 Oct;103(1):pzac136. [doi: 10.1093/ptj/pzac136] [Medline: 36193006]

4. Merolli M, Gray K, Choo D, Lawford BJ, Hinman RS. Use, and acceptability, of digital health technologies in musculoskeletal physical therapy: a survey of physical therapists and patients. Musculoskeletal Care 2022 Sep;20(3):641-659. [doi: 10.1002/msc.1627] [Medline: 35278266]
5. Ammann-Reiffer C, Kläy A, Keller U. Virtual reality as a therapy tool for walking activities in pediatric neurorehabilitation: usability and user experience evaluation. JMIR Serious Games 2022 Jul 14;10(3):e38509. [doi: 10.2196/38509] [Medline: 35834316]
6. Fahr A, Kläy A, Keller JW, van Hedel HJA. An interactive computer game for improving selective voluntary motor control in children with upper motor neuron lesions: development and preliminary feasibility study. JMIR Serious Games 2021 Jul 28;9(3):e26028. [doi: 10.2196/26028] [Medline: 34319236]
7. Shanthikumar S, Ruseckaite R, Corda J, Mulrennan S, Ranganathan S, Douglas T. Telehealth use in Australian cystic fibrosis centers: clinician experiences. Pediatr Pulmonol 2023 Oct;58(10):2906-2915. [doi: 10.1002/ppul.26612] [Medline: 37477510]
8. Drabble SJ, O'Cathain A, Scott AJ, et al. Mechanisms of action of a web-based intervention with health professional support to increase adherence to nebulizer treatments in adults with cystic fibrosis: qualitative interview study. J Med Internet Res 2020 Oct 6;22(10):e16782. [doi: 10.2196/16782] [Medline: 32697197]
9. Jackson J. Cloud-based health monitor improves care for CF patients during Covid. National Health Executive. 2021 May 24. URL: https://www.nationalhealthexecutive.com/articles/cloud-based-health-monitor-care-cf-patients-covid [accessed 2024-07-05]
10. Morrison L, Parrott H. Standards of Care and Good Clinical Practice for the Physiotherapy Management of Cystic Fibrosis: Cystic Fibrosis Trust; 2020.
11. Southern KW, Castellani C, Lammertyn E, et al. Standards of care for CFTR variant-specific therapy (including modulators) for people with cystic fibrosis. J Cyst Fibros 2023 Jan;22(1):17-30. [doi: 10.1016/j.jcf.2022.10.002] [Medline: 36916675]
12. Southern KW, Addy C, Bell SC, et al. Standards for the care of people with cystic fibrosis; establishing and maintaining health. J Cyst Fibros 2024 Jan;23(1):12-28. [doi: 10.1016/j.jcf.2023.12.002] [Medline: 38129255]
13. Rodriguez JA, Shachar C, Bates DW. Digital inclusion as health care - supporting health care equity with digital-infrastructure initiatives. N Engl J Med 2022 Mar 24;386(12):1101-1103. [doi: 10.1056/NEJMp2115646] [Medline: 35302722]
14. World Health Organization. Global Strategy on Digital Health 2020-2025: World Health Organization; 2021. URL: https://www.who.int/docs/default-source/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf [accessed 2024-07-08]
15. Proud D, Duckers J. Weight a minute: exploring the effect on weight and body composition after the initiation of elexacaftor/tezacaftor/ivacaftor in adults with CF. J Cyst Fibros 2023 Sep;22(5):847-850. [doi: 10.1016/j.jcf.2023.06.002] [Medline: 37355345]
16. Saunders T, Burgner D, Ranganathan S. Identifying and preventing cardiovascular disease in patients with cystic fibrosis. Nat Cardiovasc Res 2022 Mar;1(3):187-188. [doi: 10.1038/s44161-022-00030-y]
17. Poulsen M, Holland AE, Button B, Jones AW. Preferences and perspectives regarding telehealth exercise interventions for adults with cystic fibrosis: a qualitative study. Pediatr Pulmonol 2024 May;59(5):1217-1226. [doi: 10.1002/ppul.26889] [Medline: 38289142]
18. Bass R, Bourke S, Morrison L, et al. Is an online exercise platform, such as Pactster/Beam an acceptable tool to promote exercise participation in adults with cystic fibrosis, with or without online physiotherapy support? Journal of the Association of Chartered Physiotherapists in Respiratory Care 2022 Dec;54(3):47-61. [doi: 10.56792/KFHR9391]
19. Cox NS, Eldridge B, Rawlings S, et al. A web-based intervention to promote physical activity in adolescents and young adults with cystic fibrosis: protocol for a randomized controlled trial. BMC Pulm Med 2019 Dec 19;19(1):253. [doi: 10.1186/s12890-019-0942-3] [Medline: 31856791]
20. Morrison L, McCrea G, Palmer S. Online activity - a beaming good initiative! delivering alternative exercise opportunities for people with cystic fibrosis. Physiother Theory Pract 2024 Jul;40(7):1609-1615. [doi: 10.1080/09593985.2023.2182654] [Medline: 36809231]
21. Albon D, Thomas L, Hoberg L, et al. Cystic fibrosis learning network telehealth innovation lab during the COVID-19 pandemic: a success QI story for interdisciplinary care and agenda setting. BMJ Open Qual 2022 May;11(2):e001844. [doi: 10.1136/bmjoq-2022-001844] [Medline: 35589277]
22. Calthorpe RJ, Smith S, Gathercole K, Smyth AR. Using digital technology for home monitoring, adherence and self-management in cystic fibrosis: a state-of-the-art review. Thorax 2020 Jan;75(1):72-77. [doi: 10.1136/thoraxjnl-2019-213233] [Medline: 31594802]
23. Wong CH, Smith S, Kansra S. Digital technology for early identification of exacerbations in people with cystic fibrosis. Cochrane Database Syst Rev 2023 Apr 14;4(4):CD014606. [doi: 10.1002/14651858.CD014606.pub2] [Medline: 37057835]
24. Moor CC. Home monitoring for cystic fibrosis: the future is now. J Cyst Fibros 2022 Jan;21(1):15-17. [doi: 10.1016/j.jcf.2021.12.005] [Medline: 34906432]
25. Lechtzin N, Mayer-Hamblett N, West NE, et al. Home monitoring of patients with cystic fibrosis to identify and treat acute pulmonary exacerbations. eICE study results. Am J Respir Crit Care Med 2017 Nov 1;196(9):1144-1151. [doi: 10.1164/rccm.201610-2172OC] [Medline: 28608719]

26. Pittman A, Luo NM. Methods for monitoring pulmonary health in cystic fibrosis patients in a remote-first care environment - a survey [Poster]. Pediatr Pulmonol 2020;55(S2) [FREE Full text]
27. Cox NS, Alison JA, Rasekaba T, Holland AE. Telehealth in cystic fibrosis: a systematic review. J Telemed Telecare 2012 Mar;18(2):72-78. [doi: 10.1258/jtt.2011.110705] [Medline: 22198961]
28. Brown C, Sabadosa K, Zhang C, et al. P092 preliminary observations of treatment and symptom reporting in the home-reported outcomes in cystic fibrosis study (HERO-2) [Poster]. J Cyst Fibros 2023 Jun;22:S92. [doi: 10.1016/S1569-1993(23)00467-8]
29. Ren C, Psoter K, Sabadosa K, et al. P113 home reported outcomes (HERO-2) in people with cystic fibrosis taking elexacaftor/tezacaftor/ivacaftor: self-reported changes in use of chronic daily therapies at enrollment [Poster]. J Cyst Fibros 2023 Jun;22:S98. [doi: 10.1016/S1569-1993(23)00488-5]
30. Gruet M, Saynor ZL, Urquhart DS, Radtke T. Rethinking physical exercise training in the modern era of cystic fibrosis: a step towards optimising short-term efficacy and long-term engagement. J Cyst Fibros 2022 Mar;21(2):e83-e98. [doi: 10.1016/j.jcf.2021.08.004] [Medline: 34493444]
31. Bannell DJ, France-Ratcliffe M, Buckley BJR, et al. Adherence to unsupervised exercise in sedentary individuals: a randomised feasibility trial of two mobile health interventions. Digit Health 2023 Jun;9:20552076231183552. [doi: 10.1177/20552076231183552] [Medline: 37426588]
32. Clarkson P, Stephenson A, Grimmett C, et al. Digital tools to support the maintenance of physical activity in people with long-term conditions: a scoping review. Digit Health 2022 Apr;8:20552076221089778. [doi: 10.1177/20552076221089778] [Medline: 35433017]
33. Cox NS, Alison JA, Button BM, Wilson JW, Holland AE. Feasibility and acceptability of an internet-based program to promote physical activity in adults with cystic fibrosis. Respir Care 2015 Mar;60(3):422-429. [doi: 10.4187/respcare.03165] [Medline: 25425703]
34. Cox NS, Eldridge B, Rawlings S, et al. Web-based physical activity promotion in young people with CF: a randomised controlled trial. Thorax 2023 Jan;78(1):16-23. [doi: 10.1136/thorax-2022-218702] [Medline: 36180067]
35. Latour JM, Tomlinson OW. A systematic review to explore how exercise-based physiotherapy via telemedicine can promote health related benefits for people with cystic fibrosis. PLOS Digit Health 2023 Feb;2(2):e0000201. [doi: 10.1371/journal.pdig.0000201] [Medline: 36848358]
36. Reilly C, Sails J, Stavropoulos-Kalinoglou A, et al. Physical activity promotion interventions in chronic airways disease: a systematic review and meta-analysis. Eur Respir Rev 2023 Mar 31;32(167):220109. [doi: 10.1183/16000617.0109-2022] [Medline: 36697208]
37. Greenwood SA, Young HML, Briggs J, et al. Evaluating the effect of a digital health intervention to enhance physical activity in people with chronic kidney disease (Kidney BEAM): a multicentre, randomised controlled trial in the UK. Lancet Digit Health 2024 Jan;6(1):e23-e32. [doi: 10.1016/S2589-7500(23)00204-2] [Medline: 37968170]
38. Chen JJ, Cooper DM, Haddad F, Sladkey A, Nussbaum E, Radom-Aizik S. Tele-exercise as a promising tool to promote exercise in children with cystic fibrosis. Front Public Health 2018 Sep;6:269. [doi: 10.3389/fpubh.2018.00269] [Medline: 30324099]
39. Elborn JS. Digital healthcare in cystic fibrosis. Learning from the pandemic to innovate future care (commentary). J Cyst Fibros 2021 Sep;20 Suppl 3:64-66. [doi: 10.1016/j.jcf.2021.09.003] [Medline: 34565704]
40. Raywood E, Shannon H, Filipow N, et al. Quantity and quality of airway clearance in children and young people with cystic fibrosis. J Cyst Fibros 2023 Mar;22(2):344-351. [doi: 10.1016/j.jcf.2022.09.008] [Medline: 36210322]
41. Morrison L, Thornton CS. Quality over quantity: the next ACT in airway clearance in cystic fibrosis. Eur Respir J 2023 Sep;62(3):2301354. [doi: 10.1183/13993003.01354-2023] [Medline: 37690789]
42. Curran M, Tierney AC, Collins L, et al. Steps ahead: optimising physical activity in adults with cystic fibrosis: a pilot randomised trial using wearable technology, goal setting and text message feedback. J Cyst Fibros 2023 May;22(3):570-576. [doi: 10.1016/j.jcf.2022.11.002] [Medline: 36402730]
43. Holland AE, Malaguti C, Hoffman M, et al. Home-based or remote exercise testing in chronic respiratory disease, during the COVID-19 pandemic and beyond: a rapid review. Chron Respir Dis 2020 Jan;17:1479973120952418. [doi: 10.1177/1479973120952418] [Medline: 32840385]
44. Vagg T, Shanthikumar S, Ibrahim H, et al. Telehealth in cystic fibrosis. A systematic review incorporating a novel scoring system and expert weighting to identify a 'top 10 manuscripts' to inform future best practices implementation. J Cyst Fibros 2023 Jul;22(4):598-606. [doi: 10.1016/j.jcf.2023.05.012] [Medline: 37230808]
45. Digital health and care strategy. Scottish Government. 2021 Oct 27. URL: https://www.gov.scot/publications/scotlands-digital-health-care-strategy/ [accessed 2024-07-08]
46. Ruth J, Willwacher S, Korn O. Acceptance of digital sports: a study showing the rising acceptance of digital health activities due to the SARS-CoV-19 pandemic. Int J Environ Res Public Health 2022 Jan 5;19(1):596. [doi: 10.3390/ijerph19010596] [Medline: 35010849]
47. Holtrop JS, Estabrooks PA, Gaglio B, et al. Understanding and applying the RE-AIM framework: clarifications and resources. J Clin Transl Sci 2021 May;5(1):e126. [doi: 10.1017/cts.2021.789] [Medline: 34367671]

48. Abimbola S, Patel B, Peiris D, et al. The NASSS framework for ex post theorisation of technology-supported change in healthcare: worked example of the TORPEDO programme. BMC Med 2019 Dec 30;17(1):233. [doi: 10.1186/s12916-019-1463-x] [Medline: 31888718]
49. Carr SB, Ronan P, Lorenc A, Mian A, Madge SL, Robinson N. Children and Adults Tai Chi Study (CF-CATS2): a randomised controlled feasibility study comparing internet-delivered with face-to-face tai chi lessons in cystic fibrosis. ERJ Open Res 2018 Oct;4(4):00042-2018. [doi: 10.1183/23120541.00042-2018] [Medline: 30568967]
50. Stoumpos AI, Kitsios F, Talias MA. Digital transformation in healthcare: technology acceptance and its applications. Int J Environ Res Public Health 2023 Feb 15;20(4):3407. [doi: 10.3390/ijerph20043407] [Medline: 36834105]
51. Parker K, Uddin R, Ridgers ND, et al. The use of digital platforms for adults' and adolescents' physical activity during the COVID-19 pandemic (Our Life at Home): survey study. J Med Internet Res 2021 Feb 1;23(2):e23389. [doi: 10.2196/23389] [Medline: 33481759]
52. Merolli M, Hinman RS, Lawford BJ, Choo D, Gray K. Digital health interventions in physiotherapy: development of client and health care provider survey instruments. JMIR Res Protoc 2021 Jul 28;10(7):e25177. [doi: 10.2196/25177] [Medline: 34319242]
53. Smith S, Calthorpe R, Herbert S, Smyth AR. Digital technology for monitoring adherence to inhaled therapies in people with cystic fibrosis. Cochrane Database Syst Rev 2023 Feb 3;2(2):CD013733. [doi: 10.1002/14651858.CD013733.pub2] [Medline: 36734528]
54. Arias López MDP, Ong BA, Borrat Frigola X, et al. Digital literacy as a new determinant of health: a scoping review. PLOS Digit Health 2023 Oct;2(10):e0000279. [doi: 10.1371/journal.pdig.0000279] [Medline: 37824584]
55. Fitzpatrick PJ. Improving health literacy using the power of digital communications to achieve better health outcomes for patients and practitioners. Front Digit Health 2023 Nov;5:1264780. [doi: 10.3389/fdgth.2023.1264780] [Medline: 38046643]
56. Vagg T, Shanthikumar S, Morrissy D, Chapman WW, Plant BJ, Ranganathan S. Telehealth and virtual health monitoring in cystic fibrosis. Curr Opin Pulm Med 2021 Nov 1;27(6):544-553. [doi: 10.1097/MCP.0000000000000821] [Medline: 34431789]

Abbreviations

CF: cystic fibrosis
DHT: digital health technology
HEMT: highly effective modulator therapy
NASSS: nonadoption, abandonment, scale-up, spread, sustainability
RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance

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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

Ashan Wijekoon[1,2,3], BSc(Hons)PT, PGCert; Dilanthi Gamage Dona[1], BSc; Subashini Jayawardana[2], PhD; Abigail Beane[1,4,5], PhD

[1]National Intensive Care Surveillance, Mahidol Oxford Tropical Medicine Research Unit, Colombo, Sri Lanka

[2]Department of Allied Health Sciences, Faculty of Medicine, University of Colombo, Colombo, Sri Lanka

[3]Department of Health and Care Professions, Faculty of Health and Wellbeing, University of Winchester, Winchester, United Kingdom

[4]Mahidol-Oxford Tropical Medicine Research Unit, Faculty of Tropical Medicine, Mahidol University, Bangkok, Thailand

[5]Centre for Inflammation Research, University of Edinburgh, Scotland, United Kingdom

Corresponding Author:
Ashan Wijekoon, BSc(Hons)PT, PGCert
Department of Allied Health Sciences
Faculty of Medicine
University of Colombo
25 Kynsey Road
Colombo, 00800
Sri Lanka
Phone: 94 112695300
Email: ashan@nicslk.com

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

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).

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,

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.

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).

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).

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.

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.

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

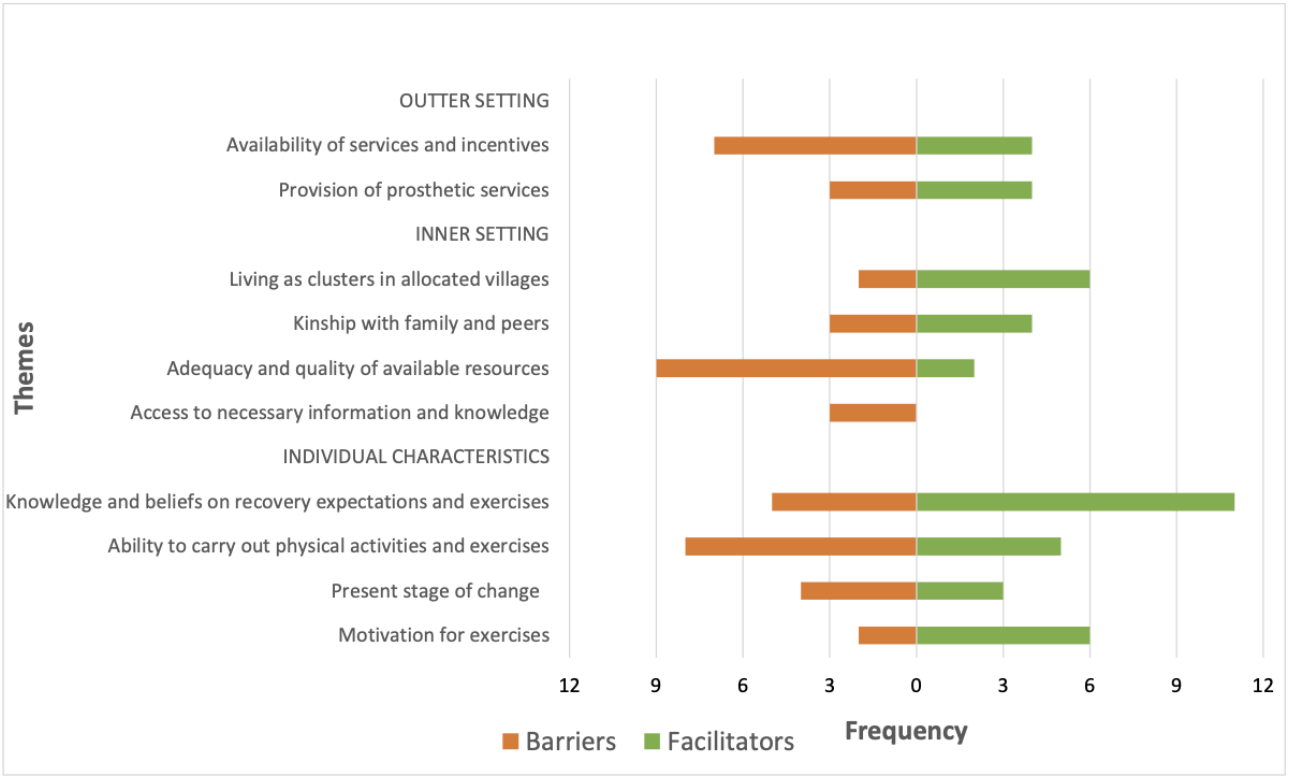


Table 6. Representative participant quotes for themes related to the barriers and facilitators to physical activity participation.

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

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.

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.

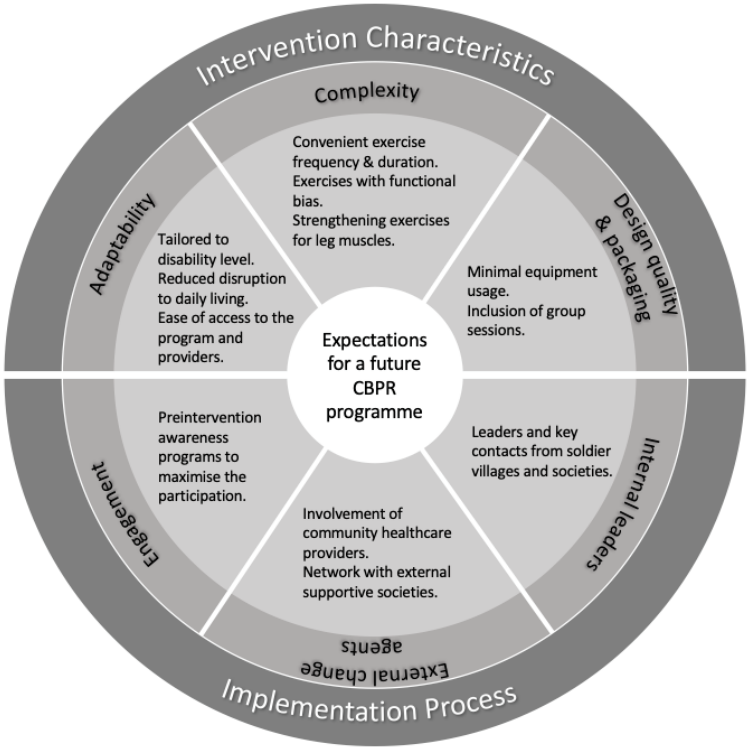


Table 7. Representative participant quotes for themes of expectations for a future community-based physical rehabilitation program.

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."

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

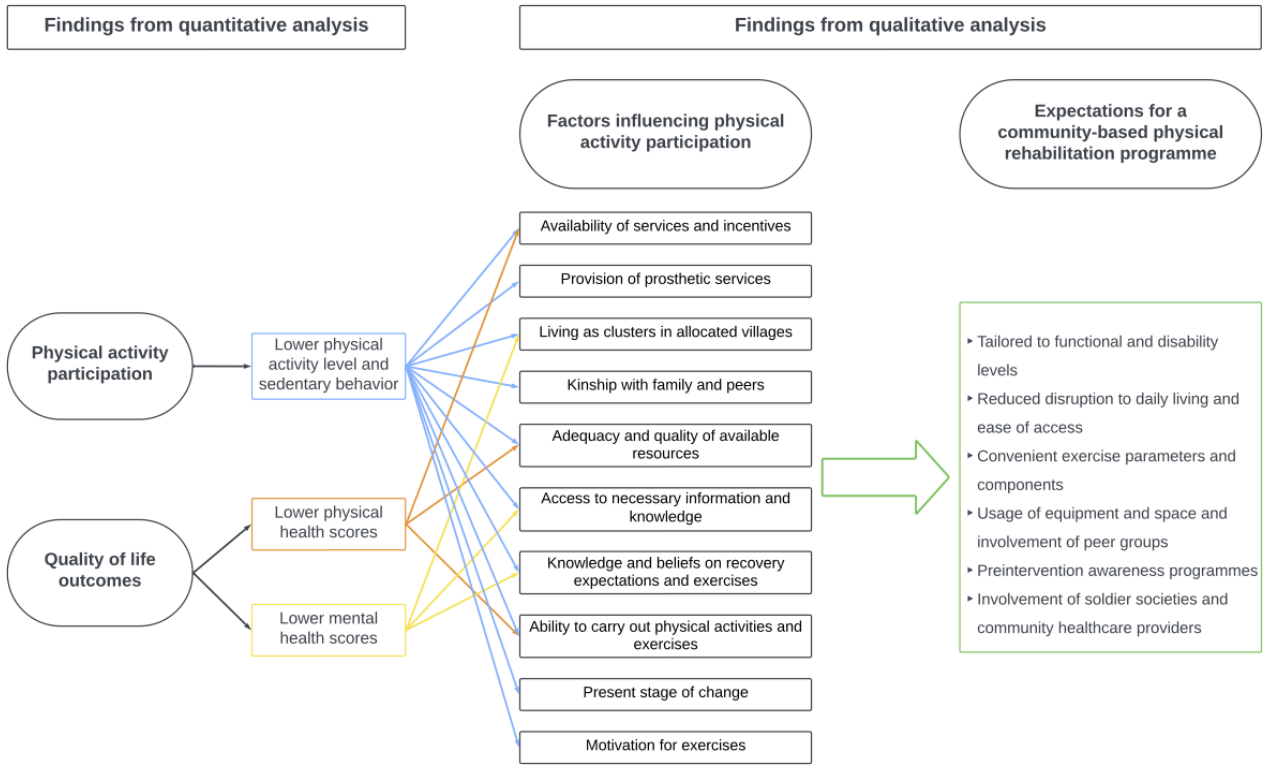
Veterans highlighted the necessity of key contact from both veterans and rehabilitation providers for each village. This is to communicate the necessary information smoothly and get advice when necessary.

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.

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

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]

References

1. Pooja GD, Sangeeta L. Prevalence and aetiology of amputation in Kolkata, India: a retrospective analysis. Hong Kong Physiotherapy J 2013 Jun;31(1):36-40. [doi: 10.1016/j.hkpj.2012.12.002]
2. Fortington L, Geertzen J, van Netten J, Postema K, Rommers G, Dijkstra P. Short and long term mortality rates after a lower limb amputation. Eur J Vasc Endovasc Surg 2013 Jul;46(1):124-131 [FREE Full text] [doi: 10.1016/j.ejvs.2013.03.024] [Medline: 23628328]
3. Christensen J, Ipsen T, Doherty P, Langberg H. Physical and social factors determining quality of life for veterans with lower-limb amputation(s): a systematic review. Disabil Rehabil 2016 Dec;38(24):2345-2353 [FREE Full text] [doi: 10.3109/09638288.2015.1129446] [Medline: 26985705]
4. Foote CE, Kinnon JM, Robbins C, Pessagno R, Portner MD. Long-term health and quality of life experiences of Vietnam veterans with combat-related limb loss. Qual Life Res 2015 Dec;24(12):2853-2861. [doi: 10.1007/s11136-015-1029-0] [Medline: 26038223]
5. Gowinnage S, Arambepola C. Quality of life and its determinants among community re-integrated soldiers with permanent disabilities following traumatic limb injuries. Qual Life Res 2020 Aug;29(8):2119-2127. [doi: 10.1007/s11136-020-02473-x] [Medline: 32222929]
6. Shahriar SH, Masumi M, Edjtehadi F, Soroush MR, Soveid M, Mousavi B. Cardiovascular risk factors among males with war-related bilateral lower limb amputation. Mil Med 2009 Oct;174(10):1108-1112. [doi: 10.7205/milmed-d-00-0109] [Medline: 19891226]
7. Sinha R, van den Heuvel W, Arokiasamy P. Factors affecting quality of life in lower limb amputees. Prosthet Orthot Int 2011 Mar;35(1):90-96. [doi: 10.1177/0309364610397087] [Medline: 21515894]
8. Farrokhi S, Mazzone B, Schneider M, Gombatto S, Mayer J, Highsmith M, et al. Biopsychosocial risk factors associated with chronic low back pain after lower limb amputation. Med Hypotheses 2017 Oct;108:1-9. [doi: 10.1016/j.mehy.2017.07.030] [Medline: 29055379]
9. Olsen S, Aparicio E, Jaeger P, Howard D. Exploring motivations to be active among amputees: a phenomenological approach to leisure time physical activity. Int J Qual Stud Health Well-being 2023 Dec;18(1):2143053 [FREE Full text] [doi: 10.1080/17482631.2022.2143053] [Medline: 36351569]
10. Keeves J, Hutchison A, D'Cruz K, Anderson S. Social and community participation following traumatic lower limb amputation: an exploratory qualitative study. Disabil Rehabil 2023 Dec;45(26):4404-4412. [doi: 10.1080/09638288.2022.2152114] [Medline: 36448299]
11. Directorate of Rehabilitation. Sri Lanka Army. URL: https://alt.army.lk/rrc/others-institutes [accessed 2024-05-24]
12. Rimmer J, Braddock D. Health promotion for people with physical, cognitive and sensory disabilities: an emerging national priority. Am J Health Promot 2002;16(4):220-4, ii. [doi: 10.4278/0890-1171-16.4.220] [Medline: 11913327]
13. Deans S, McFadyen A, Rowe P. Physical activity and quality of life: A study of a lower-limb amputee population. Prosthet Orthot Int 2008 Jul;32(2):186-200 [FREE Full text] [doi: 10.1080/03093640802016514] [Medline: 18569887]
14. Caspersen C, Powell K, Christenson G. Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research. Public Health Rep 1985;100(2):126-131 [FREE Full text] [Medline: 3920711]
15. Haskell W, Lee I, Pate R, Powell K, Blair S, Franklin B, et al. Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. Med Sci Sports Exerc 2007 Aug;39(8):1423-1434. [doi: 10.1249/mss.0b013e3180616b27] [Medline: 17762377]

16. Lee L, Hitzig S, Mayo A, Devlin M, Dilkas S, MacKay C. Factors influencing physical activity among individuals with lower limb amputations: a qualitative study. Disabil Rehabil 2023 May;45(9):1461-1470. [doi: 10.1080/09638288.2022.2065539] [Medline: 35452590]
17. Miller MJ, Jones J, Anderson CB, Christiansen CL. Factors influencing participation in physical activity after dysvascular amputation: a qualitative meta-synthesis. Disabil Rehabil 2019 Dec;41(26):3141-3150 [FREE Full text] [doi: 10.1080/09638288.2018.1492031] [Medline: 30261758]
18. Batten H, Lamont R, Kuys S, McPhail S, Mandrusiak A. What are the barriers and enablers that people with a lower limb amputation experience when walking in the community? Disabil Rehabil 2020 Dec;42(24):3481-3487. [doi: 10.1080/09638288.2019.1597177] [Medline: 30982367]
19. Littman A, Bouldin E, Haselkorn J. This is your new normal: A qualitative study of barriers and facilitators to physical activity in Veterans with lower extremity loss. Disabil Health J 2017 Oct;10(4):600-606. [doi: 10.1016/j.dhjo.2017.03.004] [Medline: 28377115]
20. Anaforoğlu B, Erbahçeci F, Aksekili M. The effectiveness of a back school program in lowerlimb amputees: a randomized controlled study. Turk J Med Sci 2016 Jul 23;46(4):1122-1129 [FREE Full text] [doi: 10.3906/sag-1503-131] [Medline: 27513414]
21. Demirdel S, Erbahçeci F. Investigation of the effects of dual-task balance training on gait and balance in transfemoral amputees: a randomized controlled trial. Arch Phys Med Rehabil 2020 Oct;101(10):1675-1682. [doi: 10.1016/j.apmr.2020.06.009] [Medline: 32653580]
22. Wijekoon A, Jayawardana S, Milton-Cole R, Chandrathilaka KRM, Jones A, Cook S, et al. Effectiveness and equity in community-based rehabilitation on pain, physical function, and quality of life after unilateral lower limb amputation: a systematic review. Arch Phys Med Rehabil 2023 Oct;104(9):1484-1497 [FREE Full text] [doi: 10.1016/j.apmr.2023.02.009] [Medline: 36893877]
23. Gailey R, Gaunaurd I, Raya M, Kirk-Sanchez N, Prieto-Sanchez L, Roach K. Effectiveness of an evidence-based amputee rehabilitation program: a pilot randomized controlled trial. Phys Ther 2020 May 18;100(5):773-787. [doi: 10.1093/ptj/pzaa008] [Medline: 31951260]
24. Sinha R, Van Den Heuvel WJA. A systematic literature review of quality of life in lower limb amputees. Disabil Rehabil 2011;33(11):883-899. [doi: 10.3109/09638288.2010.514646] [Medline: 20825359]
25. Gunawardena NS, Seneviratne R, Athauda T. Functional outcomes of unilateral lower limb amputee soldiers in two districts of Sri Lanka. Mil Med 2006 May;171(4):283-287. [doi: 10.7205/milmed.171.4.283] [Medline: 16673739]
26. Littman A, Haselkorn J, Arterburn D, Boyko E. Pilot randomized trial of a telephone-delivered physical activity and weight management intervention for individuals with lower extremity amputation. Disabil Health J 2019 Jan;12(1):43-50. [doi: 10.1016/j.dhjo.2018.08.002] [Medline: 30115584]
27. Friel K, Domholdt E, Smith DG. Physical and functional measures related to low back pain in individuals with lower-limb amputation: an exploratory pilot study. J Rehabil Res Dev 2005;42(2):155-166 [FREE Full text] [doi: 10.1682/jrrd.2004.08.0090] [Medline: 15944880]
28. Kumara A. Rehabilitation Management System for the Directorate of Rehabilitation of the Sri Lanka Army. Digital Library of University of Colombo School of Computing. 2015. URL: https://dl.ucsc.cmb.ac.lk/jspui/handle/123456789/2865 [accessed 2024-05-24]
29. Moseholm E, Fetters M. Conceptual models to guide integration during analysis in convergent mixed methods studies. Methodological Innovations 2017 Dec 14;10(2):205979911770311 [FREE Full text] [doi: 10.1177/2059799117703118]
30. Creswell J. Educational Research: Planning, Conducting, and Evaluating Quantitative and Qualitative Research. London, UK: Pearson Education; 2002.
31. Gorman E, Chudyk A, Hoppmann C, Hanson H, Guy P, Sims-Gould J, et al. Exploring older adults' patterns and perceptions of exercise after hip fracture. Physiotherapy Canada 2013 Jan;65(1):86-93 [FREE Full text] [doi: 10.3138/ptc.2012-01bh]
32. Charan J, Biswas T. How to calculate sample size for different study designs in medical research? Indian J Psychol Med 2013 May;35(2):121-126 [FREE Full text] [doi: 10.4103/0253-7176.116232] [Medline: 24049221]
33. Garg R. Methodology for research I. Indian J Anaesth 2016 Oct;60(9):640-645 [FREE Full text] [doi: 10.4103/0019-5049.190619] [Medline: 27729690]
34. Iliyasu R, Etikan I. Comparison of quota sampling and stratified random sampling. Biom Biostat Int J 2021 Feb 25;10(1):24-27 [FREE Full text] [doi: 10.15406/bbij.2021.10.00326]
35. Gailey R, Roach K, Applegate E, Cho B, Cunniffe B, Licht S, et al. The amputee mobility predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate. Arch Phys Med Rehabil 2002 May;83(5):613-627. [doi: 10.1053/apmr.2002.32309] [Medline: 11994800]
36. Vogel TR, Petroski GF, Kruse RL. Impact of amputation level and comorbidities on functional status of nursing home residents after lower extremity amputation. J Vasc Surg 2014 May;59(5):1323-30.e1 [FREE Full text] [doi: 10.1016/j.jvs.2013.11.076] [Medline: 24406089]
37. Ware JE, Sherbourne CD. The MOS 36-ltem Short-Form Health Survey (SF-36). Med Care 1992;30(6):473-483. [doi: 10.1097/00005650-199206000-00002]

38. Craig C, Marshall A, Sjöström M, Bauman A, Booth M, Ainsworth B, et al. International physical activity questionnaire: 12-country reliability and validity. Med Sci Sports Exerc 2003 Aug;35(8):1381-1395. [doi: 10.1249/01.MSS.0000078924.61453.FB] [Medline: 12900694]
39. Dougherty PJ. Long-term follow-up of unilateral transfemoral amputees from the Vietnam war. J Trauma 2003 May;54(4):718-723. [doi: 10.1097/01.TA.0000046260.16866.A9] [Medline: 12707534]
40. Langford J, Dillon M, Granger C, Barr C. Physical activity participation amongst individuals with lower limb amputation. Disabil Rehabil 2019 May;41(9):1063-1070. [doi: 10.1080/09638288.2017.1422031] [Medline: 29303002]
41. Gunawardena NS, Seneviratne RDA, Atauda TA. An approach to validation of a multidimensional tool. J Coll Community Phys Sri Lanka 2003 Dec 30;8(1):18. [doi: 10.4038/jccpsl.v8i1.8302]
42. Arambepola C. Abdominal obesity and its association with selected risk factors of coronary heart disease in an adult population in the district of Colombo. MD Community Medicine. URL: http://archive.cmb.ac.lk:8080/research/bitstream/70130/689/1/117.pdf [accessed 2024-05-24]
43. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implement Sci 2017 Jul 21;12(1):77 [FREE Full text] [doi: 10.1186/s13012-017-0605-9] [Medline: 28637486]
44. Guidelines for data processing analysis of the International Physical Activity Questionnaire (IPAQ) - Short and long forms. IPAQ Research Committee. 2005. URL: https://cir.nii.ac.jp/crid/1573950400545533440 [accessed 2024-05-24]
45. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007 Dec;19(6):349-357. [doi: 10.1093/intqhc/mzm042] [Medline: 17872937]
46. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci 2009 Aug 07;4:50 [FREE Full text] [doi: 10.1186/1748-5908-4-50] [Medline: 19664226]
47. Birken SA, Powell BJ, Presseau J, Kirk MA, Lorencatto F, Gould NJ, et al. Combined use of the Consolidated Framework for Implementation Research (CFIR) and the Theoretical Domains Framework (TDF): a systematic review. Implement Sci 2017 Jan 05;12(1):2 [FREE Full text] [doi: 10.1186/s13012-016-0534-z] [Medline: 28057049]
48. Damschroder L, Reardon C, Lowery J. The Consolidated Framework for Implementation Research (CFIR). In: Nilsen P, Birken SA, editors. Handbook on Implementation Science. Cheltenham, UK: Edward Elgar Publishing; 2020:88-113.
49. Wijekoon A, Gamage Dona D, Jayawardana S. Prevalence of physical health comorbidities and long-term functional outcomes among community-reintegrated veterans following lower limb amputation in Sri Lanka. BMJ Mil Health 2023 Dec 21:1-6. [doi: 10.1136/military-2023-002578] [Medline: 37989534]
50. Knežević A, Salamon T, Milankov M, Ninković S, Jeremić Knežević M, Tomašević Todorović S. Assessment of quality of life in patients after lower limb amputation. Med Pregl 2015;68(3-4):103-108. [doi: 10.2298/mpns1504103k] [Medline: 26214989]
51. Taghipour H, Moharamzad Y, Mafi A, Amini A, Naghizadeh M, Soroush M, et al. Quality of life among veterans with war-related unilateral lower extremity amputation: a long-term survey in a prosthesis center in Iran. J Orthop Trauma 2009 Aug;23(7):525-530. [doi: 10.1097/BOT.0b013e3181a10241] [Medline: 19633463]
52. Schoppen T, Boonstra A, Groothoff JW, Vries DJ, Göeken NH, Eisma WH. Epidemiologic characteristics and quality of life of lower limb amputee patients in adulthood in the Netherlands. In: Schoppen T, editor. Functional Outcome After a Lower Limb Amputation. Groningen: Northern Centre for Healthcare Research; 2002.
53. Hagberg K, Brånemark R. Consequences of non-vascular trans-femoral amputation: a survey of quality of life, prosthetic use and problems. Prosthet Orthot Int 2001 Dec;25(3):186-194 [FREE Full text] [doi: 10.1080/03093640108726601] [Medline: 11860092]
54. Owens J, Blair J, Patzkowski J, Blanck RV, Hsu J, Skeletal Trauma Research Consortium. Return to running and sports participation after limb salvage. J Trauma 2011 Jul;71(1 Suppl):S120-S124. [doi: 10.1097/TA.0b013e3182219225] [Medline: 21795870]
55. Ladlow P, Phillip R, Etherington J, Coppack R, Bilzon J, McGuigan M, et al. Functional and mental health status of United Kingdom military amputees postrehabilitation. Arch Phys Med Rehabil 2015 Nov;96(11):2048-2054 [FREE Full text] [doi: 10.1016/j.apmr.2015.07.016] [Medline: 26254949]
56. Gallagher P, Maclachlan M. The Trinity Amputation and Prosthesis Experience Scales and quality of life in people with lower-limb amputation. Arch Phys Med Rehabil 2004 May;85(5):730-736. [doi: 10.1016/j.apmr.2003.07.009] [Medline: 15129396]
57. Hoekstra F, Hettinga F, den Breejen M, Duijf M, van der Woude L, Dekker R, et al. Professionals' perceptions of factors affecting implementation and continuation of a physical activity promotion programme in rehabilitation: A qualitative study. J Rehabil Med 2017 May 16;49(5):385-394 [FREE Full text] [doi: 10.2340/16501977-2220] [Medline: 28440840]
58. Samdal G, Eide G, Barth T, Williams G, Meland E. Effective behaviour change techniques for physical activity and healthy eating in overweight and obese adults; systematic review and meta-regression analyses. Int J Behav Nutr Phys Act 2017 Mar 28;14(1):42 [FREE Full text] [doi: 10.1186/s12966-017-0494-y] [Medline: 28351367]

59. Michie S, Abraham C. Interventions to change health behaviours: evidence-based or evidence-inspired? Psychology & Health 2004 Feb;19(1):29-49 [FREE Full text] [doi: 10.1080/0887044031000141199]

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

Rahat Jahangir Rony[1], BSc; Shajnush Amir[2], MSc; Nova Ahmed[3], PhD; Samuelson Atiba[4], BTech; Nervo Verdezoto[1], PhD; Valerie Sparkes[5], PhD; Katarzyna Stawarz[1], PhD

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Corresponding Author:
Katarzyna Stawarz, PhD

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

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.

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.

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

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*

> *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

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

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.

References

1. GBD 2016 Traumatic Brain Injury and Spinal Cord Injury Collaborators. Global, regional, and national burden of traumatic brain injury and spinal cord injury, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet Neurol 2019 Jan;18(1):56-87. [doi: 10.1016/S1474-4422(18)30415-0] [Medline: 30497965]

2. GBD 2016 Stroke Collaborators. Global, regional, and national burden of stroke, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet Neurol 2019 May;18(5):439-458. [doi: 10.1016/S1474-4422(19)30034-1] [Medline: 30871944]
3. Chakraborty PK, Islam MJ, Hossain MS, Barua SK, Rahman S. Profile of patients receiving stroke rehabilitation in a tertiary care hospital. Chatt Maa Shi Hosp Med Coll J 2018 Dec 26;17(1):9-12. [doi: 10.3329/cmoshmcj.v17i1.39435]
4. Giustini A, Pistarini C, Pisoni C. Traumatic and nontraumatic brain injury. Handb Clin Neurol 2013;110:401-409. [doi: 10.1016/B978-0-444-52901-5.00034-4] [Medline: 23312659]
5. Wilson BA. Brain injury: recovery and rehabilitation. Wiley Interdiscip Rev Cogn Sci 2010 Jan;1(1):108-118. [doi: 10.1002/wcs.15] [Medline: 26272844]
6. Mlinac ME, Feng MC. Assessment of activities of daily living, self-care, and independence. Arch Clin Neuropsychol 2016 Sep;31(6):506-516. [doi: 10.1093/arclin/acw049] [Medline: 27475282]
7. Jack K, McLean SM, Moffett JK, Gardiner E. Barriers to treatment adherence in physiotherapy outpatient clinics: a systematic review. Man Ther 2010 Jun;15(3):220-228. [doi: 10.1016/j.math.2009.12.004] [Medline: 20163979]
8. Ietswaart M, Johnston M, Dijkerman HC, et al. Mental practice with motor imagery in stroke recovery: randomized controlled trial of efficacy. Brain 2011 May;134(Pt 5):1373-1386. [doi: 10.1093/brain/awr077] [Medline: 21515905]
9. Sunderland A, Tuke A. Neuroplasticity, learning and recovery after stroke: a critical evaluation of constraint-induced therapy. Neuropsychol Rehabil 2005 May;15(2):81-96. [doi: 10.1080/09602010443000047] [Medline: 16353503]
10. Mawson S, Nasr N, Parker J, Davies R, Zheng H, Mountain G. A personalized self-management rehabilitation system with an intelligent shoe for stroke survivors: a realist evaluation. JMIR Rehabil Assist Technol 2016 Jan 7;3(1):e1. [doi: 10.2196/rehab.5079] [Medline: 28582250]
11. Mamin FA, Islam MS, Rumana FS, Faruqui F. Profile of stroke patients treated at a rehabilitation centre in Bangladesh. BMC Res Notes 2017 Oct 27;10(1):520. [doi: 10.1186/s13104-017-2844-x] [Medline: 29078803]
12. Uddin T, Islam M, Rathore F, O'Connell C. Disability and rehabilitation medicine in Bangladesh: current scenario and future perspectives. J Int Soc Phys Rehabil Med 2019;2(4):168-177. [doi: 10.4103/jisprm.jisprm_61_19]
13. Bassett SF. The assessment of patient adherence to physiotherapy rehabilitation. NZ J Physiother 2003 Jul 1;31(2):60-67 [FREE Full text]
14. Bonnechre B, Jansen B, Omelina L, Jan S. Do patients perform their exercises at home and why (not)? A survey on patients' habits during rehabilitation exercises. Ulutas Med J 2016;2(1):41-46. [doi: 10.5455/umj.20160210060312]
15. Sniehotta FF, Scholz U, Schwarzer R. Bridging the intention–behaviour gap: planning, self-efficacy, and action control in the adoption and maintenance of physical exercise. Psychology & Health 2005 Apr;20(2):143-160. [doi: 10.1080/08870440512331317670]
16. Li P. Construction and simulation on intelligent medical equipment system based on virtual reality technology and human-computer interaction model. Int J Biomed Eng Technol 2017;23(2/3/4):213-231. [doi: 10.1504/IJBET.2017.082666]
17. Tognetti A, Lorussi F, Bartalesi R, et al. Wearable kinesthetic system for capturing and classifying upper limb gesture in post-stroke rehabilitation. J Neuroeng Rehabil 2005 Mar 2;2(1):8. [doi: 10.1186/1743-0003-2-8] [Medline: 15743530]
18. Ahmed MS, Amir S, Atiba S, et al. A low-cost Wearable system to support upper limb rehabilitation in resource-constrained settings. In: Tsanas A, Triantafyllidis A, editors. Pervasive Computing Technologies for Healthcare PH 2022 Lecture Notes of the Institute for Computer Sciences, Social Informatics and Telecommunications Engineering, Vol 488: Springer; 2023:33-45. [doi: 10.1007/978-3-031-34586-9]
19. Chen Y, Abel KT, Janecek JT, Chen Y, Zheng K, Cramer SC. Home-based technologies for stroke rehabilitation: a systematic review. Int J Med Inform 2019 Mar;123:11-22. [doi: 10.1016/j.ijmedinf.2018.12.001] [Medline: 30654899]
20. Chae SH, Kim Y, Lee KS, Park HS. Development and clinical evaluation of a web-based upper limb home rehabilitation system using a smartwatch and machine learning model for chronic stroke survivors: prospective comparative study. JMIR Mhealth Uhealth 2020 Jul 9;8(7):e17216. [doi: 10.2196/17216] [Medline: 32480361]
21. Amirabdollahian F, Ates S, Basteris A, et al. Design, development and deployment of a hand/wrist exoskeleton for home-based rehabilitation after stroke - script project. Robotica 2014 Dec;32(8):1331-1346. [doi: 10.1017/S0263574714002288]
22. McCabe J, Monkiewicz M, Holcomb J, Pundik S, Daly JJ. Comparison of robotics, functional electrical stimulation, and motor learning methods for treatment of persistent upper extremity dysfunction after stroke: a randomized controlled trial. Arch Phys Med Rehabil 2015 Jun;96(6):981-990. [doi: 10.1016/j.apmr.2014.10.022] [Medline: 25461822]
23. Maciejasz P, Eschweiler J, Gerlach-Hahn K, Jansen-Troy A, Leonhardt S. A survey on robotic devices for upper limb rehabilitation. J Neuroeng Rehabil 2014 Jan 9;11:3. [doi: 10.1186/1743-0003-11-3] [Medline: 24401110]
24. Low KS, Lee GX, Taher T. A wearable wireless sensor network for human limbs monitoring. Presented at: IEEE Instrumentation and Measurement Technology Conference; May 5 to 7, 2009; Singapore. [doi: 10.1109/IMTC.2009.5168662]
25. Maceira-Elvira P, Popa T, Schmid AC, Hummel FC. Wearable technology in stroke rehabilitation: towards improved diagnosis and treatment of upper-limb motor impairment. J Neuroeng Rehabil 2019 Nov 19;16(1):142. [doi: 10.1186/s12984-019-0612-y] [Medline: 31744553]

26. Anowar J, Ali AA, Amin MA. A low-cost wearable rehabilitation device. In: Proceedings of the 2020 12th International Conference on Computer and Automation Engineering: Association for Computing Machinery; 2020:125-128. [doi: 10.1145/3384613.3384628]
27. Hughes CML, Louie A, Sun S, et al. Development of a post-stroke upper limb rehabilitation wearable sensor for use in sub-Saharan Africa: a pilot validation study. Front Bioeng Biotechnol 2019;7:322. [doi: 10.3389/fbioe.2019.00322] [Medline: 31781556]
28. Ploderer B, Fong J, Withana A, et al. Armsleeve: a patient monitoring system to support occupational therapists in stroke rehabilitation. In: Proceedings of the 2016 ACM Conference on Designing Interactive Systems: Association for Computing Machinery; 2016:700-711. [doi: 10.1145/2901790.2901799]
29. Yardley L, Morrison L, Bradbury K, Muller I, Yardley L. The person-based approach to intervention development: application to digital health-related behavior change interventions. J Med Internet Res 2015 Jan 30;17(1):e30. [doi: 10.2196/jmir.4055] [Medline: 25639757]
30. Preece J, Sharp H, Rogers Y. Interaction Design: Beyond Human-Computer Interaction: John Wiley & Sons; 2015.
31. Etikan I, Musa SA, Alkassim RS. Comparison of convenience sampling and purposive sampling. Am J Theor Appl Stat 2016;5(1):1. [doi: 10.11648/j.ajtas.20160501.11]
32. Ritchie J, Lewis J, Nicholls CM, Ormston R, editors. Qualitative Research Practice: A Guide for Social Science Students and Researchers: Sage; 2013.
33. Rigby JM, Stawarz K, Preist C, et al. Exploring the information needs of Somaliland pastoralists: design considerations for digital climate adaptation services. In: DIS '23: Proceedings of the 2023 ACM Designing Interactive Systems Conference: Association for Computing Machinery; 2023:1548-1565. [doi: 10.1145/3563657.3596061]
34. Lu X, Jo E, Park S, Hong H, Chen Y, Epstein DA. Understanding cultural influence on perspectives around contact tracing strategies. Proc ACM Hum-Comput Interact 2022 Nov 7;6(CSCW2):1-26. [doi: 10.1145/3555569]
35. Stenberg G, Ahlgren C. A gender perspective on physiotherapy treatment in patients with neck and back pain. Adv Physiother 2010 Jan;12(1):35-41. [doi: 10.3109/14038190903174270]
36. Stenberg G, Fjellman-Wiklund A, Strömbäck M, et al. Gender matters in physiotherapy. Physiother Theory Pract 2022 Nov;38(13):2316-2329. [doi: 10.1080/09593985.2021.1970867] [Medline: 34470538]
37. Giaquinto S, Sarno S, Dall'Armi V, Spiridigliozzi C. Religious and spiritual beliefs in stroke rehabilitation. Clin Exp Hypertens 2010;32(6):329-334. [doi: 10.3109/10641960903443566] [Medline: 21028994]
38. Rennick-Egglestone S, Mawson S. Homes of stroke survivors are a challenging environment for rehabilitation technologies. JMIR Rehabil Assist Technol 2021 Jun 17;8(2):e12029. [doi: 10.2196/12029] [Medline: 34137728]
39. Kerr A, Smith M, Reid L, Baillie L. Adoption of stroke rehabilitation technologies by the user community: qualitative study. JMIR Rehabil Assist Technol 2018 Aug 17;5(2):e15. [doi: 10.2196/rehab.9219] [Medline: 30120086]
40. Rausch AK, Baur H, Reicherzer L, et al. Physiotherapists' use and perceptions of digital remote physiotherapy during COVID-19 lockdown in Switzerland: an online cross-sectional survey. Arch Physiother 2021 Jul 7;11(1):18. [doi: 10.1186/s40945-021-00112-3] [Medline: 34233763]
41. Stock R, Gaarden AP, Langørgen E. The potential of wearable technology to support stroke survivors' motivation for home exercise - focus group discussions with stroke survivors and physiotherapists. Physiother Theory Pract 2023 May 29:1-12. [doi: 10.1080/09593985.2023.2217987] [Medline: 37246716]
42. Islam MN, Khan NI, Inan TT, Sarker IH. Designing user interfaces for illiterate and semi-literate users: a systematic review and future research agenda. Sage Open 2023 Apr;13(2). [doi: 10.1177/21582440231172741]
43. Dunphy E, Hamilton FL, Spasić I, Button K. Acceptability of a digital health intervention alongside physiotherapy to support patients following anterior cruciate ligament reconstruction. BMC Musculoskelet Disord 2017 Nov 21;18(1):471. [doi: 10.1186/s12891-017-1846-0] [Medline: 29162071]
44. Antonio MG, Williamson A, Kameswaran V, et al. Targeting patients' cognitive load for telehealth video visits through student-delivered helping sessions at a United States federally qualified health center: equity-focused, mixed methods pilot intervention study. J Med Internet Res 2023 Feb 1;25(1):e42586. [doi: 10.2196/42586] [Medline: 36525332]
45. Sultana S, Guimbretière F, Sengers P, Dell N. Design within a patriarchal society: opportunities and challenges in designing for rural women in Bangladesh. In: CHI '18: Proceedings of the 2018 CHI Conference on Human Factors in Computing Systems: Association for Computing Machinery; 2018:1-13. [doi: 10.1145/3173574.3174110]
46. Bhat KS, Kumar N. Sociocultural dimensions of tracking health and taking care. Proc ACM Hum-Comput Interact 2020 Oct 14;4(CSCW2):1-24. [doi: 10.1145/3415200]
47. Alsswey A, Al-Samarraie H. Elderly users' acceptance of mHealth user interface (UI) design-based culture: the moderator role of age. J Multimodal User Interfaces 2020 Mar;14(1):49-59. [doi: 10.1007/s12193-019-00307-w]
48. Villada Castillo JF, Montoya Vega MF, Muñoz Cardona JE, et al. Design of virtual reality exergames for upper limb stroke rehabilitation following iterative design methods: usability study. JMIR Serious Games 2024 Jan 11;12:e48900. [doi: 10.2196/48900] [Medline: 38206670]
49. Wu AY, Munteanu C. Understanding older users' acceptance of wearable interfaces for sensor-based fall risk assessment. In: CHI '18: Proceedings of the 2018 CHI Conference on Human Factors in Computing Systems: Association for Computing Machinery; 2018:1-13. [doi: 10.1145/3173574.3173693]

50. Jacklin K, Pitawanakwat K, Blind M, Lemieux AM, Sobol A, Warry W. Peace of mind: a community-industry-academic partnership to adapt dementia technology for Anishinaabe communities on Manitoulin Island. J Rehabil Assist Technol Eng 2020 Sep;7. [doi: 10.1177/2055668320958327] [Medline: 32999732]
51. Stawarz K, Preist C, Tallon D, et al. Design considerations for the integrated delivery of cognitive behavioral therapy for depression: user-centered design study. JMIR Ment Health 2020 Sep 3;7(9):e15972. [doi: 10.2196/15972] [Medline: 32880580]
52. Stawarz K, Liang IJ, Alexander L, Carlin A, Wijekoon A, Western MJ. Exploring the potential of technology to promote exercise snacking for older adults who are prefrail in the home setting: user-centered design study. JMIR Aging 2023 May 24;6(1):e41810. [doi: 10.2196/41810] [Medline: 37223992]
53. Caine K. Local standards for sample size at CHI. In: CHI '16: Proceedings of the 2016 CHI Conference on Human Factors in Computing Systems: Association for Computing Machinery; 2016:981-992. [doi: 10.1145/2858036.2858498]

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

Saloni Butala[1], BS; Pearl Valentine Galido[1], BS, BA; Benjamin K P Woo[2], BSE, MD

[1]College of Osteopathic Medicine of the Pacific, Western University of Health Sciences, Pomona, CA, United States

[2]Chinese American Health Promotion Laboratory, University of California, Los Angeles, Los Angeles, CA, United States

Corresponding Author:
Saloni Butala, BS
College of Osteopathic Medicine of the Pacific
Western University of Health Sciences
309 E Second Street
Pomona, CA, 91766
United States
Phone: 1 310 765 0324
Email: salonibutala96@g.ucla.edu

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.

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.

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.*

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

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

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.

References

1. Putukian M. The psychological response to injury in student athletes: a narrative review with a focus on mental health. Br J Sports Med 2016;50(3):145-148 [FREE Full text] [doi: 10.1136/bjsports-2015-095586] [Medline: 26719498]
2. Smith AB, Cooper S, Hanning J, Buckley C. The humanistic and economic burden of work-related musculoskeletal pain: a cross-sectional survey of workers in the United Kingdom. BMC Res Notes 2023;16(1):186 [FREE Full text] [doi: 10.1186/s13104-023-06461-5] [Medline: 37620927]
3. Blyth FM, Noguchi N. Chronic musculoskeletal pain and its impact on older people. Best Pract Res Clin Rheumatol 2017;31(2):160-168. [doi: 10.1016/j.berh.2017.10.004] [Medline: 29224694]
4. de Melo Espirito Santo C, Santos VS, Kamper SJ, Williams CM, Miyamoto GC, Yamato TP. Overview of the economic burden of musculoskeletal pain in children and adolescents: a systematic review with meta-analysis. Pain 2023;165(2):296-323. [doi: 10.1097/j.pain.0000000000003037] [Medline: 37755391]
5. Vassilaki M, Hurwitz EL. Insights in public health: perspectives on pain in the low back and neck: global burden, epidemiology, and management. Hawaii J Med Public Health 2014;73(4):122-126 [FREE Full text] [Medline: 24765562]
6. Sams L, Langdown BL, Simons J, Vseteckova J. The effect of percussive therapy on musculoskeletal performance and experiences of pain: a systematic literature review. Int J Sports Phys Ther 2023;18(2):309-327 [FREE Full text] [doi: 10.26603/001c.73795] [Medline: 37020441]
7. Peloquin K, Barnhardt M, Behling G, Braun S. The immediate effect of percussion myofascial release therapy on hamstring flexibility and hip flexion range of motion among active young adults. Int J Res Ex Phys 2022;17(2):48-61 [FREE Full text]
8. Bordoni B, Sugumar K, Varacallo M. Myofascial Pain. Treasure Island, FL: StatPearls Publishing; 2023.
9. Schleip R, Müller DG. Training principles for fascial connective tissues: scientific foundation and suggested practical applications. J Bodyw Mov Ther 2013;17(1):103-115. [doi: 10.1016/j.jbmt.2012.06.007] [Medline: 23294691]
10. Konrad A, Glashüttner C, Reiner MM, Bernsteiner D, Tilp M. The acute effects of a percussive massage treatment with a hypervolt device on plantar flexor muscles' range of motion and performance. J Sports Sci Med 2020;19(4):690-694 [FREE Full text] [Medline: 33239942]

11. Li Q, Liu P, Wang Z, Li X. Vibration therapy to improve pain and function in patients with chronic low back pain: a systematic review and meta-analysis. J Orthop Surg Res 2023;18(1):727 [FREE Full text] [doi: 10.1186/s13018-023-04217-2] [Medline: 37752526]
12. Wang SQ, Jiang AY, Gao Q. Effect of manual soft tissue therapy on the pain in patients with chronic neck pain: a systematic review and meta-analysis. Complement Ther Clin Pract 2022;49:101619. [doi: 10.1016/j.ctcp.2022.101619] [Medline: 35988324]
13. Jurecka A, Papież M, Skucińska P, Gądek A. Evaluating the effectiveness of soft tissue therapy in the treatment of disorders and postoperative conditions of the knee joint-a systematic review. J Clin Med 2021;10(24):5944 [FREE Full text] [doi: 10.3390/jcm10245944] [Medline: 34945240]
14. Im D, Pyo J, Lee H, Jung H, Ock M. Qualitative research in healthcare: data analysis. J Prev Med Public Health 2023;56(2):100-110 [FREE Full text] [doi: 10.3961/jpmph.22.471] [Medline: 37055353]
15. Nowell LS, Norris JM, White DE, Moules NJ. Thematic analysis. Int J Qual Methods 2017;16(1):1-13 [FREE Full text] [doi: 10.1177/1609406917733847]
16. Roberts K, Dowell A, Nie J. Attempting rigour and replicability in thematic analysis of qualitative research data; a case study of codebook development. BMC Med Res Methodol 2019;19(1):66 [FREE Full text] [doi: 10.1186/s12874-019-0707-y] [Medline: 30922220]
17. Chong KPL, Guo JZ, Deng X, Woo BKP. Consumer perceptions of wearable technology devices: retrospective review and analysis. JMIR Mhealth Uhealth 2020;8(4):e17544 [FREE Full text] [doi: 10.2196/17544] [Medline: 32310148]
18. Vollero A, Sardanelli D, Siano A. Exploring the role of the Amazon effect on customer expectations: an analysis of user-generated content in consumer electronics retailing. J Consum Behav 2021;22(5):1062-1073 [FREE Full text] [doi: 10.1002/cb.1969]
19. Zhu P, Woo BKP. Nonprescription products of internet retailers for the prevention and management of herpes zoster and postherpetic neuralgia: analysis of consumer reviews on Amazon. JMIR Dermatol 2021;4(1):e24971 [FREE Full text] [doi: 10.2196/24971] [Medline: 37632802]
20. Chung S, Woo BK. Using consumer perceptions of a voice-activated speaker device as an educational tool. JMIR Med Educ 2020;6(1):e17336 [FREE Full text] [doi: 10.2196/17336] [Medline: 32329740]
21. Pomarensky M, Macedo L, Carlesso L. Management of chronic musculoskeletal pain through a biopsychosocial lens. J Athl Train 2022;57(4):312-318 [FREE Full text] [doi: 10.4085/1062-6050-0521.20] [Medline: 35439311]
22. Woolf AD, Erwin J, March L. The need to address the burden of musculoskeletal conditions. Best Pract Res Clin Rheumatol 2012;26(2):183-224. [doi: 10.1016/j.berh.2012.03.005] [Medline: 22794094]
23. Gorasso V, Van der Heyden J, De Pauw R, Pelgrims I, De Clercq EM, De Ridder K, et al. The health and economic burden of musculoskeletal disorders in Belgium from 2013 to 2018. Popul Health Metr 2023;21(1):4 [FREE Full text] [doi: 10.1186/s12963-023-00303-z] [Medline: 37085871]
24. Shivakumar M, Welsh V, Bajpai R, Helliwell T, Mallen C, Robinson M, et al. Musculoskeletal disorders and pain in agricultural workers in low- and middle-income countries: a systematic review and meta-analysis. Rheumatol Int 2023 [FREE Full text] [doi: 10.1007/s00296-023-05500-5] [Medline: 37999798]
25. Aegerter AM, Deforth M, Volken T, Johnston V, Luomajoki H, Dressel H, et al. A multi-component intervention (NEXpro) reduces neck pain-related work productivity loss: a randomized controlled trial among Swiss office workers. J Occup Rehabil 2023;33(2):288-300 [FREE Full text] [doi: 10.1007/s10926-022-10069-0] [Medline: 36167936]
26. Harcombe H, McBride D, Derrett S, Gray A. Prevalence and impact of musculoskeletal disorders in New Zealand nurses, postal workers and office workers. Aust N Z J Public Health 2009;33(5):437-441 [FREE Full text] [doi: 10.1111/j.1753-6405.2009.00425.x] [Medline: 19811479]
27. Silva L, Costa N, Rosa CS, Paulo II, da Silva NM, Giracca C, et al. Ergonomic assessment of postal workers' pain symptoms and musculoskeletal risks related to parcel processing activity for delivery. EXCLI J 2022;21:744-756 [FREE Full text] [doi: 10.17179/excli2022-4857] [Medline: 35721575]
28. García-Sillero M, Jurado-Castro JM, Benítez-Porres J, Vargas-Molina S. Acute effects of a percussive massage treatment on movement velocity during resistance training. Int J Environ Res Public Health 2021;18(15):7726 [FREE Full text] [doi: 10.3390/ijerph18157726] [Medline: 34360032]
29. Ferreira RM, Silva R, Vigário P, Martins PN, Casanova F, Fernandes RJ, et al. The effects of massage guns on performance and recovery: a systematic review. J Funct Morphol Kinesiol 2023;8(3):138 [FREE Full text] [doi: 10.3390/jfmk8030138] [Medline: 37754971]
30. Mbue ND, Wang W. Nurses' experience with chronic foot pain and their job-the national science foundation foot health survey. Heliyon 2023;9(3):e14485 [FREE Full text] [doi: 10.1016/j.heliyon.2023.e14485] [Medline: 36967960]
31. Snodgrass SJ, Weerasekara I, Edwards S, Heneghan NR, Puentedura EJ, James C. Relationships between the physical work environment, postures and musculoskeletal pain during COVID-19: a survey of frequent computer users. J Occup Environ Med 2022;64(11):e782-e791 [FREE Full text] [doi: 10.1097/JOM.0000000000002698] [Medline: 36075375]
32. Ye S, Jing Q, Wei C, Lu J. Risk factors of non-specific neck pain and low back pain in computer-using office workers in China: a cross-sectional study. BMJ Open 2017;7(4):e014914 [FREE Full text] [doi: 10.1136/bmjopen-2016-014914] [Medline: 28404613]

33. Cheatham SW, Baker RT, Behm DG, Stull K, Kolber MJ. Mechanical percussion devices: a survey of practice patterns among healthcare professionals. Int J Sports Phys Ther 2021;16(3):766-777 [FREE Full text] [doi: 10.26603/001c.23530] [Medline: 35382115]
34. Imtiyaz S, Veqar Z, Shareef MY. To compare the effect of vibration therapy and massage in prevention of Delayed Onset Muscle Soreness (DOMS). J Clin Diagn Res 2014;8(1):133-136 [FREE Full text] [doi: 10.7860/JCDR/2014/7294.3971] [Medline: 24596744]
35. Veqar Z, Imtiyaz S. Vibration therapy in management of Delayed Onset Muscle Soreness (DOMS). J Clin Diagn Res 2014;8(6):LE01-LE04 [FREE Full text] [doi: 10.7860/JCDR/2014/7323.4434] [Medline: 25121012]
36. Furie K, Park AL, Wong SE. Mental health and involuntary retirement from sports post-musculoskeletal injury in adult athletes: a systematic review. Curr Rev Musculoskelet Med 2023;16(5):211-219 [FREE Full text] [doi: 10.1007/s12178-023-09830-6] [Medline: 37014610]
37. Marconcin P, Silva AL, Flôres F, Nunes A, Lourenço JF, Peralta M, et al. Association between musculoskeletal injuries and depressive symptoms among athletes: a systematic review. Int J Environ Res Public Health 2023;20(12):6130 [FREE Full text] [doi: 10.3390/ijerph20126130] [Medline: 37372717]
38. Sabol J, Kane C, Wilhelm MP, Reneker JC, Donaldson MB. The comparative mental health responses between post-musculoskeletal injury and post-concussive injury among collegiate athletes: a systematic review. Int J Sports Phys Ther 2021;16(1):1-11 [FREE Full text] [doi: 10.26603/001c.18682] [Medline: 33604129]
39. Wally MK, Hsu JR, Seymour RB. Musculoskeletal pain management and patient mental health and well-being. J Orthop Trauma 2022;36(Suppl 5):S19-S24 [FREE Full text] [doi: 10.1097/BOT.0000000000002457] [Medline: 36121327]
40. Cross SJ, Gill DL, Brown PK, Reifsteck EJ. Prior injury, health-related quality of life, disablement, and physical activity in former women's soccer players. J Athl Train 2022;57(1):92-98 [FREE Full text] [doi: 10.4085/1062-6050-0731.20] [Medline: 34185853]
41. Gimigliano F, Resmini G, Moretti A, Aulicino M, Gargiulo F, Gimigliano A, et al. Epidemiology of musculoskeletal injuries in adult athletes: a scoping review. Medicina (Kaunas) 2021;57(10):1118 [FREE Full text] [doi: 10.3390/medicina57101118] [Medline: 34684155]
42. Kerr ZY, Marshall SW, Dompier TP, Corlette J, Klossner DA, Gilchrist J. College sports-related injuries—United States, 2009-10 through 2013-14 academic years. MMWR Morb Mortal Wkly Rep 2015;64(48):1330-1336 [FREE Full text] [doi: 10.15585/mmwr.mm6448a2] [Medline: 26655724]
43. Coluccia A, Pozza A, Gusinu R, Gualtieri G, Muzii VF, Ferretti F. Do patients with chronic low-back pain experience a loss of health-related quality of life? A protocol for a systematic review and meta-analysis. BMJ Open 2020;10(2):e033396 [FREE Full text] [doi: 10.1136/bmjopen-2019-033396] [Medline: 32041856]
44. Kohrt BA, Griffith JL, Patel V. Chronic pain and mental health: integrated solutions for global problems. Pain 2018;159 Suppl 1(Suppl 1):S85-S90 [FREE Full text] [doi: 10.1097/j.pain.0000000000001296] [Medline: 30113952]
45. Ahmed H, Saeed MA, Attique F. The burden of musculoskeletal pain, associated sociodemographic factors, and disability in Pakistan. Int J Rheum Dis 2023. [doi: 10.1111/1756-185X.14972] [Medline: 37997543]
46. Nephew BC, Incollingo Rodriguez AC, Melican V, Polcari JJ, Nippert KE, Rashkovskii M, et al. Depression predicts chronic pain interference in racially diverse, income-disadvantaged patients. Pain Med 2022;23(7):1239-1248 [FREE Full text] [doi: 10.1093/pm/pnab342] [Medline: 34908146]
47. Newman AK, Kapoor S, Thorn BE. Health care utilization for chronic pain in low-income settings. Pain Med 2018;19(12):2387-2397 [FREE Full text] [doi: 10.1093/pm/pny119] [Medline: 29905879]
48. Turner BJ, Rodriguez N, Valerio MA, Liang Y, Winkler P, Jackson L. Less exercise and more drugs: how a low-income population manages chronic pain. Arch Phys Med Rehabil 2017;98(11):2111-2117 [FREE Full text] [doi: 10.1016/j.apmr.2017.02.016] [Medline: 28341586]
49. Chen J, Zhang F, Chen H, Pan H. Rhabdomyolysis after the use of percussion massage gun: a case report. Phys Ther 2021;101(1):pzaa199 [FREE Full text] [doi: 10.1093/ptj/pzaa199] [Medline: 33156927]
50. Sulkowski K, Grant G, Brodie T. Case report: vertebral artery dissection after use of handheld massage gun. Clin Pract Cases Emerg Med 2022;6(2):159-161 [FREE Full text] [doi: 10.5811/cpcem.2022.2.56046] [Medline: 35701359]
51. Mu J, Fan W. Lens subluxation after use of a percussion massage gun: a case report. Medicine (Baltimore) 2022;101(49):e31825 [FREE Full text] [doi: 10.1097/MD.0000000000031825] [Medline: 36626450]
52. Needs D, Blotter J, Cowan M, Fellingham G, Johnson AW, Feland JB. Effect of localized vibration massage on popliteal blood flow. J Clin Med 2023;12(5):2047 [FREE Full text] [doi: 10.3390/jcm12052047] [Medline: 36902835]
53. Szymczyk P, Węgrzynowicz K, Trybulski R, Spieszny M, Ewertowska P, Wilk M, et al. Acute effects of percussive massage treatment on drop jump performance and achilles tendon stiffness. Int J Environ Res Public Health 2022;19(22):15187 [FREE Full text] [doi: 10.3390/ijerph192215187] [Medline: 36429903]
54. Yang C, Huang X, Li Y, Sucharit W, Sirasaporn P, Eungpinichpong W. Acute effects of percussive massage therapy on thoracolumbar fascia thickness and ultrasound echo intensity in healthy male individuals: a randomized controlled trial. Int J Environ Res Public Health 2023;20(2):1073 [FREE Full text] [doi: 10.3390/ijerph20021073] [Medline: 36673829]
55. Woo BKP. Effects of traditional Chinese exercises on geriatric mental health. Sleep Breath 2023 [FREE Full text] [doi: 10.1007/s11325-023-02906-0] [Medline: 37592112]

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Original Paper

Technology Use for Home-Based Stroke Rehabilitation in Switzerland From the Perspectives of Persons Living With Stroke, Informal Caregivers, and Therapists: Qualitative Interview and Focus Group Study

Lena Sauerzopf[1,2], MSc; Andreas Luft[3], Prof Dr Med; Valeria Maeusli[1], BScPT; Verena Klamroth-Marganska[4], Dr Med; Michael Sy[1], PhD; Martina Rebekka Spiess[1], Prof Dr

[1]Institute of Occupational Therapy, School of Health Sciences, ZHAW Zurich University of Applied Sciences, Winterthur, Switzerland

[2]Faculty of Medicine, University of Zurich, Zurich, Switzerland

[3]Division of Vascular Neurology and Neurorehabilitation, Department of Neurology, University of Zurich, Zurich, Switzerland

[4]Rehaklinik Bellikon, Bellikon, Switzerland

Corresponding Author:
Lena Sauerzopf, MSc
Institute of Occupational Therapy
School of Health Sciences
ZHAW Zurich University of Applied Sciences
Katharina-Sulzer-Platz 9
Winterthur, 8401
Switzerland
Phone: 41 58 934 44 56
Email: lena.sauerzopf@zhaw.ch

Abstract

Background: Stroke is a leading cause for long-term disability, requiring both inpatient and outpatient rehabilitation and self-training in the home environment. Technology-based tools are gradually gaining acceptance as additional and suitable options for extending the rehabilitation process. While the experiences of persons living with stroke, therapists, and informal caregivers with respect to technology use have already been investigated in other countries, this topic is underexplored in the Swiss context.

Objective: We aimed to explore the experiences and needs of persons living with stroke, informal caregivers, and therapists in using technology-based tools in a home environment for stroke rehabilitation in Switzerland.

Methods: This study followed a qualitative descriptive methodology, including semistructured interviews and focus group discussions. We applied a deductive template analysis alongside the accessibility, adaptability, accountability, and engagement framework to analyze the qualitative data sets for technology-assisted solutions for poststroke rehabilitation.

Results: We collected the experiences and needs of persons living with stroke (7/23, 30%), informal caregivers (4/23, 17%), and therapists (occupational and physical therapists; 12/23, 52%). The 4 categories we used to organize the analysis and results were *accessibility to quality rehabilitation*, *adaptability to patient differences*, *accountability or compliance with rehabilitation*, and *engagement with rehabilitation*. Persons living with stroke stated that they use various tools within their rehabilitation process depending on their specific needs. They felt that there is a plethora of tools available but sometimes felt overwhelmed with the selection process. Informal caregivers indicated that they generally felt underserved and insufficiently informed throughout the rehabilitation process. They reported that they use technology-based tools to support their relatives affected by stroke in becoming more independent. Therapists appreciate the numerous possible applications of technology-based tools in rehabilitation. At the same time, however, they express dissatisfaction with the lack of clarity in Switzerland regarding cost coverage, recommendations, and training opportunities.

Conclusions: Persons living with stroke, informal caregivers, and therapists in Switzerland reported varied and unique experiences and needs with the use of technology-based tools in outpatient stroke rehabilitation. Written recommendations, the assumption of financial costs, and the provision of information and education could foster increased confidence in the use of technology-based tools for patients and therapists.

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KEYWORDS

home-based therapy; technology-based tools; app; stroke; outpatient rehabilitation; occupational therapy; physiotherapy; mobile phone

Introduction

Background

Persons living with stroke frequently face persistent limitations in various domains, such as motor function and cognition, influencing daily life activities and participation [1]. Therefore, a considerable proportion of these individuals require long-term outpatient and home-based therapeutic interventions [2]. Previous research highlights that the use of technology-based tools at home can serve as a means to complement non–technology-based therapy in stroke rehabilitation [3].

For example, mobile apps are often used in combination with wearable sensors to increase therapy intensity and adherence to home exercise programs [4-6]. Other technologies, such as virtual reality serious games, augmented reality scenarios, and wearable sensors, allow the asynchronous monitoring of the recovery process and synchronous connections between health care providers and patients and provide education for clients or informal caregivers [7,8]. These examples illustrate the versatile use of technology-based tools for stroke rehabilitation for the home setting.

Previous research also indicates that such rehabilitation services, delivered through information and communication technology (ICT) and technology-based tools, result in comparable outcomes to those achieved through non–technology-based rehabilitation [9]. This leads to the fact that professional associations and health organizations advocate for the use of technology-based tools in rehabilitation [10-12]. Specifically, in their Regional Digital Health Action Plan for the European Region 2023-2030, the World Health Organization supports the continuous promotion and expansion of digital solutions to enhance health outcomes for all individuals and to push forward digital transformation [12,13].

Context of Practice

The needs and experiences of at least occupational and physical therapists and survivors of stroke with regard to technology-based tools for the home-based setting have been investigated in other countries already [14-16].

One study [14] explored how physical and occupational therapists in Denmark view using ICT, such as apps, in stroke rehabilitation. They found that ICT could improve communication, documentation, and overall rehabilitation by empowering survivors of stroke and caregivers, facilitating follow-up care, and enhancing communication across sectors [14]. This study delved into the design needs for at-home poststroke rehabilitation robots in Ontario, Canada, contrasting perspectives between survivors of stroke and therapists. Through interviews with both groups, key design recommendations, potential features, and barriers emerged, highlighting the importance of incorporating the insights of survivors of stroke into home environments and therapists' expertise in therapy methodology and safety. The findings underscored the necessity of tailored design approaches that consider a range of impairments, incorporate household items, and address individual motion requirements [15]. Another study [16] investigated Swedish health care professionals' use of ICT for person-centered stroke rehabilitation. Findings suggest that integrating ICT could enhance collaboration between patients and therapists, as well as patient participation, guiding the development of a multidisciplinary intervention [16].

In Switzerland, the health care system is characterized by its federalist structure and combines both private and public elements. The quality of this health care system is considered very high [17]. However, the digitalization of health care, including rehabilitation, is still in its early stages [18]. Traditionally, inpatient stays in acute hospitals in Switzerland have been comparatively long, averaging 17 days [19]. Recently, a shift to a shorter length of inpatient stays and earlier outpatient treatment is visible as a trend to counteract high and increasingly high health care costs [18]. Because of this transition, we need new solutions. The use of technology-based tools is one possibility. This transition holds potential for the use of technology-based tools in outpatient and home-based stroke rehabilitation.

For the successful development and implementation of technology-based instruments, the needs and experiences of relevant groups are essential and should be considered. Research indicates that technology adoption depends on the perceived utility of the target groups [20]. However, today, most health care technologies are still designed *for* the target group rather than *cocreated with* the target group, leading to reduced rates of technology uptake [21]. A true user-centered, cocreative design approach emphasizes the relevance of investigating the experiences and needs of the person who will use these tools. In health care, and thus in stroke rehabilitation, we have the special case of having several user groups. Users include not only persons living with stroke and therapists (eg, occupational and physical therapists) but also informal caregivers. Informal caregivers are, for example, spouses, partners, and (adult) children. These are individuals who often provide their support without or with minimal reimbursement and specialized education. Their responsibilities span a wide range of tasks, from offering basic aid in daily activities (instrumental caregiving) to playing more complex roles such as coordinating health care requirements [22].

The lack of research on the use of technology in home-based stroke rehabilitation in Switzerland poses a challenge to obtaining a comprehensive understanding of the specific needs, experiences, and potential benefits and barriers in the Swiss context. It is unclear how far the needs and experiences of involved individuals in Switzerland are similar to those in other countries (translate over different health systems).

In this study, we aim to investigate the needs and experiences of persons living with stroke, therapists, and informal caregivers with regard to the use of technology-based tools in home-based stroke rehabilitation in Switzerland. We aim to provide a basis for the user-centered development of technology-based tools to support home-based stroke rehabilitation. Therefore, in this study, we sought to answer the following research question: What are the experiences and needs of persons living with stroke, informal caregivers, and therapists in using technology-based tools in home-based stroke rehabilitation within the Swiss context?

Methods

Design

We chose a qualitative, descriptive methodology approach using semistructured interviews and focus group discussions. This study followed a deductive template analysis (TA), in which the qualitative data sets were analyzed using the so-called *accessibility*, *adaptability*, *accountability*, and *engagement* (A3E) framework for technology-assisted solutions for poststroke rehabilitation [23-25]. We considered the A3E framework to be appropriate for the aim of our study, as the themes are addressing existing barriers in delivering technology-assisted stroke rehabilitation and potential solutions to enhance stroke rehabilitation through technology [17]. While inductive content analysis is used when no previous research has dealt with the phenomenon, deductive content analysis is used, for example, when an existing theory is tested in a new situation [26]. Because we are referring to an existing framework and comparable research has already been conducted in other geographical contexts, we considered a deductive approach to be suitable for this study. Furthermore, the pragmatic design of this approach makes it suitable for questions regarding the health environment and descriptions of the experiences and needs of the target group [27,28].

Participant Selection

The sample comprised 3 cohorts: persons living with stroke, informal caregivers of persons living with stroke, and therapists of persons living with stroke. All participants from these 3 cohorts were required to speak Standard German or Swiss German and provide informed consent to participate in the study. We included persons living with stroke if they (1) were aged >18 years, (2) had a history of stroke in the past, (3) were currently living in a home-based setting, (4) were currently undergoing or had undergone outpatient therapy, and (5) were able to participate in an interview or discussion lasting at least 30 minutes. We included informal caregivers of persons living with stroke if they (1) were adult informal caregivers, (2) were currently living in the same household with a person living with stroke, and (3) were currently or had been involved in the outpatient rehabilitation process of this person living with stroke. Therapists were needed to (1) have experience in the treatment of persons living with stroke, (2) work in outpatient rehabilitation, and (3) have a professional background as occupational therapists or physical therapists or in a related therapeutic field (eg, sports therapy).

We recruited participants using a combination of email and telephone outreach through snowball sampling, contacting the patient's and informal caregiver's organization, rehabilitation clinics, outpatient therapy practices, therapists, or personal contacts of persons of 1 of the 3 cohorts. We spread a call for participation through the newsletter of the ZHAW Zurich University of Applied Sciences, School of Health Sciences. Individuals interested in participating in the study were encouraged to contact the research team. Comprehensive details regarding the research project, data security, data storage, and data processing were provided.

We inquired about the participants' preferences for data collection methods, providing options for both face-to-face and web-based settings. Most people in all cohorts expressed a preference for the web-based setting (20/23, 87%). In the end, only focus group 1 (3/23, 13%) of persons living with stroke took place in person at a rehabilitation clinic in Switzerland. In addition, we proposed the option of individual interviews. This possibility was frequently favored due to its flexibility. It was more compatible with the participants' daily routines and other responsibilities, particularly those of informal caregivers. We arranged the focus groups based on their respective cohorts, intentionally avoiding mixing different groups. Our focus was to create an environment where all participants felt free to talk openly. Due to potential interdependencies among participants from the different cohorts (eg, between persons living with stroke and informal caregivers, between persons living with stroke and therapists, and between informal caregivers and therapists), this separation was considered necessary and appreciated by our participants.

Data Collection

Focus group discussions and semistructured interviews were conducted between March 2023 and February 2024 by 1 moderator (LS) and 1 observer (MS), both experienced in conducting these procedures. The moderator guided the conversations using a semistructured discussion guide with open-ended questions. The questions in the discussion guide were adapted slightly depending on the cohort. An example of a semistructured discussion guide used for the cohort of persons living with stroke is shown in Textbox 1. Meanwhile, the observer took discussion notes, posted clarifying questions, and monitored compliance with the specified meeting agenda.

The discussions that took place on the web were conducted and recorded using web-based conference and meetings programs (Webex [Cisco] and Microsoft Teams). Before the discussions, we provided participants with written instructions on using the videoconferencing program. In the group of persons living with stroke, some participants were dependent on private support to set up the videoconference but managed to organize it. The discussions were conducted in a mix of Swiss German and Standard German, depending on the participant's mother tongue. All participants, as well as the research team, were able to understand both Swiss and Standard German and responded in the language they preferred. We video and audio recorded the conversations and ensured confidentiality.

Focus groups discussions and semistructured interviews lasted between 46 and 90 minutes.

Textbox 1. Semistructured discussion guide.

Questions

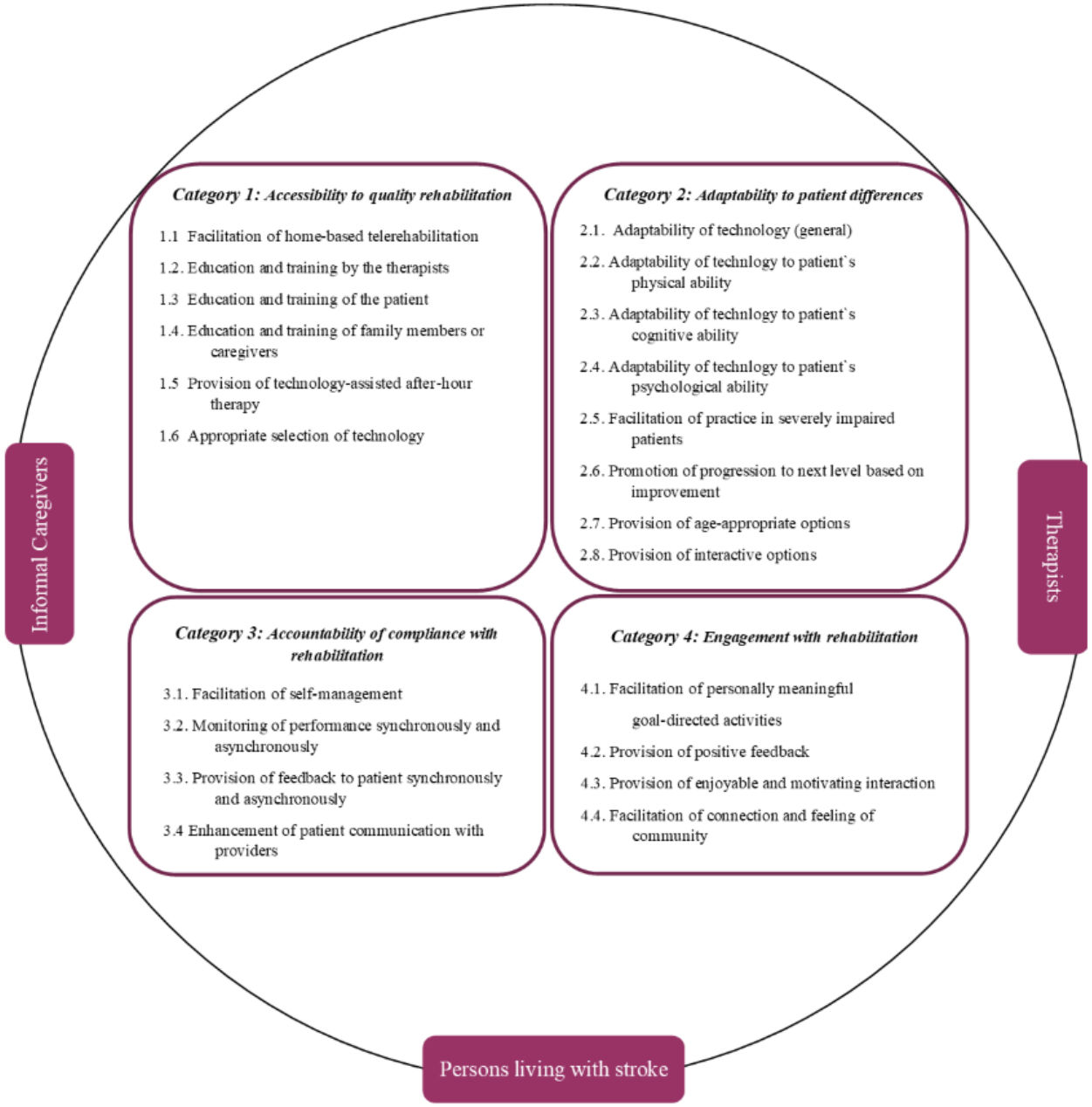
1. What technologies do you use in everyday life?
    1.1 For what daily activities do you use technology?
    1.2 What do you like about it?
    1.3 What don't you like about it?
    1.4 What have you found challenging?
    1.5 What have you experienced helpful?
    1.6 What technologies do you use in relation to health topics?
2. What does using technology in your daily life mean to you? How important is this use for you?
3. Which technologies have you already used in rehabilitation?
    3. 1 What do you like about it?
    3. 2 What don't you like about it?
    3.3 What have you found challenging?
    3.4 What have you experienced helpful?
4. If you could “imagine” an ideal product for home training, what would it look like?

Data Analysis

We transcribed the focus group and individual interviews in Standard German. The interviews conducted in Swiss German were also transcribed into Standard German. The translation of the quotes from Standard German to English took place during the preparation of this paper. We aligned the transcription following the simple rules put forth by Dresing and Pehl [29] and analyzed the data using the TA model for thematic analysis according to Brooks et al [23] with the software MAXQDA Analytics Pro (VERBI GmbH) [30]. We selected the technique of TA because it is generally highly flexible, although it follows a systematic approach, and allows researchers to customize the procedures to align with their specific requirements. Furthermore, it is an effective approach for investigating diverse perspectives of different cohorts within one common context. TA involves the creation and subsequent refinement of a coding template to represent the themes identified in the transcripts [25]. Our initial template was based on the A3E framework for technology-assisted solutions for poststroke rehabilitation, consisting of the following four major themes: (1) accessibility to quality rehabilitation, (2) adaptability to patient differences, (3) accountability or compliance with rehabilitation, and (4) engagement with rehabilitation [24]. We adopted the 4 major themes of this framework as categories. Furthermore, we adapted the subcategories based on the original model developed by Jayasree-Krishnan et al [24] and used them as our themes. We adjusted the wording of the subcategories and themes accordingly. Furthermore, we split some subcategories or themes that were rich and diverse in content into multiple subcategories or themes. An illustration of the adapted version of the A3E framework is displayed in Figure 1.

We proceeded in the following adapted steps [25]. The first step was the definition of “a priori” themes based on the A3E framework [24]. Afterward, we conducted an initial coding of a subset of the first 3 transcripts by assigning text sections to the a priori themes, including the rejection and modification of preliminary themes. The third step included the application of the template to the full data set.

Figure 1. Adapted version of the accessibility, adaptability, accountability, and engagement (A3E) framework.



Rigor and Trustworthiness

To maintain rigor and trustworthiness, we adhered to the principles outlined by Nowell et al [31]. To ensure credibility, the participants had the option to pose questions and clarify their responses. In addition, we verified the accuracy of our transcriptions by comparing them to the original recordings. Furthermore, we incorporated peer debriefing as external feedback, seeking input from colleagues to ensure the rigor of our research process. We ensured transferability by applying a template derived from the A3E framework [24] that can be transferred to other socioeconomic systems and across various geographical regions. To strengthen dependability, we documented our research process, including the recruitment strategy and data analysis, in a clear and logical manner and relied on our documentation throughout the process.

Ethical Considerations

We integrated ethical considerations into our research. Recognizing the far-reaching obligations of our participants and aiming to respect their limited time, we provided the option of participating in individual interviews alongside the focus groups to work around time constraints. We also submitted our research project to the cantonal ethics committee of Zurich (BASEC-Nr. Req-2023-00106). This committee determined that the research project does not fall within the scope of the Human Research Act and, therefore, does not fall within its remit. We explicitly informed participants about confidentiality concerns and their right to withdraw from the study at any point without stating reasons. Each participant gave a written declaration of consent. Study data, including identifying information and transcriptions, were deidentified.

Positionality Statement

The first author, LS, is a doctoral student (Care and Rehabilitation Science), bringing a background and clinical experience as an occupational therapist. AL is a medical doctor, an academic, a researcher, and a rehabilitation clinic manager. VM is a master's student (physical therapy, focusing on professional development). VK-M is a former academic and researcher currently working as a medical doctor in a rehabilitation setting. MS is an academic and a researcher and has a professional background in occupational therapy (OT) and occupational science. MRS is a professor, a rehabilitation scientist, and an academic researcher and a physical therapist by training. All authors have experience in researching technology in the context of stroke neurorehabilitation and are experienced in the Swiss health care system.

We as a team of authors cultivated a contextual constructivist position, recognizing the existence of multiple interpretations for any given phenomenon and depending on the contextual aspects of the research [32].

Results

Description of Participants

In total, we included 23 participants in this study. Of them, 12 (52%) participants were therapists (female: 12/12, 100%), 7 (30%) participants were persons living with stroke (female: n=3, 43%; male: n=4, 57%), and 4 (17%) participants were informal caregivers (female: n=3, 75%; male: n=1, 25%). Further details are provided in Table 1.

Table 1. Participant's characteristics.

Cohort, focus group or interview, and ID	Sex (male, female, or intersex)	Country of residence	Canton or federal state of residence	Professional background
Therapists				
Focus group 1				
T1	Female	Switzerland	Zurich	OT[a]
T2	Female	Switzerland	Berne	OT
T3	Female	Switzerland	Berne	OT
T4	Female	Switzerland	Zurich	OT
T5	Female	Austria	Vienna	OT
T6	Female	Switzerland	Zurich	OT
T7	Female	Switzerland	Zurich	PT[b]
T8	Female	Switzerland	Berne	OT
Focus group 2				
T9	Female	Switzerland	Zurich	OT
T10	Female	Switzerland	Zurich	PT
T11	Female	Switzerland	Zurich	ST[c]
T12	Female	Switzerland	Zurich	PT
Persons living with stroke				
Focus group 1				
S1	Male	Switzerland	Thurgau	—[d]
S2	Female	Switzerland	St Gallen	—
S3	Male	Switzerland	Thurgau	—
Interview 1				
S4	Male	Switzerland	Fribourg	—
Interview 2				
S5	Male	Germany	Bavaria	—
Interview 3				
S6	Female	Switzerland	Thurgau	—
Interview 4				
S7	Female	Switzerland	St Gallen	—
Informal caregivers				
Focus group 1				
C1	Female	Germany	Baden-Wurttemberg	—
C2	Female	Switzerland	Thurgau	—
Interview 1				
C3	Female	Switzerland	Thurgau	—
Interview 2				
C4	Male	Switzerland	St Gallen	—

[a]OT: occupational therapy.

[b]PT: physiotherapy.

[c]ST: sports therapy.

[d]Not applicable.

The participants were residents of 5 different cantons of Switzerland and spoke Swiss German or Standard German: 35% (8/23) from Zurich; 22% (5/23) from Thurgau; 13% (3/23) from Berne; 13% (3/23) from St Gallen; and 4% (1/23) from Fribourg. Of the 23 participants, 2 (9%) were residents of Germany, and 1 (4%) lived in Austria. Participants who resided abroad had a strong connection to Switzerland and its health care system, such as undergoing rehabilitation treatment at a clinic in Switzerland, working within the Swiss health care system, or caring for a relative in Switzerland. All therapists who participated in the focus groups had experience in providing therapeutic support to persons living with stroke who were already living in the community.

Of the 7 persons living with stroke, 6 (86%) were of employable age (range 30-63 years). At the time of their stroke, these 6 persons living with stroke were actively employed, and 5 (83%) of them were also able to return to work after stroke. The sixth person living with stroke chose early retirement. The seventh person living with stroke, despite already being aged 79 years, self-identified as being professionally still active.

All informal caregivers included in the study described themselves as being employed.

Thematic Analysis According to the A3E Framework

Overview

A pattern of cohort-specific needs and experiences with technology-based tools in outpatient stroke rehabilitation emerged. We classified these experiences into the 4 categories: *accessibility to quality rehabilitation*, *adaptability to patient differences*, *accountability of compliance with rehabilitation*, and *engagement with rehabilitation* [24]. Statements from participants are incorporated in this *Results* section. A detailed overview of additional quotes can be found in Multimedia Appendix 1. In the subsequent descriptions of the findings across the 4 categories, we have included the categorization into the corresponding subcategories or quotes within parentheses to enhance clarity.

Category 1: Accessibility to Quality Rehabilitation

Given that technologies are an option to provide appropriate access to rehabilitation, several topics regarding the accessibility to quality rehabilitation were discussed. Some therapists in our study reported that they had their first experience with synchronous telerehabilitation during the COVID-19 pandemic (subcategory 1.1 in Figure 1). Before that, the topic was not perceived as being present in the Swiss health care system. One of the therapists had already used telerehabilitation abroad. During the pandemic, several occupational and physical therapists found this option useful for conducting remote therapy sessions. However, not all participating occupational and physical therapists made use of this option. In addition to the finding that the provision of telerehabilitation services in the workplace was not feasible for some of the therapists, the tariff structure proved to be another significant challenge. Although the costs for providing occupational and physical therapy at a distance were covered during the COVID-19 pandemic, this was not consistently maintained for occupational and physical therapists afterward. None of the interviewed persons living with stroke or caregivers had any experience with synchronous telerehabilitation (subcategory 1.1 in Figure 1). However, there was interest in telerehabilitation; S7 expressed, “I think that [telerehabilitation] would surely make sense, but I don’t know if there’s an offer where I could do that” (original: “Also i dänk das [Telerehabilitation] wär sicher sinnvoll aber i wüsst gar nöd wos so eis Angebot gäbte”). The topics of education and training of the individual target groups regarding asynchronous technology-based tools for outpatient rehabilitation were discussed intensively in all interviews and focus groups, irrespective of the cohort. Overall, persons living with stroke preferred therapists (subcategory 1.2 in Figure 1) to take on the task of providing them with the relevant information. One of the participants said, for example, that it would be beneficial for him if the therapist could inform him about the available technology-based tools and their practical relevance in individual cases. Informal caregivers concurred with this perspective (subcategories 1.2 and 1.3 in Figure 1). They also perceived therapists as experts who should lead patients and assist them in the implementation of technology-based tools. One of the caregivers stated the following:

> *I’m the kind of a person who thinks that there are experts for that. I think it’s important for us caregivers, we already take on so much...Especially elderly caregivers. I already find our life so radically different; if we had to program the tool ourselves, it would be annoying...And I have realized, I can only speak for myself; it is much more effective if other people tell him something...That’s why I believe it’s more important for him to do it with therapists. (Original: I bin det dure eher so igstellt, dass i find für da gits Fachlüüt. I find wie für üs Aghörige wichtig, mer übernehmet bereits so viel...Au bei älteri Aghörige. I find üser Lebe is scho so krass andersch; wenn mer ez no muesset das Tool vilicht programmiere halbe, dann nervts einem vilicht au...I ha fescht gmerkt, i cha da nur für mi rede, es nützt viel mehr wenns andre Mensche ihm seget...Drum glaubi is es wichtiger, macht er da mit Therapeute.)* [C3]

All informal caregivers reported feeling overwhelmed by the transition, having to take on new tasks that were previously carried out by the persons living with stroke or jointly with them. Examples such as household budget planning, paying bills, and planning and making purchases were mentioned. Most therapists aimed to minimize the involvement of informal caregivers, recognizing the stress and pressure informal caregivers already endure (subcategory 1.4 in Figure 1). A topic that was prominently discussed in the focus groups and all interviews of the caregivers was the wish for more information on technology-based support devices and education on stroke rehabilitation in general to help them navigate the changes in their daily life with persons living with stroke. They expressed a strong need for education and training in this regard:

> *My husband was in rehab, and he had a full schedule. He sent me that, then I saw what he was doing. People were taking care of him. And I was at home, had four children, one is going through a tough puberty. Then*

> *nothing happened. So, I didn't receive any information about the meaning [of his health condition] and how he would behave when he returns. (Original: Mi Maa isch in der Klinik gsi, er het immer voll Programm gha. Er het mers gschickt, damit i gseh was er macht. Ma het uf ihn glueget. I bin dihei gsi, ha det no vier Chind dihei gha, einer starch pubertierend. Denn isch eigentlich nüd cho. I han kei Info übercho wa bedüdtet da [seine Gesundheitssituation] und wie isch er denn.)* [C1]

Therapists found education and training for themselves and for individuals living with stroke and informal caregivers to be challenging. T2 expressed a need for action recommendations for using technology-based tools in rehabilitation. T10 felt reluctant to use technology due to the time commitment required for familiarization and training. Tasks such as this often have to take place outside of working hours, and therapists cannot claim any reimbursement for their time (subcategory 1.2 in Figure 1).

As for the appropriate selection of technology (subcategory 1.6 in Figure 1), therapists in both focus groups argued that the tool should be user-friendly, such as having the possibility of adaptations for different needs. Participating occupational therapists highlighted the use of everyday life tools that are already integrated into patients' lives, such as tablets or smartwatches, alongside tools developed for therapeutic purposes. In addition, most therapists considered it crucial for persons living with stroke to use these tools as independently as possible to prevent conflicts and dependencies between them and their informal caregivers. Some therapists used the exchange at specialist meetings and with interest groups to help the therapists select appropriate tools. T6 stated that they [T6 and T1] had a specialist meeting the year before with the interest group technologies in OT, where they received many new ideas. T10 also added that she thinks it is important that the Swiss professional OT and physiotherapy associations recognize technology as part of the profession and that it is anchored accordingly in the tariff structure.

Several persons living with stroke stated that they were overwhelmed with the choice of technology-based tools (subcategory 1.6 in Figure 1), particularly with the selection and installation of training apps. For example, S6 expressed that, especially, the process of finding a suitable app from the app store was perceived as time-consuming, as well as evaluating the app in advance regarding its quality, which led to wrong purchases. Another person living with stroke stated that she had difficulty understanding the apps and was, therefore, unable to learn how to use them. Most of the persons living with stroke stated that the process should be simple and straightforward.

Category 2: Adaptability to Patient Differences

Among the persons living with stroke and therapists, the possibility to adapt the technology, in the sense of personalization, was considered as a relevant criterion for the selection of the tool. Some therapists expressed that to correctly and confidently personalize the technology to their patient, such as by selecting suitable exercises, they needed an extended phase of familiarization with the tool. This was perceived as time consuming and a hindrance to implementation (subcategory 2.1 in Figure 1):

> *I also needed a lot of time at the beginning...until I became familiar with it...It took a lot of clicks...you still have to individualize everything a bit. Yes, I was a bit afraid to really put it into practice. (Original: Also bi dem Tool hani am Afang au extrem viel Ziit bruucht...bis i selbscht es biz Routine gha han...Es het extrem viel Klicks brucht...Ma het immer no alles muesse individualisiere. Ja, da hani mi biz gschüüt am Afang davor das au würkli denn ind Praxis ine zneh.)* [T12]

Persons living with stroke encountered challenges in accessing and using a familiar technology, such as a PC or tablet, for outpatient stroke rehabilitation. For example, S7 reported that she was no longer able to switch on the PC and log in without help because her hand and arm function was impaired (subcategory 2.2 in Figure 1). She always needed to ask her husband for support. She also reported that she struggled remembering passwords (subcategory 2.3 in Figure 1). In some cases, persons living with stroke used the possibility to adapt the technology to accommodate for these difficulties. For example, persons living with stroke were able to use voice input and biometrical authentication on their technologies (subcategory 2.2 in Figure 1). In other cases, however, they rejected using these options, as they felt that they had to adapt to the new situation and gradually regain their ability to use of these tools (subcategory 2.1 in Figure 1). S2 stated, "I had the feeling that it [the rehabilitation process] takes time and that you have to accept it [own limitations]" (original: "I han mer sGfühl, es het Ziit brucht und eifach au es anneh, ez im Moment hanis usgschöpft").

Therapists see technologies as providing some advantages, specifically for persons living with stroke with severe impairments (subcategory 2.5 in Figure 1). For example, some of the persons living with stroke live with severe impairments, making the journey to a clinic challenging to organize and conduct. Therapy intensity can then be increased by conducting parts of the therapy in the home environment, using technology-based tools. In facilitating the practice for these people, according to the experience of some of the therapists, informal caregivers play a crucial role. They regularly assist in the use of the technology-based tools, for example, in selecting the right exercises (subcategory 2.5 in Figure 1).

Both persons living with stroke and therapists valued the option that tools automatically adjust their levels (subcategory 2.6 in Figure 1). This was seen as an opportunity to shape the therapy. Furthermore, persons living with stroke appreciated the shaping of the therapy to their needs, such as gradually increasing the difficulty level according to their individual abilities. However, one of the persons living with stroke reported feeling overwhelmed even with the lowest level of a cognitive training program. A therapist noticed that she was familiar with cognitive training tools that automatically adapt but was unaware of tools for other functional areas, such as for motor training, that are available in Switzerland (subcategory 2.5 in Figure 1).

The topic of age-appropriate option (subcategory 2.7 in Figure 1) was briefly discussed. Some therapists had observed that older persons tend to face more challenges with videoconferencing tools, leading to a shift to telephone contact. The option of videoconferencing was used more often with younger persons:

> *The elderly patients said that [videoconferencing] was too complicated. We often just called them and asked how things are going and whether they performed their exercises... (Original: Die älteren Patienten sagten, das [Videokonferenzen] ist wie zu kompliziert. Wir haben dann oft einfach angerufen und gefragt wie's geht und ob die Übungen möglich sind...)* [T3]

> *I did a few videoconferencing sessions...but they were all with younger patients after stroke. (Original: Ich habe einige Videokonferenz-Sitzungen gemacht...aber es waren alles jüngere Schlaganfallpatient:innen.)* [T1]

Category 3: Accountability or Compliance With Rehabilitation

Overall, persons living with stroke recognized the utility of technology-based tools in assuming responsibility for their own outpatient rehabilitation process (subcategory 3.1 in Figure 1). This was mainly due to the feedback they received from technology-based tools and autonomy they had in selecting individual exercises. S4 described the following experience (subcategory 3.2 in Figure 1):

> *After half an hour, you will have an evaluation on the screen of what you did wrong, what was good and what progress you have made. That is certainly good and motivating (Original: Auf dem Bildschirm hat man nach einer halben Stunde die Auswertung, was hast du recht falsch gemacht, was war gut, was hast du für Fortschritte gemacht. Das wär sicher sehr wichtig und motivierend auch)*

Likewise, some of them found reminders to be helpful for staying on the rehabilitation track and for structuring their days in addition to therapy. A minority experienced limited additional benefits in their therapy process, primarily attributed to the absence of direct interaction with a therapist (subcategory 3.4 in Figure 1). S6 expressed difficulties in interpreting the scores of technology-based tools (subcategory 3.2 in Figure 1): "It is therefore inexplicable to me how it [the feedback] is created. I can't understand the ratings" (original: "Also es ist mir unerklärlich, wie sich das [Feedback] zusammensetzt. Die Bewertungen kann ich nicht nachvollziehen").

Informal caregivers viewed the assumption of personal responsibility by the persons living with stroke positively. One of the informal caregivers mentioned implementing specific tools to support his wife's independence at home during the rehabilitation process. They purchased a smartwatch to enable her to make phone calls independently, which was not possible with a mobile phone at that time.

Therapists argued that it was important for them to enable the self-management of persons living with stroke when using technology-based tools (subcategory 3.1 in Figure 1). T10 shared the following experience: "My situation is like T12. We try to incorporate this [technology] into self-management, even if it is associated with limitations [of technology use]. I try to find a level at which the patient can still take responsibility for themselves" (original: "Bei mir ist es wahrscheinlich ähnlich wie bei T12. Wir versuchen es im Selbstmanagement einzubauen, auch wenn es mit Einschränkungen [der Technologienutzung] verbunden ist. Ich versuche dann lieber ein Level zu finden, bei dem der Patient Selbstverantwortung übernehmen kann."). For these therapists, this includes enabling persons living with stroke to use the devices independently, that is, without the support of informal caregivers if possible.

The provision of feedback (subcategory 3.3 in Figure 1) was also mentioned by most therapists as a criterion to which they pay attention. For them, it was important to personally provide feedback to the persons living with stroke on the use and progress of technology-based tools. They also emphasized the importance of the tools themselves providing direct feedback when the persons living with stroke use them at home.

Category 4: Engagement With Rehabilitation

To maintain engagement in home-based rehabilitation, establishing personalized and meaningful goals is beneficial (subcategory 4.1 in Figure 1). Some of the persons living with stroke found it supportive to identify achievable goals that can be targeted during technology-supported therapy. Establishing meaningful goals allowed them to evaluate their progress and ensure that they are staying on track with their rehabilitation journey. For example, S7 elaborated that her goals include devising compensatory strategies for everyday life tasks, such as zipping her pants with one arm. She explained that to reach this goal, she frequently consults instructional videos on YouTube (Google LLC) for guidance. Therapists, especially some of the participating occupational therapists, expressed that they find it challenging to integrate technologies into reaching goals. For occupational therapists, it is essential that the specific goals align with the client's daily life challenges. They regarded technologies as having the drawback of being constructed environments that, in their perspective, cannot be seamlessly integrated into individual everyday life. Occupational therapists questioned whether technologies could be used to achieve meaningful goals:

> *For me, it's always a bit of the specific goal and that is simply always everyday-life oriented and individual at best. That's why I'm also critical of technologies in the broadest sense, whether they can really do justice to the complexity of everyday life...[Goal setting including technologies] usually rather limited, as they are always constructed settings or are modeled on an everyday life situation...I think that's the main limitation, it's always an imagined reality. (Original: Für mi isch's halt au immer biz e so d'Frog nach der konkrete Zielsetzig und die isch halt im beschte Fall scho immer alltagsorientiert und sehr individuell. Drum bin ich det scho kritisch gegenüber Technologie im wiiteschte Sinn, ob die denn würkli so dere Komplexität vom Alltag überhaupt chönt*

> *grecht werde...[Zielsetzung, die Technologien inkludiert] isch scho eher limitiert, es sind jo immer konschtruierti Settings, oder wo denn möglichscht irgendeinere Alltagssituation nachempfunde sind...I glaub scho chli das isch d Hauptlimitation, es isch immer e usdänkti Realität.)* [T9]

To address these challenges, some occupational therapists developed strategies (subcategory 4.1 in Figure 1). They used everyday life apps, such as public transportation apps or reminder apps, incorporating them into treatment planning and establishing links to daily activities:

> *What I always try to use are apps, calendar apps on the mobile phone, so that you can really concentrate on the activity. Or also the SBB app [public transportation]. I've practiced for hours with patients on reminder functions and apps, where you can make notes or something. The things that I also use myself. (Original: Was ich auch immer wieder versuche zu nutzen sind Apps, Kalenderapps auf dem Handy, um die Betätigung möglichst ins Zentrum zu rücken. Oder auch die SBB App [öffentliche Verkehrsmittel]. Da habe ich schon stundenlang mit Patienten geübt, oder auch irgendwelche Erinnerungsfunktionen und Erinnerungsapps, wo man sich auch Notizen machen kann oder so. Die Dinge ich halt auch selber benutze.)* [T4]

Most persons living with stroke experienced that positive feedback (subcategory 4.2 in Figure 1), such as good scores in a game, can contribute to a positive user experience. Persons living with stroke also frequently mentioned that they appreciate the option to personalize the technology-based tool in an appealing way (eg, color and background selection; 4.3). Negative feedback, such as bad scores in a game, by contrast, is perceived as demotivating (eg, the feeling of being too slow). Therapists concurred with this experience reported by persons living with stroke. They confirmed the positive effect of the incorporation of a reward system, the graphical representation of successes, or the presence of a checklist where completed exercises could be marked on motivation and adherence to therapy (subcategory 4.2 in Figure 1).

Persons living with stroke had controversial perceptions about the effect of technology-based therapy on human connections and their experience of community (subcategory 4.4 in Figure 1). S5 experienced practicing with technology-based tools as isolating, as he was missing the dialogue with people and, in his case, with therapists. S1 reported that the use of technology-based tools in his outpatient rehabilitation process brings him closer to his children, who played the training games together with him.

Informal caregivers reflected on their role in the rehabilitation process. All informal caregivers experienced a lack of community and a sense of belonging (subcategory 4.4 in Figure 1). They particularly felt abandoned during the transition from inpatient to outpatient rehabilitation. They had the impression that they were not adequately prepared by health care professionals for the changes coming their way due to their loved one's condition. C1 described her situation as follows:

> *[I would have liked] more information about what to expect [all the bad things that could happen]. If this is not the case, you can be relieved...But it would give me the feeling that don't have to do everything on my own. (Original: Eifach mehr Informatione, was chämti uf ei zuecho. Wenns denn nid so is, cha mer jo froh sii. Es gebti es Gfühl vo mer muessti nid alles allei mache.)*

The included informal caregivers expressed that the opportunity to inform themselves as informal caregivers and possibly meet as a group could have been very helpful for them (subcategory 4.4 in Figure 1).

However, several informal caregivers expressed reservations about traditional informal caregiver support groups, as they believe these groups may not be constructive. The informal caregivers in our study associated these meetings with a tendency to wallow in self-pity within the caregiver support group. Nevertheless, most informal caregivers desired a constructive exchange and appreciated the opportunity to gain new perspectives from others facing similar situations. Technology could also be supportive in this context, as they would prefer a web-based format due to their numerous commitments. Informal caregivers perceived that technology could provide them with significant benefits here:

> *But now we know that all have a lot of commitments, things, or travel, and it has become more complicated. That's why I've realized that it's not so bad to just talk online. You can get into the topic very quickly. (Original: Aber inzwischen wir, wir haben alle sehr viele Pflichten, Sachen, oder Reisen und es ist komplizierter geworden. Deshalb merke ich auch, online einfach so Gespräche zu führen, ist auch gar nicht so schlecht. Man ist auch ganz schnell im Thema drin.)* [C2]

Discussion

Principal Findings

The objective of this study was to describe the experiences of persons living with stroke, informal caregivers, and therapists regarding the use of technology-based technology in home-based rehabilitation within the Swiss context. For this purpose, we conducted a deductive TA of the gathered data, presenting the findings following the A3E framework [24]. This approach provided a suitable foundation for reflecting influences as well as potential barriers pertinent to the Swiss health care system and society.

The participants in our study exhibited a generally positive attitude and high level of interest in the use of technology-based tools in home-based stroke rehabilitation. One of the persons living with stroke expressed criticism regarding the use of technology in therapy and everyday living.

The cohorts of persons living with stroke and informal caregivers were well mixed in terms of sex. All therapists identified as female. Furthermore, 8 (67%) out of the 12 therapists were occupational therapists. A nationwide survey revealed that 90% of occupational therapists in Switzerland

identify as female [33], which indicates an acceptable sex distribution in the cohort of therapists.

The findings of our study suggest that informal caregivers of persons living with stroke in Switzerland face similar burdens to those identified in previous studies [14-16]. Participating informal caregivers also reported that dealing with the behavioral and personality changes of their family members posed a challenge for them.

Taking on activities and tasks that were previously the responsibility of the family member affected by stroke, such as household budget planning or paying bills, and the associated change of role were perceived as stressful. All informal caregivers who participated in our study reported receiving insufficient support from clinics, particularly when it came to managing the transition back home. They would have liked, for example, more information about the personality changes (behavior and emotions) of their loved ones or support in assessing which tasks they could reasonably expect the persons living with stroke to handle. Without generalizing, these experiences do not seem to be unique to the Swiss context. For instance, qualitative studies from Malaysia, Denmark, and Australia have also described the need for information on comprehensive stroke care at home [34,35]. Apart from informal caregiver support groups, which did not appeal to the participating informal caregivers for various reasons (timing and setting), the informal caregivers were not aware of any other support services in the Swiss health care system. Because we exclusively captured the experiences and needs of 4 informal caregivers from the German-speaking part of Switzerland in this qualitative study, we plan a national survey as the necessary next step. It is a common practice [36-38] to first conduct a qualitative study, publish its findings, and then proceed with a quantitative study. In this survey, our aim is to expand upon the findings of this study and capture the needs of informal caregivers within the rehabilitation journey of their loved ones in more detail by involving a larger sample size and further regions of Switzerland.

Accessibility to Quality Rehabilitation

Synchronous telerehabilitation following stroke experienced its initial upswing in Switzerland during the COVID-19 pandemic [39]. For the first time, in Switzerland, these services were covered by the basic health insurances for occupational therapists and physical therapists [40]. In our study, therapists reported minimal use, if any, of these services during the pandemic, while persons living with stroke did not use them at all. This contrasts with the results of a national survey, where >70% of occupational therapists reported providing telerehabilitation during the pandemic [39]. A crucial obstacle for the participating therapists was the existing uncertainty surrounding financial coverage. According to the current state of knowledge, since December 2023, it remains unclear whether the costs associated with synchronous telerehabilitation in the fields of physical therapy and OT will be reimbursed by the Swiss health insurances in the future. This highlights the need for a clear and enduring inclusion within the service catalog of Swiss health insurance providers, along with the effective communication of this inclusion. These findings show clear differences from other high-income countries in which technology-supported tools and telerehabilitation are already more established in the health care systems. In Canada and Australia, for example, intensive and promising efforts have already been made to implement telerehabilitation and the use of technology-based tools in outpatient rehabilitation [4,41].

Adaptability to Patient Differences

Technology-based tools mentioned in the interviews and focus groups can be broadly categorized. These include tools specifically designed for therapy or training purposes, such as various apps and cognitive training programs for PCs or tablets. In addition, there are tools originally developed for everyday use, without initial therapeutic intentions, such as apps for public transportation, social media, and reminder functions on mobile phones.

Persons living with stroke who took part in our interviews and focus group experienced that the training tools developed for rehabilitation generally fulfill the necessary options for adaptability. However, they identified areas for improvement, especially regarding the shaping of technology, such as selecting appropriate levels and degrees of difficulty. Several persons living with stroke stated that the exercises were either too easy or too difficult, despite the tools automatically adjusting the difficulty level. However, the ideal difficulty level was often not achieved. Conversely, everyday technology devices such as smartphones, smartwatches, and tablets were commonly used. In addition, everyday apps such as reminder apps, communication apps, shopping apps, and public transport apps were frequently used. Most persons living with stroke stated that their use behavior often changed after the stroke. They used these tools more frequently. However, no cases were mentioned in which the apps or technologies used had been adapted. Nevertheless, for persons living with stroke, the use was usually possible with restrictions or only with the support of informal caregivers. A person living with stroke emphasized the importance of technologies with interactive features, such as technologies facilitating interaction with another person. This feature has the potential to enhance engagement by providing a role model or a trainer to demonstrate exercises.

Accountability or Compliance With Rehabilitation

A key factor in successfully continuing the rehabilitation process following inpatient treatment with outpatient interventions is the willingness of persons living with stroke to take responsibility for their own rehabilitation process and to remain motivated to continue practicing independently [24].

The interviews and the focus group with persons living with stroke uncovered that technology-based tools can make a significant contribution to compliance in self-guided training at home. Particularly, the automatic visualization of progress and achievement of milestones were experienced as supportive. This enabled persons living with stroke to independently track their therapy progress and course.

In all cohorts, the relevance and importance of the self-responsibility of persons living with stroke were extensively discussed. There was a great consensus that independent and autonomous use of technology-based tools by persons living

with stroke should be supported and forced. Past focus group studies conducted in Denmark have revealed similar attitudes [14]. They emphasize that technology-based tools can be viewed as an opportunity for persons to take responsibility for their own rehabilitation process. For the informal caregivers in our study, it was crucial, for example, that the persons living with stroke could complete their home-based training program independently of them. This provided some relief for informal caregivers, as they were not faced with an additional task for which they had to take responsibility. These experiences and perspectives may intersect with statements regarding the use of technology-based tools for persons living with stroke who are more severely affected. Specifically, some therapists argued that caregivers play a crucial role in the facilitation of home-based technology use for persons living with stroke with severe limitations. One potential avenue for consideration could be the recognition that clear communication between therapists and informal caregivers regarding responsibilities and the assumption of roles is important.

An additional perspective shared by all informal caregivers, which was not explicitly covered in the data analysis codes, was the significant role that technology-based tools play for them in their loved ones' rehabilitation journey. As previously noted, informal caregivers often bear a high level of responsibility and burden. To cope with this, they use various strategies, including relaxation exercises facilitated by technology-based tools. These experiences underscore the potential of technology-based tools to support informal caregivers throughout the rehabilitation process. The diverse potential for the support of informal caregivers has also been highlighted in a rapid review [42], showcasing areas such as education, remote consultations, and reminders, which can be covered through the use of various technology-based devices.

Engagement With Rehabilitation

It was particularly important for the participating occupational therapists that the use of technology-based tools added value to the patient's everyday lives, which aligns with their professional profile. Ensuring this was described as a considerable hurdle. The therapists of both professions saw one way of overcoming this in anchoring technology-based interventions in tariff systems and establishing further training opportunities and recommendations on the part of professional associations. In Switzerland, occupational therapists and physical therapists are represented by professional associations. In addition to negotiating contracts for therapists with health insurance companies, the strategy of these associations is to further develop and train the profession and ensure quality assurance [43,44].

A key resource appears to be the exchange in professional networks and interest groups at the national level, which are also anchored in the professional associations.

Persons living with stroke use technology-based tools in Swiss outpatient stroke rehabilitation both to engage in their exercise programs or work on their recovery and to facilitate their daily activities. These uses often overlap. Some persons living with stroke reported using more technologies after stroke and even purchasing new devices (such as tablets or smartwatches). These people use these devices in their daily lives, particularly for compensation or training. The use of technology-based tools is strongly influenced by the limitations that persons living with stroke experience. This indicates a need for a high degree of adaptability of the corresponding tools. The group of persons living with stroke trusted and relied on the recommendations of their treating therapists when selecting suitable tools.

Strengths and Limitations

This study possesses both strengths and limitations. We want to emphasize that the research team consisted of health care professionals, including 2 occupational therapists, 2 physical therapists, and 2 neurologists, all of whom are very familiar with the health care system in Switzerland. Moreover, 5 (83%) out of the 6 authors even possess several years of experience in clinical practice. This enabled them to compile and interpret the data results for the Swiss context appropriately.

The study presents some limitations, including a small sample size from 1 country and context. The findings only reflect the experiences of persons living with stroke, informal caregivers, and therapists in the German-speaking part of Switzerland. Further studies are needed to gather experiences from people of the Italian- and French-speaking parts of Switzerland. Furthermore, the focus of this study was on experiences using technology-based tools. We realized that in the interviews and focus groups, the informal caregivers reported on their experiences of how they perceive their role in the rehabilitation process and what they would have needed in detail. We tried to acknowledge these findings partly in our discussion. However, we could not delve into all aspects of these experiences, as these findings were beyond the codes and the scope of this study and were not explored and reflected in depth. Nevertheless, we consider it relevant to include the experiences of informal caregivers in the improvement of Swiss home-based stroke rehabilitation.

Furthermore, we were confronted with language-related issues. As described in the *Methods* section, the interviews and focus groups were conducted in Standard or Swiss German. The various dialects of the Swiss language have different grammar and sentence structures compared to Standard German. As we opted for a literal and simplified transcription and translation into Standard German and, subsequently, into English, some quotes may appear unfamiliar to native English speakers. To address this issue, we have added the original statements in Swiss German to the corresponding quotes in this paper.

Practical Study Implications

For practicing occupational and physical therapists, the experiences and needs described by the 3 cohorts in this study can be used to reflect on their own practical experiences and perspectives. For example, a point of reflection could be the role and responsibility they attribute to informal caregivers and persons living with stroke regarding technology-based, home-based training. These considerations should also influence the selection and potential adaptation of technology-based tools in the home-based rehabilitation process after stroke. Furthermore, this study revealed that various conditions (funding, the selection of appropriate tools, guidelines,

recommendations, etc) are not satisfactorily addressed for occupational and physical therapists within the Swiss health care system. This could motivate practicing therapists to actively participate, for example, in professional associations and in shaping further developments.

Persons living with stroke and informal caregivers who read this study may recognize themselves in the experiences of our participants and might feel a sense of belonging to these cohorts. Sharing these findings could also be enriching and valuable for others, such as informal caregiver support groups.

Conclusions

The objective of this study was to describe the experiences of persons living with stroke, informal caregivers, and therapists regarding the use of technology-based technology in home-based rehabilitation within the Swiss context. Persons living with stroke, informal caregivers, and therapists had very different and unique experiences with the use of technology-based tools in this setting. It was shown that a broad spectrum of different tools is already available and is also being used. However, there remain uncertainties and ambiguities regarding financial reimbursement and education on the use of such tools in Switzerland. Furthermore, written recommendations for the use of technology-based tools in stroke rehabilitation are needed for the Swiss context. Clarification of these points could lead to greater confidence in the use of such tools, both on the part of therapists and on the part of persons living with stroke. With this research, we have illustrated the experiences and needs of our cohorts within the Swiss context. Therefore, conducting a national survey is the next step to depict the needs of informal caregivers in greater detail and breadth.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Quotes from study participants.
[DOC File , 105 KB - rehab_v11i1e59781_app1.doc]

References

1. Kwakkel G, Stinear C, Essers B, Munoz-Novoa M, Branscheidt M, Cabanas-Valdés R, et al. Motor rehabilitation after stroke: European Stroke Organisation (ESO) consensus-based definition and guiding framework. Eur Stroke J 2023 Dec 07;8(4):880-894 [FREE Full text] [doi: 10.1177/23969873231191304] [Medline: 37548025]
2. Olasoji EB, Uhm DK, Awosika OO, Doré S, Geis C, Simpkins AN. Trends in outpatient rehabilitation use for stroke survivors. J Neurol Sci 2022 Nov 15;442:120383. [doi: 10.1016/j.jns.2022.120383] [Medline: 36041328]
3. Sun X, Ding J, Dong Y, Ma X, Wang R, Jin K, et al. A survey of technologies facilitating home and community-based stroke rehabilitation. Int J Hum Comput Interact 2022 Apr 20;39(5):1016-1042. [doi: 10.1080/10447318.2022.2050545]
4. Simpson DB, Bird M, English C, Gall SL, Breslin M, Smith S, et al. "Connecting patients and therapists remotely using technology is feasible and facilitates exercise adherence after stroke". Top Stroke Rehabil 2020 Mar 25;27(2):93-102. [doi: 10.1080/10749357.2019.1690779] [Medline: 31762412]
5. Burridge JH, Lee AC, Turk R, Stokes M, Whitall J, Vaidyanathan R, et al. Telehealth, wearable sensors, and the internet: will they improve stroke outcomes through increased intensity of therapy, motivation, and adherence to rehabilitation programs? J Neurol Phys Ther 2017 Jul;41 Suppl 3:S32-S38. [doi: 10.1097/NPT.0000000000000183] [Medline: 28628594]
6. Chen Y, Abel KT, Janecek JT, Chen Y, Zheng K, Cramer SC. Home-based technologies for stroke rehabilitation: a systematic review. Int J Med Inform 2019 Mar;123:11-22 [FREE Full text] [doi: 10.1016/j.ijmedinf.2018.12.001] [Medline: 30654899]
7. Postolache O, Hemanth DJ, Alexandre R, Gupta D, Geman O, Khanna A. Remote monitoring of physical rehabilitation of stroke patients using IoT and virtual reality. IEEE J Select Areas Commun 2021 Feb;39(2):562-573. [doi: 10.1109/jsac.2020.3020600]
8. Moro C, Smith J, Finch E. Improving stroke education with augmented reality: a randomized control trial. Comput Educ Open 2021 Dec;2:100032. [doi: 10.1016/j.caeo.2021.100032]
9. Laver KE, Adey-Wakeling Z, Crotty M, Lannin NA, George S, Sherrington C. Telerehabilitation services for stroke. Cochrane Database Syst Rev 2020 Jan 31;1(1):CD010255 [FREE Full text] [doi: 10.1002/14651858.CD010255.pub3] [Medline: 32002991]
10. Guidelines on the use of telehealth as alternative form of occupational therapy service provision. The Philippine Academy of Occupational Therapists. 2022. URL: https://tinyurl.com/48tv8jht [accessed 2022-09-29]

11. Position statement occupational therapy and telehealth. World Federation of Occupational Therapists. 2021. URL: https://www.wfot.org/resources/occupational-therapy-and-telehealth [accessed 2021-05-30]
12. Regional digital health action plan for the WHO European Region 2023-2030. World Health Organization. URL: https://iris.who.int/bitstream/handle/10665/360950/72wd05e-DigitalHealth-220529.pdf?sequence=2 [accessed 2024-02-26]
13. The European health report 2021. Taking stock of the health-related sustainable development goals in the COVID-19 era with a focus on leaving no one behind. World Health Organization, Europe. URL: https://www.who.int/europe/publications/i/item/9789289057547 [accessed 2024-04-29]
14. Marwaa MN, Kristensen HK, Guidetti S, Ytterberg C. Physiotherapists' and occupational therapists' perspectives on information and communication technology in stroke rehabilitation. PLoS One 2020 Aug 28;15(8):e0236831 [FREE Full text] [doi: 10.1371/journal.pone.0236831] [Medline: 32857781]
15. Forbrigger S, Liblong M, Davies T, DePaul V, Morin E, Hashtrudi-Zaad K. Considerations for at-home upper-limb rehabilitation technology following stroke: perspectives of stroke survivors and therapists. J Rehabil Assist Technol Eng 2023 Apr 20;10:20556683231171840 [FREE Full text] [doi: 10.1177/20556683231171840] [Medline: 37124709]
16. Gustavsson M, Ytterberg C, Guidetti S. Exploring future possibilities of using information and communication technology in multidisciplinary rehabilitation after stroke - a grounded theory study. Scand J Occup Ther 2020 Apr 23;27(3):223-230 [FREE Full text] [doi: 10.1080/11038128.2019.1666918] [Medline: 31545665]
17. de Pietro C, Camenzind P, Sturny I, Crivelli L, Edwards-Garavoglia S, Spranger A, et al. Health systems in transition. Switzerland Health System Review. 2015. URL: https://iris.who.int/bitstream/handle/10665/330252/HiT-17-4-2015-eng.pdf [accessed 2024-04-29]
18. Die gesundheitspolitische strategie des bundesrats 2020–2030. Federal Council, Switzerland. 2019. URL: https://www.bag.admin.ch/bag/en/home/strategie-und-politik/gesundheit-2030/gesundheitspolitische-strategie-2030.html [accessed 2024-04-29]
19. Medizinische statistik der krankenhäuser:anzahl fälle und durchschnittliche aufenthaltsdauer (DAD) nach altersklasse und diagnosekode. Bundesamt für Statistik. 2024. URL: https://www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/gesundheitswesen/spitaeler/patienten-hospitalisierungen.assetdetail.28625238.html [accessed 2024-04-29]
20. Batavia AI, Hammer GS. Toward the development of consumer-based criteria for the evaluation of assistive devices. J Rehabil Res Dev 1990;27(4):425-436. [doi: 10.1682/jrrd.1990.10.0425] [Medline: 2089152]
21. Matthew-Maich N, Harris L, Ploeg J, Markle-Reid M, Valaitis R, Ibrahim S, et al. Designing, implementing, and evaluating mobile health technologies for managing chronic conditions in older adults: a scoping review. JMIR Mhealth Uhealth 2016 Jun 09;4(2):e29 [FREE Full text] [doi: 10.2196/mhealth.5127] [Medline: 27282195]
22. Charalambous A. Informal Caregivers: From Hidden Heroes to Integral Part of Care. Cham, Switzerland: Springer; 2023.
23. Brooks J, McCluskey S, Turley E, King N. The utility of template analysis in qualitative psychology research. Qual Res Psychol 2015 Apr 03;12(2):202-222 [FREE Full text] [doi: 10.1080/14780887.2014.955224] [Medline: 27499705]
24. Jayasree-Krishnan V, Ghosh S, Palumbo A, Kapila V, Raghavan P. Developing a framework for designing and deploying technology-assisted rehabilitation after stroke: a qualitative study. Am J Phys Med Rehabil 2021 Aug 01;100(8):774-779. [doi: 10.1097/PHM.0000000000001634] [Medline: 33141773]
25. King N. Using templates in the thematic analysis of text. In: Cassell C, Symon G, editors. Essential Guide to Qualitative Methods in Organizational Research. Thousand Oaks, CA: Sage Publications; 2004:256-270.
26. Elo S, Kyngäs H. The qualitative content analysis process. J Adv Nurs 2008 Apr 18;62(1):107-115. [doi: 10.1111/j.1365-2648.2007.04569.x] [Medline: 18352969]
27. Colorafi KJ, Evans B. Qualitative descriptive methods in health science research. HERD 2016 Jul 19;9(4):16-25 [FREE Full text] [doi: 10.1177/1937586715614171] [Medline: 26791375]
28. Nayar S, Stanley M. Qualitative Research Methodologies for Occupational Science and Occupational Therapy. New York, NY: Routledge; 2015.
29. Dresing T, Pehl T. Praxisbuch Interview, Transkription & Analyse: Anleitungen und Regelsysteme für Qualitativ Forschende. Marburg, Germany: Self-published; 2018.
30. MAXQDA. VERBI Software. 2021. URL: https://www.maxqda.com/about [accessed 2024-04-29]
31. Nowell LS, Norris JM, White DE, Moules NJ. Thematic analysis: striving to meet the trustworthiness criteria. Int J Qual Methods 2017 Oct 02;16(1):160940691773384. [doi: 10.1177/1609406917733847]
32. Madill A, Jordan A, Shirley C. Objectivity and reliability in qualitative analysis: realist, contextualist and radical constructionist epistemologies. Br J Psychol 2000 Feb 24;91 (Pt 1)(1):1-20. [doi: 10.1348/000712600161646] [Medline: 10717768]
33. Ballmer T, Kühne N, Petrig A, Eggenberger B, Moioli S, Gantschnig BE. The size and structure of the Swiss occupational therapy workforce. a survey study. Int J Health Prof 2023;10(1):67 [FREE Full text] [doi: 10.2478/ijhp-2023-0007]
34. Sidek NN, Kamalakannan S, Tengku Ismail TA, Musa KI, Ibrahim KA, Abdul Aziz Z, et al. Experiences and needs of the caregivers of stroke survivors in Malaysia-a phenomenological exploration. Front Neurol 2022 Sep 23;13:996620 [FREE Full text] [doi: 10.3389/fneur.2022.996620] [Medline: 36212650]

35. Lobo EH, Frølich A, Abdelrazek M, Rasmussen LJ, Grundy J, Livingston PM, et al. Information, involvement, self-care and support-the needs of caregivers of people with stroke: a grounded theory approach. PLoS One 2023 Jan 31;18(1):e0281198 [FREE Full text] [doi: 10.1371/journal.pone.0281198] [Medline: 36719929]
36. Kyle J, Skleparis D, Mair FS, Gallacher KI. What helps and hinders the provision of healthcare that minimises treatment burden and maximises patient capacity? a qualitative study of stroke health professional perspectives. BMJ Open 2020 Mar 18;10(3):e034113 [FREE Full text] [doi: 10.1136/bmjopen-2019-034113] [Medline: 32193265]
37. Sutter-Leve R, Passint E, Ness D, Rindflesch A. The caregiver experience after stroke in a COVID-19 environment: a qualitative study in inpatient rehabilitation. J Neurol Phys Ther 2021 Jan;45(1):14-20 [FREE Full text] [doi: 10.1097/NPT.0000000000000336] [Medline: 33086240]
38. Tenny S, Brannan JM, Brannan GD. Qualitative study. StatPearls. Treasure Island, FL: Statpearls Publishing; 2024. URL: https://www.ncbi.nlm.nih.gov/books/NBK470395/ [accessed 2024-04-29]
39. Klamroth-Marganska V, Gemperle M, Ballmer T, Grylka-Baeschlin S, Pehlke-Milde J, Gantschnig BE. Does therapy always need touch? a cross-sectional study among Switzerland-based occupational therapists and midwives regarding their experience with health care at a distance during the COVID-19 pandemic in spring 2020. BMC Health Serv Res 2021 Jun 15;21(1):578 [FREE Full text] [doi: 10.1186/s12913-021-06527-9] [Medline: 34130691]
40. Faktenblatt: Kostenübernahme für ambulante Leistungen auf räumliche Distanz während der COVID-19-Pandemie. Bundesamt für Gesundheit. 2020. URL: https://tinyurl.com/jp7s68bk [accessed 2024-04-03]
41. Caughlin S, Mehta S, Corriveau H, Eng JJ, Eskes G, Kairy D, et al. Implementing telerehabilitation after stroke: lessons learned from Canadian trials. Telemed J E Health 2020 Jun 01;26(6):710-719. [doi: 10.1089/tmj.2019.0097] [Medline: 31633454]
42. Lobo EH, Abdelrazek M, Kensing F, Rasmussen LJ, Livingston PM, Grundy J, et al. Technology-based support for stroke caregiving: a rapid review of evidence. J Nurs Manag 2022 Nov 31;30(8):3700-3713. [doi: 10.1111/jonm.13439] [Medline: 34350650]
43. Strategie. Physioswiss. URL: https://www.physioswiss.ch/de/ueber-uns/strategie [accessed 2024-04-29]
44. Qualität in der ergotherapie. Ergotherapie-Verband Schweiz. URL: https://www.ergotherapie.ch/verband/qualitaetsmanagement/ [accessed 2024-04-29]

Abbreviations

A3E: accessibility, adaptability, accountability, and engagement
ICT: information and communication technology
OT: occupational therapy
TA: template analysis

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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

Lena Rettinger[1], BSc, MSc; Erna Schönthaler[2], Mag; Andrea Kerschbaumer[1], BSc, Mag, MSc; Carina Hauser[1], Bakk rer soc oec, MA; Carissa Klupper[1], BSc, MHPE; Lea Aichinger[1], BSc, MSc; Franz Werner[1], Mag, Dr techn

[1]Health Assisting Engineering, FH Campus Wien, University of Applied Sciences, Vienna, Austria

[2]Occupational Therapy, FH Campus Wien, University of Applied Sciences, Vienna, Austria

Corresponding Author:
Lena Rettinger, BSc, MSc
Health Assisting Engineering
FH Campus Wien, University of Applied Sciences
Favoritenstrasse 226
Vienna, 1100
Austria
Phone: 43 606 68 77 ext 4382
Email: lena.rettinger@fh-campuswien.ac.at

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

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).

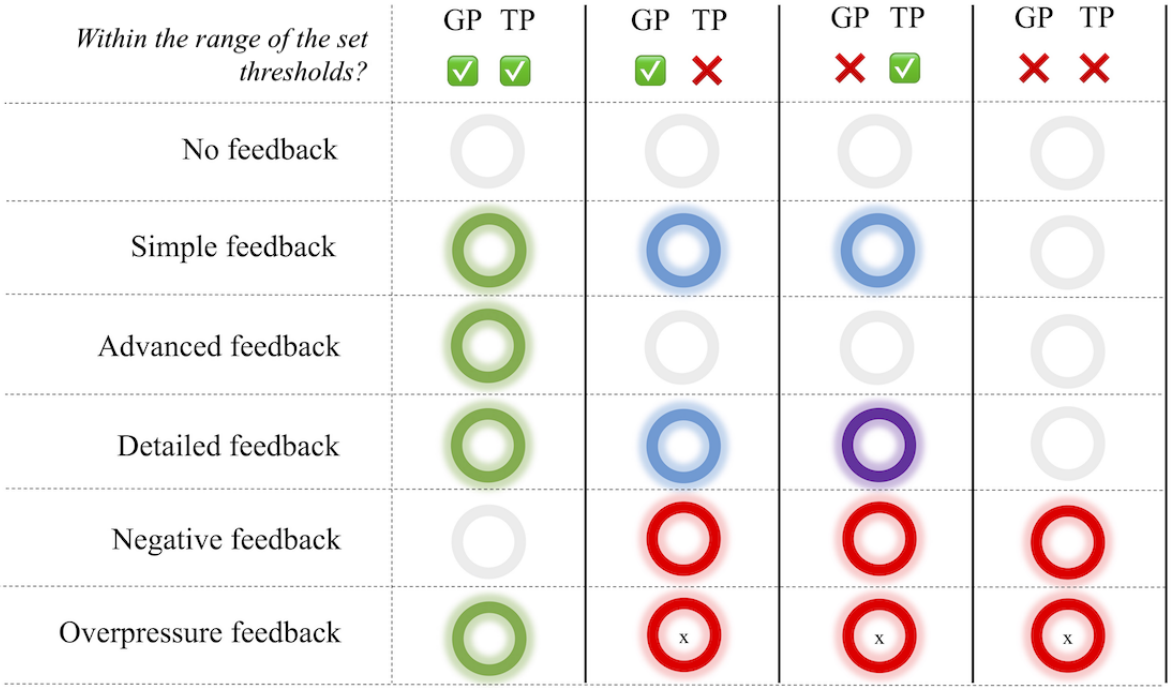
Figure 1. The SensoGrip pen with activated feedback LED and the SensoGrip app with line graphs for grip pressure (red) and tip pressure (blue).

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.

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

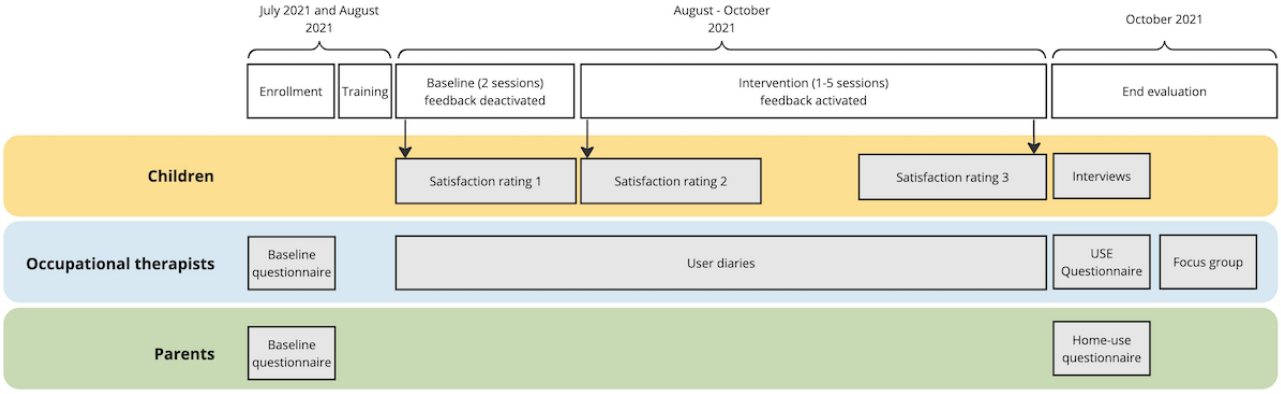
Overview and Procedure

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

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.

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

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.

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.

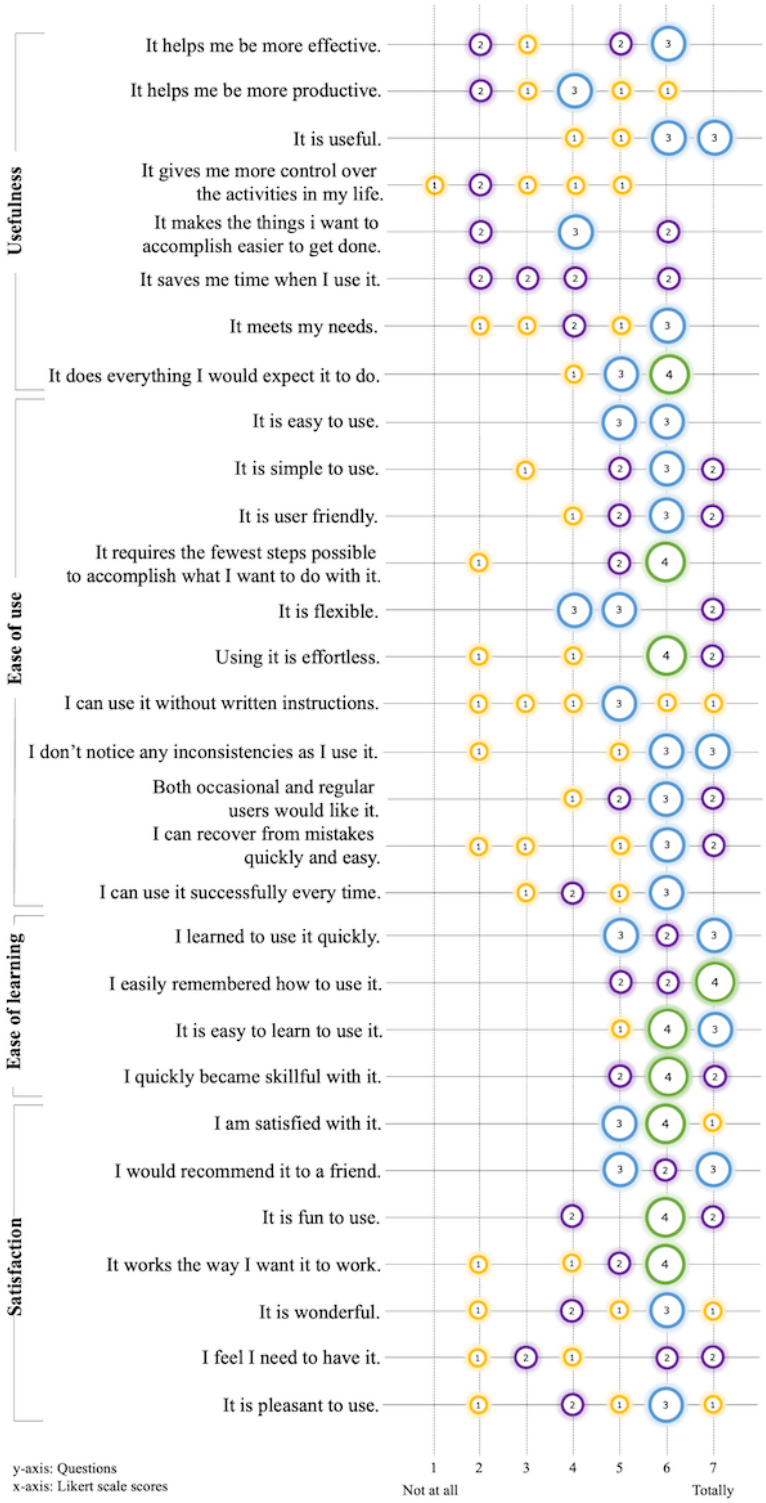
Application of the SensoGrip System in the Study

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:

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

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]

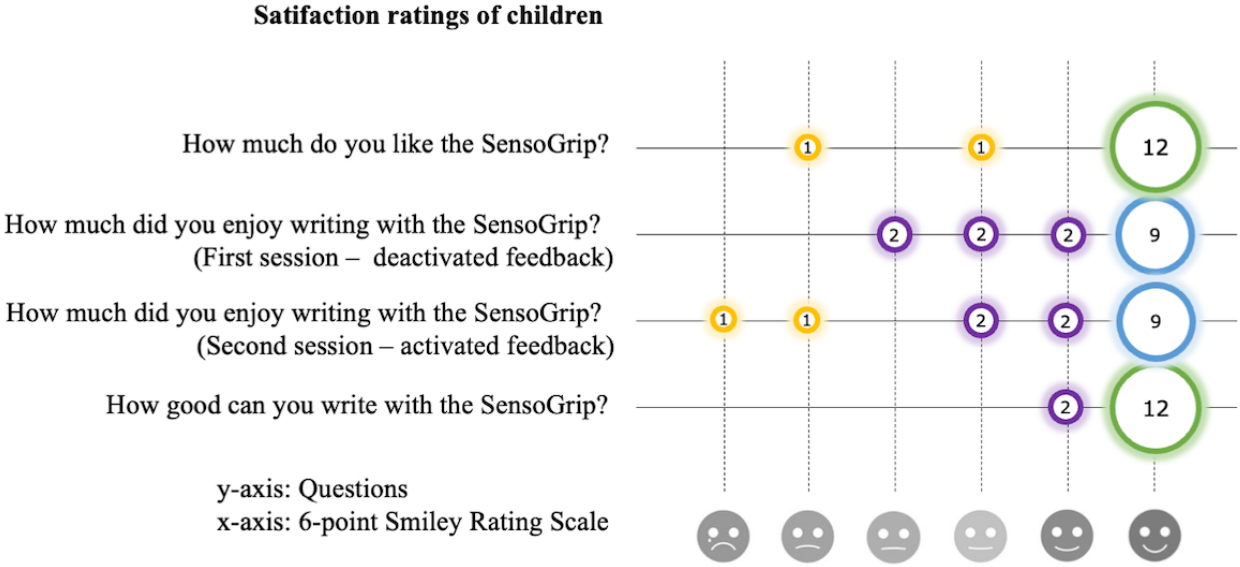
> *When I push very hard and then soft, the line goes up and down. Then again harder and softer, and so on.* [C3; aged 7 y]

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

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.

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.

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.

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]

References

1. Sassoon R. Handwriting: A New Perspective. Cheltenham, United Kingdom: Stanley Thornes; 1990.
2. Stewart SR. Development of written language proficiency: methods for teaching text structure. In: Communication Skills and Classroom Success: Therapy Methodologies for Language-Learning Disabled Students. Worthing, United Kingdom: College Hill Press; 1985.
3. Kruse O, Jakobs EM, Ruhmann G. Schlüsselkompetenz Schreiben: Konzepte, Methoden, Projekte für Schreibberatung und Schreibdidaktik an der Hochschule. Munich, Germany: Hermann Luchterhand Verlag; 1999.
4. van Hartingsveldt MJ, De Groot IJ, Aarts PB, Nijhuis-Van Der Sanden MW. Standardized tests of handwriting readiness: a systematic review of the literature. Dev Med Child Neurol 2011 Jun;53(6):506-515 [FREE Full text] [doi: 10.1111/j.1469-8749.2010.03895.x] [Medline: 21309763]
5. Chu S. Occupational therapy for children with handwriting difficulties: a framework for evaluation and treatment. J Occup Ther Educ 2016 Nov 05;60(12):514-520. [doi: 10.1177/030802269706001202]
6. Maeland AF. Handwriting and perceptual-motor skills in clumsy, dysgraphic, and 'normal' children. Percept Mot Skills 1992 Dec 31;75(3 Pt 2):1207-1217. [doi: 10.2466/pms.1992.75.3f.1207] [Medline: 1484789]
7. Wallen M, Duff S, Goyen TA, Froude E. Respecting the evidence: responsible assessment and effective intervention for children with handwriting difficulties. Aust Occup Ther J 2013 Oct 16;60(5):366-369. [doi: 10.1111/1440-1630.12045] [Medline: 24089989]
8. Diaz Meyer M, Marquardt C, Klimen A. Eltern und Lehrer beunruhigt. Die Rolle der Schreibmotorik beim Schreibenlernen. Ergotherapie Rehab 2017;56(10):18-21 [FREE Full text]
9. Lin YC, Chao YL, Wu SK, Lin HH, Hsu CH, Hsu HM, et al. Comprehension of handwriting development: pen-grip kinetics in handwriting tasks and its relation to fine motor skills among school-age children. Aust Occup Ther J 2017 Oct;64(5):369-380. [doi: 10.1111/1440-1630.12393] [Medline: 28512858]

10. Chau T, Ji J, Tam C, Schwellnus H. A novel instrument for quantifying grip activity during handwriting. Arch Phys Med Rehabil 2006 Nov;87(11):1542-1547. [doi: 10.1016/j.apmr.2006.08.328] [Medline: 17084133]
11. Falk TH, Tam C, Schwellnus H, Chau T. Grip force variability and its effects on children's handwriting legibility, form, and strokes. J Biomech Eng 2010 Nov;132(11):114504. [doi: 10.1115/1.4002611] [Medline: 21034156]
12. Giggins OM, Persson UM, Caulfield B. Biofeedback in rehabilitation. J Neuroeng Rehabil 2013 Jun 18;10(1):60 [FREE Full text] [doi: 10.1186/1743-0003-10-60] [Medline: 23777436]
13. Lengauer L. Drucksensitiver Stift für Kinder mit Kraftdosierungsproblemen während des Schreibprozesses. Partizipatorische forschungsarbeit. FH Campus Wien, University of Applied Sciences. 2018 Jun 29. URL: https://docplayer.org/220413830-Drucksensitiver-stift-fuer-kinder-mit-kraftdosierungsproblemen-waehrend-des-schreibprozesses-partizipatorische-forschungsarbeit.html [accessed 2024-02-27]
14. Rettinger L, Klupper C, Hauser C, Schönthaler E, Kerschbaumer A, Werner K, et al. Participatory design and needs assessment for a pressure-sensitive pen and mobile application (SensoGrip) for children with handwriting problems. Disabil Rehabil Assist Technol 2022 Oct 27:1-7 (forthcoming). [doi: 10.1080/17483107.2022.2138994] [Medline: 36301725]
15. Krasny-Pacini A, Evans J. Single-case experimental designs to assess intervention effectiveness in rehabilitation: a practical guide. Ann Phys Rehabil Med 2018 May;61(3):164-179 [FREE Full text] [doi: 10.1016/j.rehab.2017.12.002] [Medline: 29253607]
16. Biernacki P, Waldorf D. Snowball sampling: problems and techniques of chain referral sampling. Sociol Methods Res 2016 Jun 29;10(2):141-163. [doi: 10.1177/004912418101000205]
17. Gao M, Kortum P, Oswald F. Psychometric evaluation of the USE (usefulness, satisfaction, and ease of use) questionnaire for reliability and validity. Proc Hum Factors Ergon Soc Annu Meet 2018 Sep 27;62(1):1414-1418. [doi: 10.1177/1541931218621322]
18. Lund AM. Measuring usability with the USE questionnaire. Usability Interface 2001;8(2):3-6 [FREE Full text]
19. Kuckartz U, Rädiker S. Qualitative Inhaltsanalyse. Methoden, Praxis, Computerunterstützung. Weinheim, Germany: Beltz Juventa; 2018.
20. Council Directive 93/42/EEC of 14 June 1993. Official Journal of the European Communities. 1993 Jul 12. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31993L0042 [accessed 2024-02-21]
21. Clinical investigations with medical devices. Austrian Federal Office for Safety in Health Care. URL: https://www.basg.gv.at/en/healthcare-professionals/clinical-trials/clinical-trials-with-medical-devices [accessed 2022-09-26]
22. Zimmermann G, Weigelt C. Peripheres biofeedback bei grafomotorischen störungen – schneller schön schreiben. ergopraxis 2010 Sep 2;3(09):24-27 [FREE Full text] [doi: 10.1055/s-0030-1265877]
23. de Graaf MM, Ben Allouch S, van Dijk JA. A phased framework for long-term user acceptance of interactive technology in domestic environments. New Media Soc 2018 Jul 08;20(7):2582-2603 [FREE Full text] [doi: 10.1177/1461444817727264] [Medline: 30581364]

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

Megan Elizabeth Gately[1,2], OTD, PhD; Dylan E Waller[3], MSc; Emily E Metcalf[3,4], MA; Lauren R Moo[1,5], MD

[1]VA Bedford Health Care System, Geriatric Research Education and Clinical Center (GRECC), Bedford, MA, United States

[2]Boston University School of Medicine, Division of Geriatrics, Boston, MA, United States

[3]VA Portland Health Care System, Center to Improve Veteran Involvement in Care (CIVIC), Portland, OR, United States

[4]Oregon Medical Research Center, Portland, OR, United States

[5]Massachusetts General Hospital, Cognitive Behavioral Neurology Unit, Boston, MA, United States

Corresponding Author:
Megan Elizabeth Gately, OTD, PhD
VA Bedford Health Care System
Geriatric Research Education and Clinical Center (GRECC)
200 Springs Road
Bedford, MA, 01730
United States
Phone: 1 7816872000
Email: megan.gately@va.gov

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

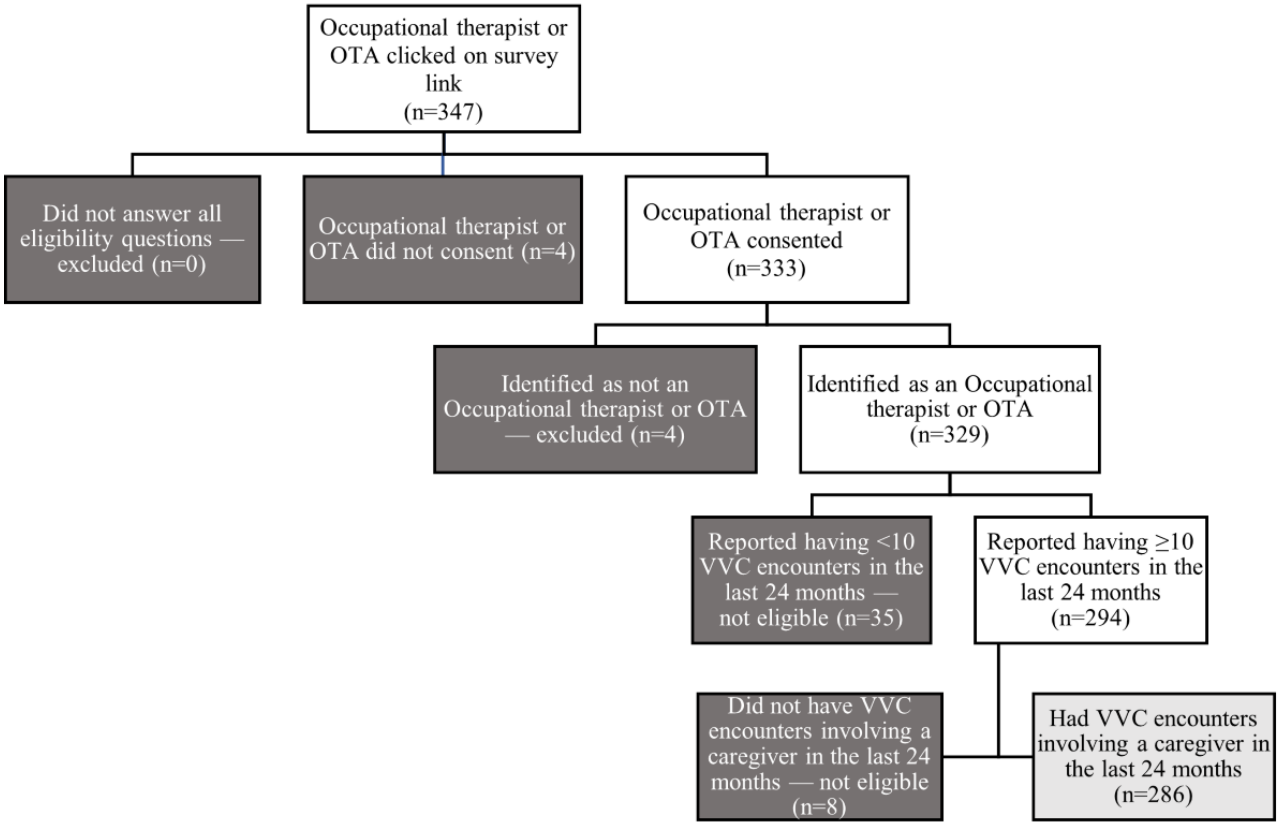
To address this knowledge gap, this study examined the caregiver's role in supporting patient engagement in in-home video telehealth visits for OT services from the perspectives of VHA OT practitioners. Specifically, we sought to identify patient factors that necessitate caregiver participation in in-home 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.

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

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

(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.

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)

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

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.

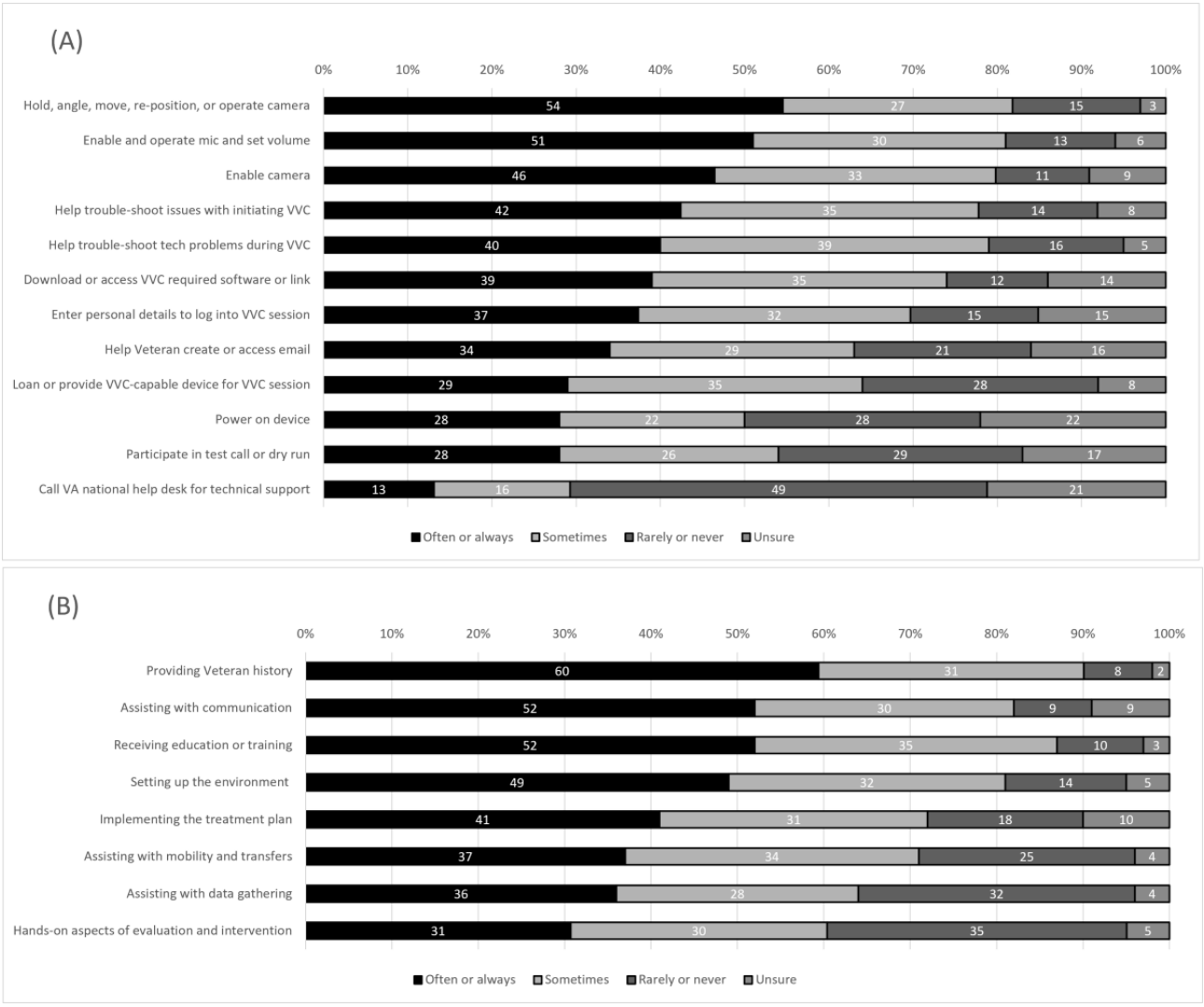
Table 2. Patient factors that contribute to caregiver participation in in-home video telehealth (n=285). Survey items were shortened for presentation; for full details, see Multimedia Appendix 1.

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%).

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

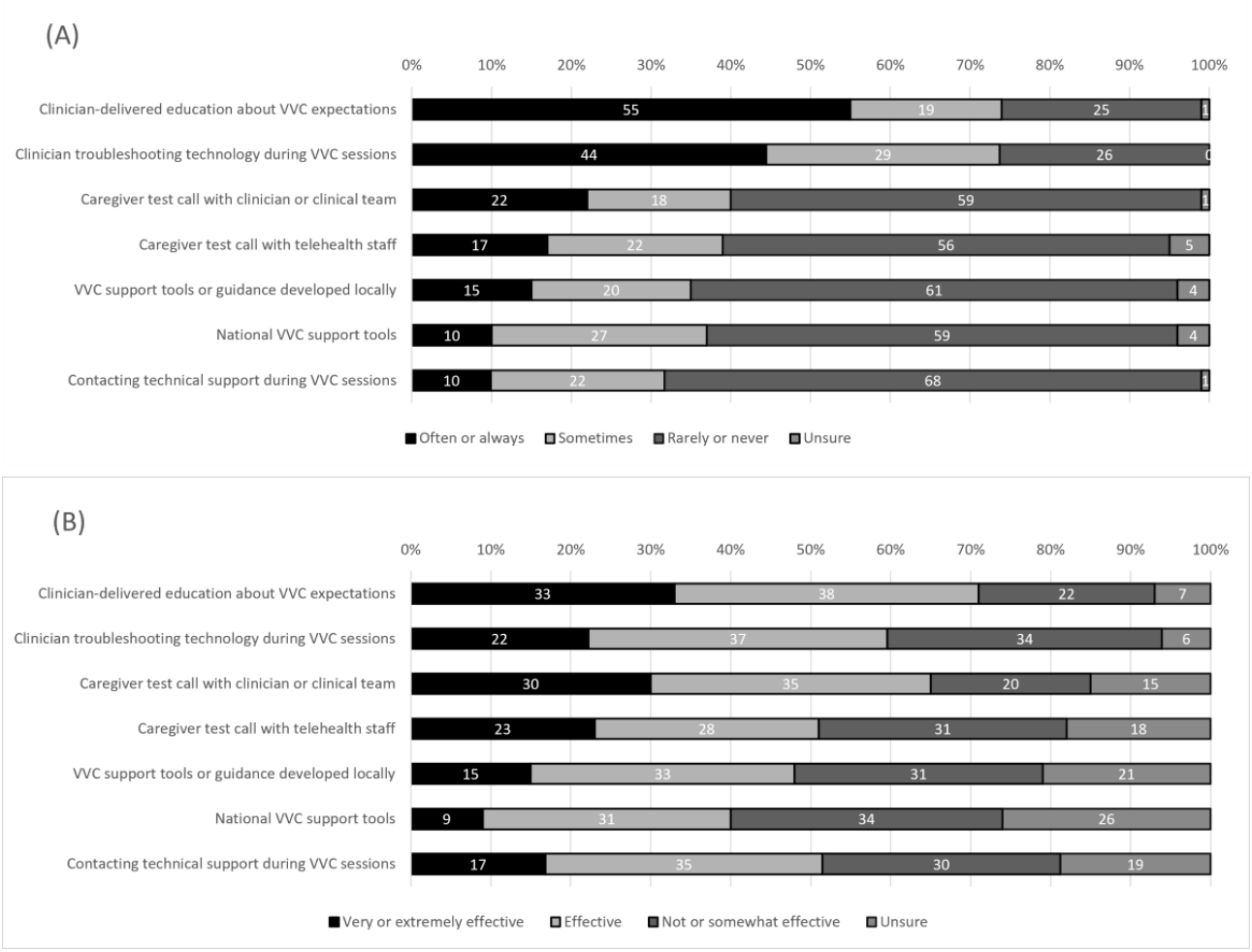
Respondents were then asked to rate the frequency of caregivers' assistance with various clinical, nontechnological tasks (Figure 2). The tasks with the highest often or always ratings were providing history (eg, offering input on patient function or details of the patient's home; 143/239, 59.8%), assisting 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%

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.

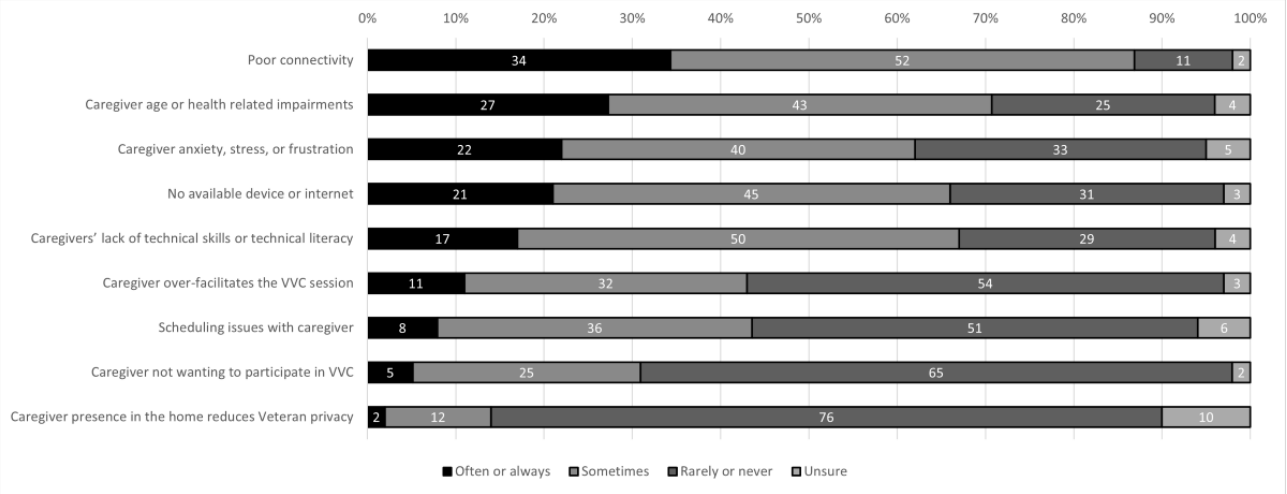
Figure 3. Facilitators of caregiver participation in video telehealth, including the frequency of occurrence and perceived effectiveness. Note: Survey items were shortened for presentation; for full details, see Multimedia Appendix 1. VVC: VA Video Connect.



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.

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.

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

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

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]

References

1. Veterans Health Administration. U.S. Department of Veteran Affairs. URL: https://www.va.gov/health/ [accessed 2023-07-19]
2. Office of Rural Health home. U.S. Department of Veterans Affairs. URL: https://www.ruralhealth.va.gov/ [accessed 2023-07-17]
3. Hale-Gallardo JL, Kreider CM, Jia H, Castaneda G, Freytes IM, Cowper Ripley DC, et al. Telerehabilitation for rural veterans: a qualitative assessment of barriers and facilitators to implementation. J Multidiscip Healthc 2020 Jul 1;13:559-570 [FREE Full text] [doi: 10.2147/JMDH.S247267] [Medline: 32669850]
4. Dobis EA, McGranahan D. Rural residents appear to be more vulnerable to serious infection or death from coronavirus COVID-19. U.S. Department of Agriculture Economic Research Service. URL: https://www.ers.usda.gov/amber-waves/2021/february/rural-residents-appear-to-be-more-vulnerable-to-serious-infection-or-death-from-coronavirus-covid-19/ [accessed 2023-07-11]
5. Cohen SA, Cook SK, Sando TA, Sabik NJ. What aspects of rural life contribute to rural-urban health disparities in older adults? Evidence from a national survey. J Rural Health 2018 Jun;34(3):293-303. [doi: 10.1111/jrh.12287] [Medline: 29193298]
6. James W, Cossman JS. Long-term trends in Black and White mortality in the rural United States: evidence of a race-specific rural mortality penalty. J Rural Health 2017 Jan;33(1):21-31. [doi: 10.1111/jrh.12181] [Medline: 27062224]
7. Cosby AG, McDoom-Echebiri MM, James W, Khandekar H, Brown W, Hanna HL. Growth and persistence of place-based mortality in the United States: the rural mortality penalty. Am J Public Health 2019 Jan;109(1):155-162. [doi: 10.2105/AJPH.2018.304787] [Medline: 30496008]
8. Richman L, Pearson J, Beasley C, Stanifer J. Addressing health inequalities in diverse, rural communities: an unmet need. SSM Popul Health 2019 Apr;7:100398 [FREE Full text] [doi: 10.1016/j.ssmph.2019.100398] [Medline: 31011618]
9. Smith AS, Trevelyan E. The older population in rural America: 2012-2016. United States Census Bureau. 2019 Sep 23. URL: https://www.census.gov/library/publications/2019/acs/acs-41.html [accessed 2023-07-16]
10. Peterson LE, Bazemore A, Bragg EJ, Xierali I, Warshaw GA. Rural-urban distribution of the U.S. Geriatrics physician workforce. J Am Geriatr Soc 2011 Apr;59(4):699-703. [doi: 10.1111/j.1532-5415.2011.03335.x] [Medline: 21438865]

11. Liu CJ, Chang WP, Chang MC. Occupational therapy interventions to improve activities of daily living for community-dwelling older adults: a systematic review. Am J Occup Ther 2018;72(4):7204190060p1-720419006p11. [doi: 10.5014/ajot.2018.031252] [Medline: 29953830]
12. Liu CJ, Chang MC. Interventions within the scope of occupational therapy practice to improve performance of daily activities for older adults with low vision: a systematic review. Am J Occup Ther 2020;74(1):7401185010p1-740118501p18 [FREE Full text] [doi: 10.5014/ajot.2020.038372] [Medline: 32078506]
13. Smallfield S, Molitor WL. Occupational therapy interventions supporting social participation and leisure engagement for community-dwelling older adults: a systematic review. Am J Occup Ther 2018;72(4):7204190020p1-7204190020p8. [doi: 10.5014/ajot.2018.030627] [Medline: 29953826]
14. Stark S, Keglovits M, Arbesman M, Lieberman D. Effect of home modification interventions on the participation of community-dwelling adults with health conditions: a systematic review. Am J Occup Ther 2017;71(2):7102290010p1-710229001p11. [doi: 10.5014/ajot.2017.018887] [Medline: 28218595]
15. Brown T, Kidwell H, Priest P, Sellers A, Serino A, Spencer B. Occupational therapy interventions to support aging in place: a rapid systematic review. Occupational Therapy Doctoral Student Rapid Systematic Reviews. Indianapolis, IN: Indiana University Purdue University Indianapolis URL: https://scholarworks.iupui.edu/server/api/core/bitstreams/a754e9c9-66fa-4b48-a578-830a31ed5385/content#:~:text=Overall%2C%20there%20is%20strong%20evidence,and%20a%20Lifestyle%20redesign%20program [accessed 2024-02-27]
16. Kaldenberg J, Smallfield S. Occupational therapy practice guidelines for older adults with low vision. Am J Occup Ther 2020;74(2):7402397010p1-740239701p23. [doi: 10.5014/ajot.2020.742003] [Medline: 32204790]
17. Jensen L, Padilla R. Effectiveness of environment-based interventions that address behavior, perception, and falls in people with Alzheimer's disease and related major neurocognitive disorders: a systematic review. Am J Occup Ther 2017;71(5):7105180030p1-710518003p10. [doi: 10.5014/ajot.2017.027409] [Medline: 28809653]
18. Struckmeyer LR, Pickens ND. Home modifications for people with Alzheimer's disease: a scoping review. Am J Occup Ther 2016;70(1):7001270020p1-7001270020p9. [doi: 10.5014/ajot.2015.016089] [Medline: 26709430]
19. Smallfield S, Kaldenberg J. Occupational therapy interventions for older adults with low vision. Am J Occup Ther 2020;74(2):7402390010p1-7402390010p5. [doi: 10.5014/ajot.2020.742004] [Medline: 32204789]
20. Harkey LC, Jung SM, Newton ER, Patterson A. Patient satisfaction with telehealth in rural settings: a systematic review. Int J Telerehabil 2020 Dec 08;12(2):53-64 [FREE Full text] [doi: 10.5195/ijt.2020.6303] [Medline: 33520095]
21. Kessler D, Anderson ND, Dawson DR. Occupational performance coaching for stroke survivors delivered via telerehabilitation using a single-case experimental design. Br J Occup Ther 2021 Aug;84(8):488-496 [FREE Full text] [doi: 10.1177/0308022620988471] [Medline: 34381289]
22. Lafaro KJ, Raz DJ, Kim JY, Hite S, Ruel N, Varatkar G, et al. Pilot study of a telehealth perioperative physical activity intervention for older adults with cancer and their caregivers. Support Care Cancer 2020 Aug;28(8):3867-3876 [FREE Full text] [doi: 10.1007/s00520-019-05230-0] [Medline: 31845007]
23. Loubani K, Schreuer N, Kizony R. Telerehabilitation for managing daily participation among breast cancer survivors during COVID-19: a feasibility study. J Clin Med 2022 Feb 16;11(4):1022 [FREE Full text] [doi: 10.3390/jcm11041022] [Medline: 35207294]
24. Proffitt R, Cason J, Little L, Pickett KA. Stimulating research to advance evidence-based applications of telehealth in occupational therapy. OTJR (Thorofare N J) 2021 Jul;41(3):153-162 [FREE Full text] [doi: 10.1177/15394492211011433] [Medline: 33926321]
25. Law M, Cooper B, Strong S, Stewart D, Rigby P, Letts L. The person-environment-occupation model: a transactive approach to occupational performance. Can J Occup Ther 2016 Apr 22;63(1):9-23. [doi: 10.1177/000841749606300103]
26. De Santis KK, Mergenthal L, Christianson L, Busskamp A, Vonstein C, Zeeb H. Digital technologies for health promotion and disease prevention in older people: scoping review. J Med Internet Res 2023 Mar 23;25:e43542 [FREE Full text] [doi: 10.2196/43542] [Medline: 36951896]
27. Gately ME, Metcalf EE, Waller DE, McLaren JE, Chamberlin ES, Hawley CE, et al. Caregiver support role in occupational therapy video telehealth: a scoping review. Top Geriatr Rehabil 2023 Oct;39(4):253-265. [doi: 10.1097/TGR.0000000000000409] [Medline: 37901356]
28. Eysenbach G. Improving the quality of web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). J Med Internet Res 2004 Sep 29;6(3):e34 [FREE Full text] [doi: 10.2196/jmir.6.3.e34] [Medline: 15471760]
29. Gately ME, Waller D, Metcalf EE, Moo LR. Occupational therapy practitioner perspectives of the role of caregivers in video telehealth. J Gerontol Nurs 2022 Oct;48(10):15-20 [FREE Full text] [doi: 10.3928/00989134-20220908-02] [Medline: 36169296]
30. Willis GB, Artino ARJ. What do our respondents think we're asking? Using cognitive interviewing to improve medical education surveys. J Grad Med Educ 2013 Sep;5(3):353-356 [FREE Full text] [doi: 10.4300/JGME-D-13-00154.1] [Medline: 24404294]
31. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2013 Nov 27;310(20):2191-2194. [doi: 10.1001/jama.2013.281053] [Medline: 24141714]

32. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009 Apr;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
33. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res 2005 Nov;15(9):1277-1288. [doi: 10.1177/1049732305276687] [Medline: 16204405]
34. Surveying the profession: 2015 AOTA the salary and workforce survey. The American Occupational Therapy Association. 2015 Jun 29. URL: https://agrability.osu.edu/sites/agrability/files/imce/OT-Volume-20-Issue-11_0.pdf [accessed 2023-07-01]
35. VA caregiver support program. U.S. Department of Veterans Affairs. URL: https://www.caregiver.va.gov/ [accessed 2022-09-08]
36. Raj M, Iott B, Anthony D, Platt J. Family caregivers' experiences with telehealth during COVID-19: insights from Michigan. Ann Fam Med 2022 Jan 24;20(1):69-71 [FREE Full text] [doi: 10.1370/afm.2760] [Medline: 35074770]
37. Telehealth and older patients. Health Resources & Services Administration. URL: https://telehealth.hhs.gov/providers/health-equity-in-telehealth/telehealth-and-older-patients [accessed 2023-07-17]
38. Shepherd-Banigan M, Sherman SR, Lindquist JH, Miller KE, Tucker M, Smith VA, et al. Family caregivers of veterans experience high levels of burden, distress, and financial strain. J Am Geriatr Soc 2020 Nov;68(11):2675-2683 [FREE Full text] [doi: 10.1111/jgs.16767] [Medline: 32822072]
39. Kalicki AV, Moody KA, Franzosa E, Gliatto PM, Ornstein KA. Barriers to telehealth access among homebound older adults. J Am Geriatr Soc 2021 Sep;69(9):2404-2411 [FREE Full text] [doi: 10.1111/jgs.17163] [Medline: 33848360]
40. Egan KJ, Pot AM. Encouraging innovation for assistive health technologies in dementia: barriers, enablers and next steps to be taken. J Am Med Dir Assoc 2016 Apr 01;17(4):357-363. [doi: 10.1016/j.jamda.2016.01.010] [Medline: 27016431]
41. Foster MV, Sethares KA. Facilitators and barriers to the adoption of telehealth in older adults: an integrative review. Comput Inform Nurs 2014 Nov;32(11):523-33; quiz 534. [doi: 10.1097/CIN.0000000000000105] [Medline: 25251862]
42. McClain C, Vogels EA, Perrin A, Sechopoulos S, Rainie L. How the internet and technology shaped Americans' personal experiences amid COVID-19. Pew Research Center. 2021 Sep 1. URL: https://www.pewresearch.org/internet/2021/09/01/how-the-internet-and-technology-shaped-americans-personal-experiences-amid-covid-19/ [accessed 2023-07-17]
43. Kaldenberg J, Smallfield S. Training older adults with low vision to use a computer tablet: a feasibility study. Br J Occup Ther 2016 Jul 20;80(2):117-122. [doi: 10.1177/0308022616648172]
44. Gately ME, Muccini S, Eggleston BA, McLaren JE. Program evaluation of My Life, My Story: virtual storytelling in the COVID-19 age. Clin Gerontol 2022;45(1):195-203. [doi: 10.1080/07317115.2021.1931610] [Medline: 34219605]
45. Berridge C, Hooyman N. The consequences of ageist language are upon us. J Gerontol Soc Work 2020 May 27;63(6-7):508-512. [doi: 10.1080/01634372.2020.1764688] [Medline: 32458755]
46. Köttl H, Gallistl V, Rohner R, Ayalon L. "But at the age of 85? Forget it!": internalized ageism, a barrier to technology use. J Aging Stud 2021 Dec;59:100971 [FREE Full text] [doi: 10.1016/j.jaging.2021.100971] [Medline: 34794716]
47. Gately ME, Tickle-Degnen L, McLaren JE, Ward N, Ladin K, Moo LR. Factors influencing barriers and facilitators to in-home video telehealth for dementia management. Clin Gerontol 2022 Jun 06;45(4):1020-1033. [doi: 10.1080/07317115.2021.1930316] [Medline: 34096477]
48. Finkelstein R, Wu Y, Brennan-Ing M. Older adults' experiences with using information and communication technology and tech support services in New York City: findings and recommendations for post-pandemic digital pedagogy for older adults. Front Psychol 2023;14:1129512 [FREE Full text] [doi: 10.3389/fpsyg.2023.1129512] [Medline: 37138998]
49. Moo LR. Home video visits: two-dimensional view of the geriatric 5 M's. J Am Geriatr Soc 2020 Nov;68(11):2425-2427. [doi: 10.1111/jgs.16843] [Medline: 32930388]
50. Jacobs JC, Blonigen DM, Kimerling R, Slightam C, Gregory AJ, Gurmessa T, et al. Increasing mental health care access, continuity, and efficiency for veterans through telehealth with video tablets. Psychiatr Serv 2019 Nov 01;70(11):976-982. [doi: 10.1176/appi.ps.201900104] [Medline: 31378193]
51. Zulman DM, Wong EP, Slightam C, Gregory A, Jacobs JC, Kimerling R, et al. Making connections: nationwide implementation of video telehealth tablets to address access barriers in veterans. JAMIA Open 2019 Oct;2(3):323-329. [doi: 10.1093/jamiaopen/ooz024] [Medline: 32766533]
52. Patel M, Berlin H, Rajkumar A, Krein SL, Miller R, DeVito J, et al. Barriers to telemedicine use: qualitative analysis of provider perspectives during the COVID-19 pandemic. JMIR Hum Factors 2023 Jun 26;10:e39249 [FREE Full text] [doi: 10.2196/39249] [Medline: 37358887]
53. Schulz R, Beach SR, Czaja SJ, Martire LM, Monin JK. Family caregiving for older adults. Annu Rev Psychol 2020 Jan 04;71:635-659 [FREE Full text] [doi: 10.1146/annurev-psych-010419-050754] [Medline: 31905111]
54. Yorkston KM, Bourgeois MS, Baylor CR. Communication and aging. Phys Med Rehabil Clin N Am 2010 May;21(2):309-319 [FREE Full text] [doi: 10.1016/j.pmr.2009.12.011] [Medline: 20494279]
55. Wootton AR, McCuistian C, Legnitto Packard DA, Gruber VA, Saberi P. Overcoming technological challenges: lessons learned from a telehealth counseling study. Telemed J E Health 2020 Oct 01;26(10):1278-1283. [doi: 10.1089/tmj.2019.0191] [Medline: 31800368]

56. Donaghy E, Atherton H, Hammersley V, McNeilly H, Bikker A, Robbins L, et al. Acceptability, benefits, and challenges of video consulting: a qualitative study in primary care. Br J Gen Pract 2019 Sep;69(686):e586-e594 [FREE Full text] [doi: 10.3399/bjgp19X704141] [Medline: 31160368]
57. Ho K, Karlinsky H, Jarvis-Selinger S, May J. Videoconferencing for telehealth: unexpected challenges and unprecedented opportunities. BC Med J 2004;46(6):285-289 [FREE Full text]
58. Gordon HS, Solanki P, Bokhour BG, Gopal RK. "I'm not feeling like I'm part of the conversation" patients' perspectives on communicating in clinical video telehealth visits. J Gen Intern Med 2020 Jun;35(6):1751-1758 [FREE Full text] [doi: 10.1007/s11606-020-05673-w] [Medline: 32016705]
59. Mao A, Tam L, Xu A, Osborn K, Sheffrin M, Gould C, et al. Barriers to telemedicine video visits for older adults in independent living facilities: mixed methods cross-sectional needs assessment. JMIR Aging 2022 Apr 19;5(2):e34326 [FREE Full text] [doi: 10.2196/34326] [Medline: 35438648]
60. Barry Walsh C, Cahalan R, Hinman RS, O' Sullivan K. Psychometric properties of performance-based measures of physical function administered via telehealth among people with chronic conditions: a systematic review. PLoS One 2022 Sep 9;17(9):e0274349 [FREE Full text] [doi: 10.1371/journal.pone.0274349] [Medline: 36083879]
61. National Academies of Sciences, Engineering, and Medicine.. The Use of Telehealth for Disability Evaluations in Medicine and Allied Health: Proceedings of a Workshop. Washington, DC: The National Academies Press; 2022.
62. Di Lorito C, Long A, Byrne A, Harwood RH, Gladman JR, Schneider S, et al. Exercise interventions for older adults: a systematic review of meta-analyses. J Sport Health Sci 2021 Jan;10(1):29-47 [FREE Full text] [doi: 10.1016/j.jshs.2020.06.003] [Medline: 32525097]
63. Gately ME, Trudeau SA, Moo LR. Feasibility of telehealth-delivered home safety evaluations for caregivers of clients with dementia. OTJR (Thorofare N J) 2020 Jan;40(1):42-49. [doi: 10.1177/1539449219859935] [Medline: 31319745]
64. L'Heureux T, Parmar J, Dobbs B, Charles L, Tian PG, Sacrey LA, et al. Rural family caregiving: a closer look at the impacts of health, care work, financial distress, and social loneliness on anxiety. Healthcare (Basel) 2022 Jun 21;10(7):1155 [FREE Full text] [doi: 10.3390/healthcare10071155] [Medline: 35885682]
65. Cohen SA, Ahmed N, Brown MJ, Meucci MR, Greaney ML. Rural-urban differences in informal caregiving and health-related quality of life. J Rural Health 2022 Mar;38(2):442-456. [doi: 10.1111/jrh.12581] [Medline: 33956360]
66. Carbone S, Kokorelias KM, Berta W, Law S, Kuluski K. Stakeholder involvement in care transition planning for older adults and the factors guiding their decision-making: a scoping review. BMJ Open 2022 Jun 13;12(6):e059446 [FREE Full text] [doi: 10.1136/bmjopen-2021-059446] [Medline: 35697455]
67. Hirschman KB, Shaid E, McCauley K, Pauly MV, Naylor MD. Continuity of care: the Transitional Care Model. Online J Issues Nurs 2015 Sep 30;20(3):1 [FREE Full text] [Medline: 26882510]
68. LeBeau K, Varma DS, Kreider CM, Castañeda G, Knecht C, Cowper Ripley D, et al. Whole Health coaching to rural veterans through telehealth: advantages, gaps, and opportunities. Front Public Health 2023;11:1057586 [FREE Full text] [doi: 10.3389/fpubh.2023.1057586] [Medline: 37050942]
69. Leung LB, Yoo C, Chu K, O'Shea A, Jackson NJ, Heyworth L, et al. Rates of primary care and integrated mental health telemedicine visits between rural and urban Veterans Affairs beneficiaries before and after the onset of the COVID-19 pandemic. JAMA Netw Open 2023 Mar 01;6(3):e231864 [FREE Full text] [doi: 10.1001/jamanetworkopen.2023.1864] [Medline: 36881410]
70. Dellasega C, Zerbe TM. Caregivers of frail rural older adults. Effects of an advanced practice nursing intervention. J Gerontol Nurs 2002 Oct;28(10):40-49. [doi: 10.3928/0098-9134-20021001-11] [Medline: 12382459]
71. Fox MT, Butler JI, Sidani S, Nguyen A. Family caregivers' preparedness to support the physical activity of patients at risk for hospital readmission in rural communities: an interpretive descriptive study. BMC Health Serv Res 2022 Jul 13;22(1):907 [FREE Full text] [doi: 10.1186/s12913-022-08289-4] [Medline: 35831904]
72. Washington KT, Oliver DP, Smith JB, Kruse RL, Meghani SH, Demiris G. A comparison of rural and urban hospice family caregivers' cancer pain knowledge and experience. J Pain Symptom Manage 2019 Oct;58(4):685-689 [FREE Full text] [doi: 10.1016/j.jpainsymman.2019.07.010] [Medline: 31325546]
73. Cascella LM. Overcoming telehealth barriers and engaging older adults in virtual care. MedPro Group. URL: https://www.medpro.com/telehealth-barriers-for-older-adults [accessed 2023-07-17]
74. Crotty BH, Hyun N, Polovneff A, Dong Y, Decker MC, Mortensen N, et al. Analysis of clinician and patient factors and completion of telemedicine appointments using video. JAMA Netw Open 2021 Nov 01;4(11):e2132917 [FREE Full text] [doi: 10.1001/jamanetworkopen.2021.32917] [Medline: 34735013]
75. Rivera V, Aldridge MD, Ornstein K, Moody KA, Chun A. RESEARCHRacial and socioeconomic disparities in access to telehealth. J Am Geriatr Soc 2021 Jan 24;69(1):44-45 [FREE Full text] [doi: 10.1111/jgs.16904] [Medline: 33075143]

Abbreviations

AOTA: American Occupational Therapy Association
LMR: Office of Labor-Management Relations
OASC: Organizational Assessment Sub-Committee

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

Multidisciplinary Home-Based Rehabilitation Program for Individuals With Disabilities: Longitudinal Observational Study

Patricio Barría[1,2], PhD; Asterio Andrade[1], PhD; Daniel Gomez-Vargas[3], MSc; Alejandro Yelincic[1], MSc; Flavio Roberti[3], Prof Dr; Eduardo Bahamonde[1], BMed; Rolando Aguilar[2], Prof Dr; Bessie Cordova[1], BEng

[1]Rehabilitation Center Club de Leones Cruz del Sur, Punta Arenas, Chile

[2]Department of Electrical Engineering, University of Magallanes, Punta Arenas, Chile

[3]Institute of Automatics, National University of San Juan, San Juan, Argentina

Corresponding Author:
Daniel Gomez-Vargas, MSc
Institute of Automatics
National University of San Juan
Av. Libertador Gral. San Martín 1102
San Juan, 5400
Argentina
Phone: 54 542644213303
Email: dgomez@inaut.unsj.edu.ar

Abstract

Background: Disability affects a significant portion of the global population nowadays, necessitating innovative approaches to access rehabilitation processes. Home-based rehabilitation has emerged as a beneficial approach, offering comfort and context-specific therapy.

Objective: This study aims to evaluate the impact of a multidisciplinary home-based rehabilitation program for individuals with moderate neuromusculoskeletal disabilities in terms of motor function and mood.

Methods: A total of 270 participants with median age of 66 (IQR 20-98) years were recruited from the National Disability Registry of Chile. The intervention involved a multidisciplinary team composed of 49 health care professionals providing personalized treatment plans over 4 months (32 sessions for physical therapy, 8 sessions for occupational therapy, 4 sessions for nutrition, 8 sessions for psychology, and 4 sessions for nursing and podiatry). This program also included 2 medical evaluations (at the beginning and the end) to monitor clinical progress in terms of motor function and mental health, using the Berg Balance Scale and Beck Depression Inventory, respectively.

Results: The home-based rehabilitation program showed significant improvements (P<.001) in motor function and balance with a reduction in fall risk. Specifically, the Berg Balance Scale score decreased close to 15% after the home-based rehabilitation program for all enrolled participants. On the other hand, depression levels showed no significant changes (P=.27), with percentages of variation less than 8% between the 2 assessed conditions. In this sense, participants remained with the same mild depression level (14 of 63) concerning the Beck Depression Inventory score.

Conclusions: This study concludes that personalized home-based rehabilitation programs are effective in enhancing motor function and balance, particularly in individuals with neurological conditions. On the other hand, the findings in terms of mood advocate for further exploration of psychological support within such programs to enhance overall patient well-being.

Trial Registration: ClinicalTrials.gov NCT06537791; https://clinicaltrials.gov/study/NCT06537791

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KEYWORDS

rehabilitation; home-based therapy; physical therapy; psychological therapy; home physiotherapy; disabilities; occupational therapy; personalized care; patient care; motor disorder; mood disorder; motor function

Introduction

Disability is a complex and multidimensional phenomenon that affects approximately 16% of the global population, equivalent to around 1.3 billion people [1]. According to the World Health Organization, disability results from the interaction between individuals' health conditions and different personal and environmental factors, such as negative attitudes and barriers related to transportation and access to public buildings. The Centers for Disease Control and Prevention also identifies disability as a condition that hinders the performance of fundamental activities and interactions with the world, affecting vital aspects such as movement and thinking [2].

In this sense, home-based rehabilitation has emerged as an innovative and growing response, providing health services in the patient's home rather than in a hospital or medical institution. Home-based rehabilitation is not only more comfortable for patients and their families, but it can also be more effective than rehabilitation in a hospital setting, as it allows patients to receive therapy in a realistic and specific context for their situation [3,4]. However, the home-based implementation presents unique challenges, such as care coordination among multiple health care providers and the need to ensure access to necessary resources for home rehabilitation [5].

Home-based rehabilitation has gained relevance due to the reported evidence related to effectiveness and user preferences. Specifically, a comparative study between hospital-based and this personalized approach revealed a distinct preference among both patients and staff for the home-based method, owing to its tailored and goal-oriented therapeutic strategies [3]. Furthermore, previous studies have also reported the benefits in patients for home-based therapies compared with hospital-based methods, considering the home environment is more conducive to adaptation and realism [4].

The home-based therapy's relevance could particularly extend to physiotherapy for patients with neurological diseases. These home-based programs could offer ongoing therapy opportunities, benefiting the retention of intervention effects and showing improvements in mobility, muscle strength, and balance [6]. Saggini et al [7] reported significant improvements in autonomy, motor skills, and quality of life during home-based rehabilitation for patients with chronic stroke. This study also emphasized the importance of a familiar and personalized environment in the rehabilitation process of the involved patients [7].

On the other hand, home-based methodologies, being more personalized and patient-centered, reflect a significant shift in how we approach health care and well-being. Thus, the home-based concept can align with the modern vision of rehabilitation as a crucial strategy for enhancing individuals' capacity to carry out daily activities and participate in society [8]. Notwithstanding, despite the advances and promising results in home-based strategies, it is necessary to recognize the limitations and gaps in current research, highlighting the need for further rigorous studies to evaluate the effectiveness and cost-effectiveness of these programs [6].

In this context, the aim of this study is to evaluate the functioning of a comprehensive home-based rehabilitation program for individuals with moderate neuromusculoskeletal-origin disabilities in the Magallanes region (Chile). The proposed program aims to offer continuous and tailored care within the familiar environment of the patients, emphasizing the pivotal role of home-based rehabilitation in promoting optimal outcomes.

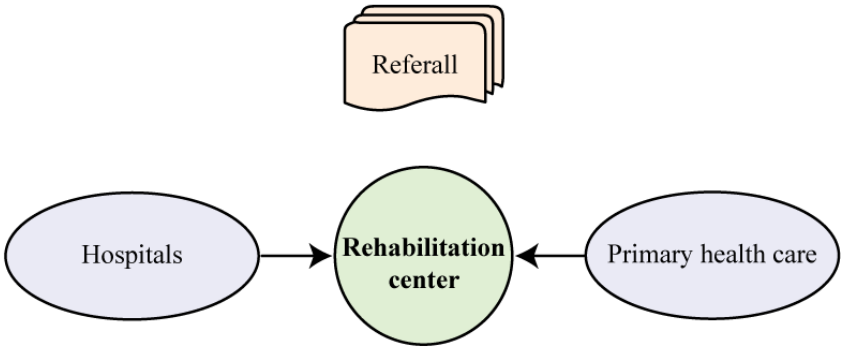
Methods

Recruitment

This study enrolled 270 people with moderate neuromusculoskeletal disabilities who were officially registered on the National Disability Registry of Chile. This protocol targeted individuals of all ages, provided they received referrals from recognized medical institutions in the Magallanes region. These institutions included the "Dr. Lautaro Navarro Avaria" Clinical Hospital, the "Dr. Augusto Essmann Burgos" Hospital in Puerto Natales, the "Marcos Chamorro I." Hospital in Puerto Porvenir, as well as primary health care facilities.

The inclusion criteria covered participants with medical referrals and clinical information available in the rehabilitation center's database (Figure 1). This requirement ensured that participants had a documented medical history accessible for a more accurate evaluation and monitoring of their health status. The exclusion criteria encompassed individuals with severe cognitive impairments that hinder their ability to follow the rehabilitation program, participants with acute medical conditions who require immediate hospitalization, and pregnant women.

Figure 1. Enrollment diagram implemented in this study.



Intervention

The home-based rehabilitation program implemented a comprehensive approach supported by a multidisciplinary team of 49 health care professionals. Participants received 4 months of a personalized treatment plan to ensure comprehensive and coordinated care.

Regarding therapies, physiotherapists provided 32 sessions per patient, focused on physical rehabilitation, while occupational therapists offered 8 sessions to improve independence in daily activities. Nutritionists conducted 4 sessions to optimize nutritional intake, and psychologists provided 4 sessions of emotional and cognitive support. In addition, this study provided four nursing and podiatry sessions focused on general health care or foot care.

Overall, the rehabilitation program provided approximately 82 hours of therapy to each patient, encompassing all clinical interventions. Specifically, participants received around 20.5 hours of therapy per month, which implies 5.12 hours per week, with each session lasting 60 minutes. This collaborative and personalized approach aimed to ensure coverage of various areas of health and well-being, as well as the effectiveness of treatment in the home setting, promoting comprehensive and maintained recovery of the patients.

This study also included two medical assessments, one at the beginning (ie, baseline) and one at the end (ie, home-based program) of the study, to monitor clinical progress and adjust treatment as necessary. In parallel, social workers conducted intake and discharge assessments to address the social and environmental patients' needs.

Study Outcomes

Patients' Characteristics and Health Conditions

The clinical and demographic characteristics of the patients were recorded and analyzed, evaluating their health status and level of functional improvement before and after their participation in the rehabilitation program. This approach allowed for a detailed understanding of the program's impact on the target population.

Motor Function

Considering the consequences of falls in patients with neuromusculoskeletal disabilities, the home-based rehabilitation program aimed to improve participants' balance during the sessions. In this sense, medical staff measured the Berg Balance Scale using a questionnaire in the 2 medical assessments. The Berg Balance Scale estimates balance capacity through a scoring system ranging from 0 (inability to maintain balance independently) to 56 (independent balance). From this range, lower scores (ie, below 45) indicate a potential necessity for assistance to mitigate falls and ensure patient safety.

Mental Health

In the mental health realm, addressing depression is fundamental, particularly within the context of home-based rehabilitation programs. Thus, this study included an assessment using the Beck Depression Inventory-II (BDI) at the beginning and end of the proposed intervention. BDI is a revised tool for assessing the severity of depression, using a 21-item scale that classifies symptoms into 4 levels. Scores of 0 to 13 indicate minimal depression, suggesting mild or nonexistent symptoms. Scores of 14 to 19 describe mild depression, where symptoms are more noticeable but still manageable. A range between 20 and 28 points denotes moderate depression, with symptoms that may significantly interfere with daily life. Finally, scores of 29 to 63 represent severe depression, with intense symptoms that generally require immediate clinical intervention.

Statistical Analysis

This study conducted a descriptive analysis to explore the enrolled patients' demographics, focusing on age, gender, and diagnosis distribution. In assessing the age distribution, mean and SD were used to estimate the central tendency and dispersion of the participants' ages. Furthermore, age data were segmented into percentiles and quartiles to understand age distribution patterns within the sample. In addition, this study quantified the number and proportion of participants based on gender and diagnosis, providing a comprehensive overview of the demographic landscape.

On the other hand, a Shapiro-Wilk test was applied to determine the normality of the variable distributions. In this sense, it is possible to define which statistical tests are appropriate for data analysis. Significant deviation from normality was considered for Shapiro-Wilk P values less than .05. Thus, data that did not follow a normal distribution used nonparametric statistical methods such as the Wilcoxon rank sum test. For the Wilcoxon test, statistical significance in the analyzed parameters was set at $P<.05$.

The calculations and statistical analyses carried out in this study were accomplished using Python (version 3.11.5; Python Software Foundation) and Pandas (version 2.1.3; Pandas Development Team). This software provides support for data processing, analysis, and graphing.

Ethical Considerations

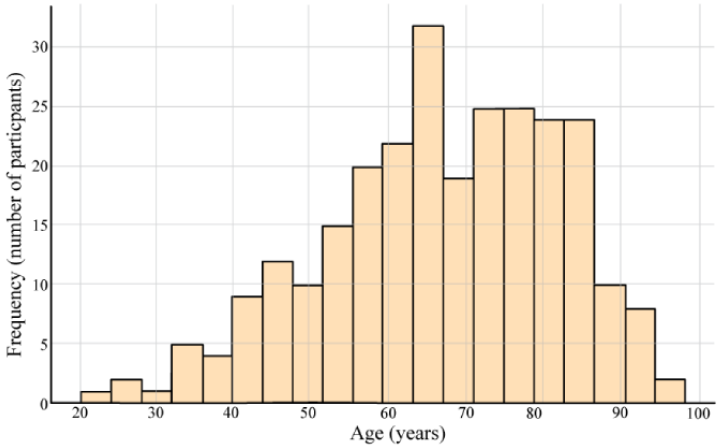
The study was approved by the institutional review committee of the Rehabilitation Center Club de Leones Cruz del Sur (approval code CRCS_UID_010223), ensuring compliance with ethical and methodological standards. All data were treated confidentially and anonymized. No compensation was provided to participants for their involvement in this study.

Results

Patients' Characteristics and Health Conditions

This study analyzed a sample of 270 patients for the motor function outcomes and 187 for the psychological health. The complete sample exhibited a wide variability in the participants' age, reflecting a broad distribution within an adult population. The mean age was 66.7 (15.3) years, indicating a tendency toward an older age group as shown in Figure 2. Likewise, the participants' age range was extensive, with a minimum of 20 years and a maximum of 98 years (Figure 2), exhibiting considerable variability in this study.

Figure 2. Histogram of age distribution of participants.



Regarding participant gender, the selected sample reflected an uneven distribution. Specifically, out of the 270 participants analyzed, 198 (73.3%) were female and 26.7% (72/270) of them were male.

Considering the inclusion criteria, the study sample was classified into 2 main diagnostic categories: (1) musculoskeletal diseases and (2) neurological diseases. The first category comprehended most cases, with 188 representing 69.6% of the analyzed sample. On the other hand, the neurological diseases category involved 82 participants, constituting 30.4% of the group.

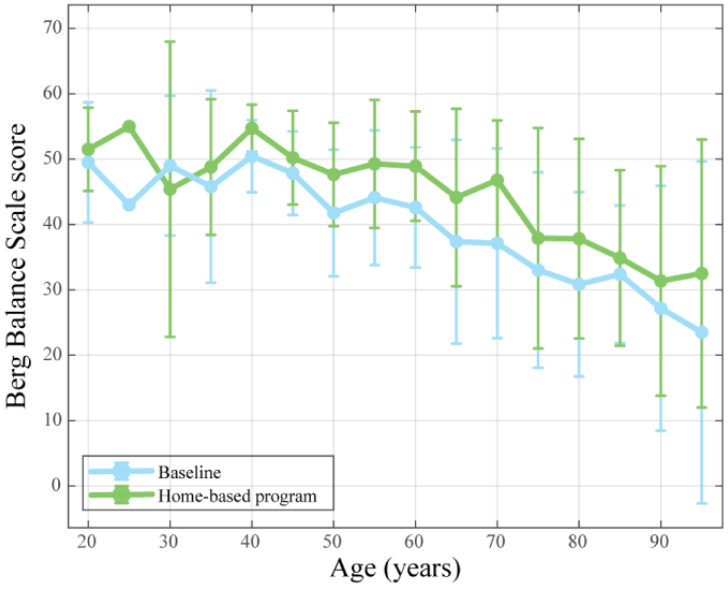
For the musculoskeletal diseases category, prevalent diagnoses reported by the participants encompassed osteoarthritis and fibromyalgia. These conditions typically manifest as pain and dysfunction within patients' joints and muscles, often constituting primary motivations for consultation and treatment within this classification. In the neurological diseases category, Parkinson's disease and sequelae of cerebrovascular diseases emerged as the most prevalent diagnoses. These conditions typically impact both the nervous system and the motor capacity of affected individuals.

Motor Function

Overall Sample

Regarding the motor function, this study presents comparative results of the scores on the Berg Balance Scale at 2 different time points, at the beginning (ie, baseline) and at the end (ie, home-based program). Figure 3 illustrates the mean value and variation of the Berg Balance Scale score across the age spectrum involved in this study. Overall, the Berg Balance Scale score increased for all age groups following the completion of the home-based program, except for the 30-year age group, which exhibited a slight decrease.

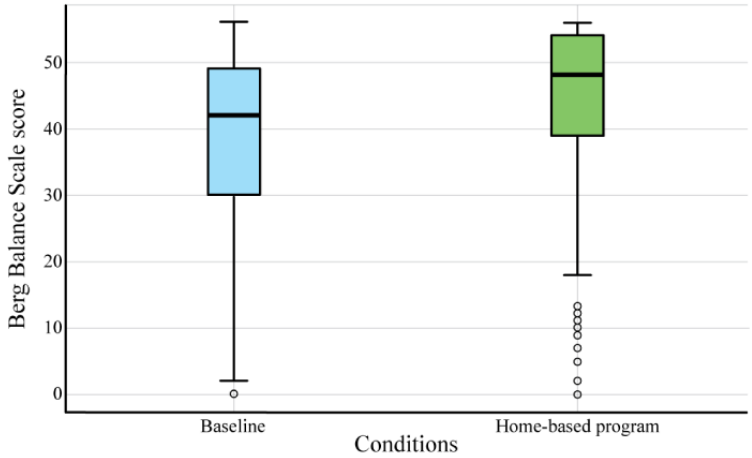
Figure 3. Mean (SD) of the Berg Balance Scale score across the age spectrum for the baseline and home-based program.



The data normality was verified through the Shapiro-Wilk test. The baseline condition did not follow a normal distribution (P<.001), so the Wilcoxon rank sum test compared the datasets. The statistical test revealed a significant difference between the baseline and home-based program (P<.001) for the participants' balance measured from the Berg Balance Scale.

Figure 4 shows the variation between both assessed conditions (ie, baseline and home-based program), with a notable increase in the median and mean values (ie, 14.8% and 16.6%, respectively) and a slight reduction in the dispersion for the home-based program (ie, –3.5%).

Figure 4. Distribution plot of Berg Balance Scale scores for the baseline and home-based program.



A detailed breakdown of the means, medians, and SDs of the Berg Balance Scale scores at both time points highlights that at baseline, the mean score was 38.3 (SD 14.1) with a median of 42.0 (IQR 30.0-49.0), while after the home-based program, the mean increased to 44.0 (SD 13.6) with a median of 49.0 (IQR 39.0-54.0). Thus, this study exhibited a percentage variation between both conditions of 14.9% for the mean and 16.7% for the median.

Diagnostic Categories

These results present the score and statistical values for each divided category (ie, neurological diseases and musculoskeletal diseases), focusing on examining the differences between the baseline and the home-based program. Initially, the Shapiro-Wilk test demonstrated that all cases did not follow a normal distribution (P<.001). Therefore, the Wilcoxon rank sum test was carried out for each category. The Berg Balance Scale scores exhibited significant differences between the baseline and the home-based program for both categories, ie, P<.001 for neurological diseases and P<.001 for musculoskeletal diseases. Likewise, the tendency to increase the mean value and reduce dispersion is also exhibited in both categories (Figure 5) as the complete sample described in the previous section.

Figure 5. Distribution plot of Berg Balance Scale scores for neurological and musculoskeletal diseases.

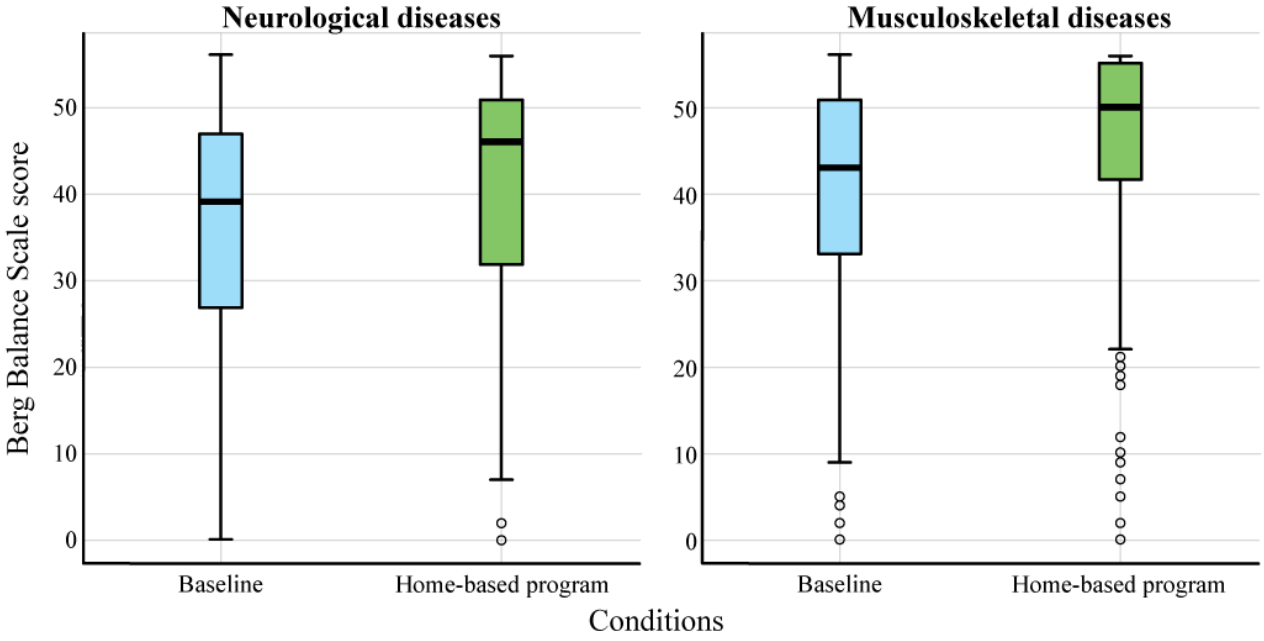


Table 1 compares the descriptive statistics, providing a detailed insight into the differences in each category for both assessed conditions (ie, baseline and home-based program).

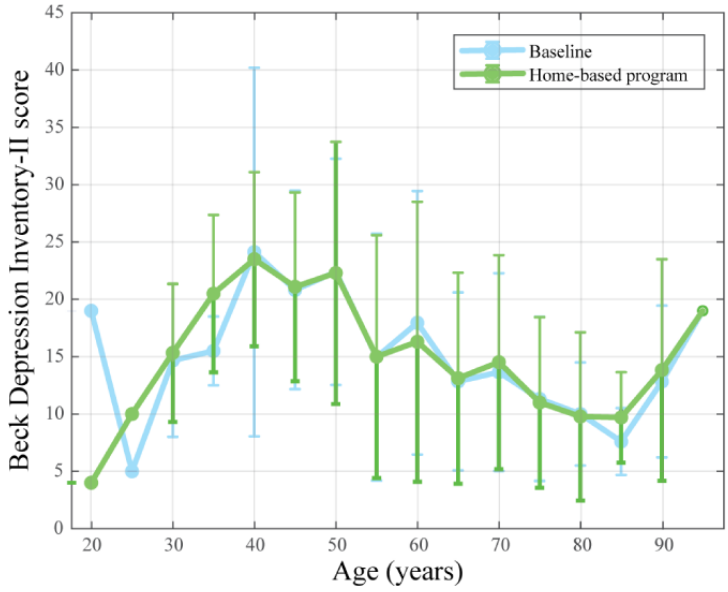
Table 1. Descriptive statistics of Berg Balance Scale scores in both assessed conditions.

Conditions	Mean (SD)	Median (IQR)
Neurological diseases		
Baseline	34.8 (15.1)	39.0 (27.0-47.0)
Home-based program	40.8 (14.6)	46.0 (32.0-51.0)
Variation (%)	17.2 (–3.3)	17.9 (18.5-8.5)
Musculoskeletal diseases		
Baseline	39.8 (13.4)	43.0 (33.0-51.0)
Home-based program	45.3 (12.9)	50.0 (41.0-55.0)
Variation (%)	13.8 (–3.7)	16.3 (24.2-7.8)

Mental Health

This study focused on assessing depression levels using the BDI to measure the participants' mental health within the evaluated condition (ie, baseline and home-based program). Considering the participants' age spectrum, Figure 6 illustrates the BDI scores measured at the beginning and the end of this study for a subset of 187 participants from the total sample of 270. Overall, the BDI scores remained similar after completing the home-based program compared with the baseline.

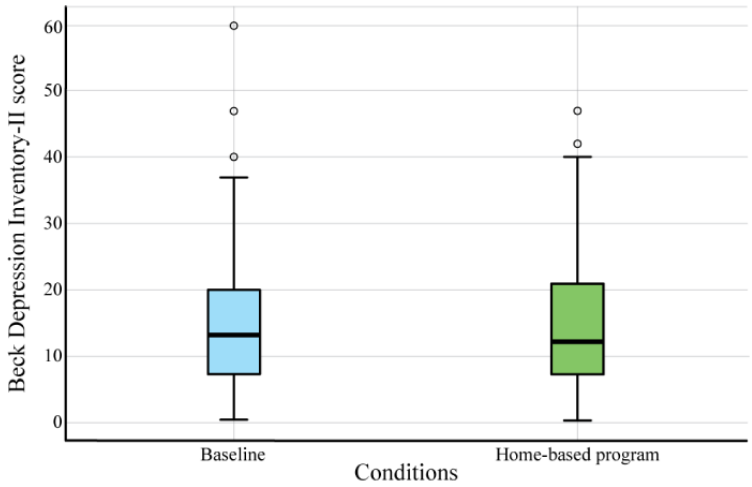
Figure 6. Mean (SD) of the Beck Depression Inventory-II score across the age spectrum for the baseline and home-based program.



In statistical terms, the Shapiro-Wilk test verified the data normality, finding that the home-based program did not follow a normal distribution (P<.001). In this sense, the comparison between conditions was accomplished with the Wilcoxon rank sum test. This test yielded a statistic of 2532.5 and a P value of around .27, so the BDI scores did not exhibit significant differences (P>.05) during the experiment. In the same line, Figure 7 illustrates the score distribution for both conditions, where medians and the IQR remain similar.

At baseline, the mean BDI score was 14.5 (SD 9.5) with a median of 13.0 (IQR 7.0-20.0). After the home-based program, the mean slightly increased to 14.6 (SD 9.7) with a median of 12.0 (IQR 7.0-21.0). The variation between both conditions shows a change of 0.7% for the mean and –7.7% for the median. Despite these changes, the participants remained within the same mild depression category (ie, BDI score of 14 to 19) after completing the rehabilitation program.

Figure 7. Distribution of Beck Depression Inventory scores for the baseline and home-based program.



Discussion

Improvement of Motor Function

This study aimed to evaluate the effectiveness of a home rehabilitation program in improving motor function in participants. The results of the study indicated significant improvements in motor function as assessed by the Berg Balance Scale. In addition, these improvements were consistent across all age groups of participants. Statistical tests revealed statistically significant differences in scores between baseline and home-based program assessments, indicating improved balance and motor function. These findings highlight the effectiveness of the home rehabilitation program, which involved a multidisciplinary team of health care professionals providing personalized care. The comprehensive approach of the program, which encompassed medical assessments, social evaluations, and various therapeutic interventions, contributed to the observed improvements in motor function.

The program's commitment to providing approximately 82 hours of therapy per patient over 4 months ensured that participants received intensive and individualized care. This approach addressed various aspects of health and well-being, resulting in substantial improvements in motor function. The dosage of therapy in rehabilitation is a crucial aspect of achieving effective outcomes in patients. Parameters such as frequency, intensity, duration, and timing of therapy must be carefully considered. Studies have shown that appropriate dosing can significantly improve recovery outcomes, while insufficient or excessive dosing can be less effective or even counterproductive. Therefore, rehabilitation professionals need to personalize the therapy dosage according to the individual needs of each patient [9].

These findings highlight the importance of adapting rehabilitation interventions to the specific needs and conditions of individuals. By understanding the unique challenges and potential for improvement in different patient populations, health care professionals can develop specific strategies to optimize motor function outcomes. The results of this study emphasize the need for comprehensive and personalized rehabilitation programs that address specific motor disabilities associated with both musculoskeletal and neurological conditions. This will help maximize the effectiveness of rehabilitation interventions and improve overall motor function and quality of life for individuals with these conditions.

The findings of the study have important implications for rehabilitation practice. They demonstrate the impact of a comprehensive and personalized approach to rehabilitation, especially in a home setting. The positive changes observed in motor function underline the importance of interventions and rehabilitation programs tailored to the specific needs of individuals with neurological conditions and those with musculoskeletal conditions. Personalized rehabilitation programs, especially those including exercises adapted to individual needs, have shown to be beneficial in improving physical outcomes in older adults living in the community. According to a systematic study conducted by Guichen et al [10], personalized exercise programs based on assessments of physical function can be a safe and effective approach to improving aspects such as balance, strength, mobility, physical activity, and disease symptoms in this population. Although the study revealed that these programs did not show advantages in terms of exercise adherence or economic benefits, the findings underscore the importance of considering both physical functions and psychological factors when developing personalized exercise programs for older adults. This research highlights the need for more high-quality studies with larger samples to better understand the effectiveness and attitudes of older individuals toward these personalized exercises [10].

In addition, the study found that participants in the musculoskeletal group had higher initial scores on the Berg Balance Scale than the neurological group. This suggests that individuals with musculoskeletal conditions may have better initial motor function than those with neurological conditions. The Berg Balance Scale proved to be an effective tool in assessing balance in patients with various musculoskeletal conditions. A key study in this area is by Bogle Thorbahn and Newton [11], where the use of the Berg Balance Scale in patients with different musculoskeletal conditions was explored [12]. The results indicated that the Berg Balance Scale is a valid and reliable instrument for measuring static and dynamic balance

in this population. This finding is significant as balance is a crucial factor in the quality of life of patients with musculoskeletal conditions, directly influencing their ability to perform daily activities and reducing the risk of falls. Furthermore, the Berg Balance Scale provides a quantitative assessment that can be used to monitor patient progress over time and modify treatment plans accordingly.

Our study found that individuals with neurological conditions experienced greater improvement in motor function when participating in a home-based rehabilitation program compared with those with musculoskeletal conditions. These findings align with a recent study by Lim et al [12], which also found significant improvements in balance and gait in patients with chronic hemiparesis following a stroke who participated in a home-based rehabilitation program. These results highlight the importance of tailoring interventions and rehabilitation programs to address the specific needs of each patient group. In addition, despite lower initial scores in the neurological group, this group showed greater improvement in motor function compared with the musculoskeletal group. This indicates that the home-based rehabilitation program was particularly effective in addressing motor disabilities associated with neurological conditions [12].

Furthermore, the observed improvement in motor function in both the neurological and musculoskeletal categories on the Berg Balance Scale has important implications for fall risk. The Berg Balance Scale is a widely used tool for assessing balance and mobility, including items specifically assessing fall risk [11]. According to the categories defined by the Berg Balance Scale, individuals with lower scores are considered to have a higher risk of falls. In our study, the initial scores for both the neurological and musculoskeletal categories were within the medium fall risk range (21-40 points). However, the improvements observed in both groups indicate a reduction in fall risk. For the neurological category, the increase in mean scores from 34.76 to 40.84 suggests a shift from medium fall risk to low fall risk. Similarly, in the musculoskeletal category, the increase in mean scores from 39.84 to 45.34 reflects a movement from medium fall risk to low fall risk. These improvements in motor function and balance likely contribute to a decrease in fall risk in both categories.

It is important to note that the Berg Balance Scale is just one tool used to assess fall risk, and other factors such as muscle strength, gait, and cognitive function also play a role in determining an individual's fall risk. However, the significant improvements observed in motor function in the neurological and musculoskeletal categories suggest a positive impact on reducing fall risk. Overall, the findings of this study highlight the potential of home-based rehabilitation programs to improve motor function and reduce fall risk in individuals with neurological conditions and those with musculoskeletal conditions. By targeting specific disabilities and providing personalized care, these programs can contribute to better balance and mobility, ultimately leading to a decrease in fall risk and an overall improvement in the quality of life for individuals with these conditions.

Scientific evidence indicates that physical rehabilitation interventions can significantly decrease the risk of falls in patients with disabilities. A systematic study found that in patients with knee osteoarthritis, physical therapies such as strength training and aerobic exercises notably improved balance and reduced the risk of falls [13]. In addition, other research revealed that exercise interventions decrease the number of falls by 32% and the number of individuals experiencing falls by 22% among healthy older adults, underscoring the value of posture-challenging exercises in fall prevention [14]. These studies demonstrate the effectiveness of physical rehabilitation interventions in reducing fall risk, which is crucial for improving safety and quality of life in patients with disabilities and vulnerable populations.

Mental Health Analysis

The results for patients on the BDI indicate that, on average, they presented mild levels of depressive symptoms both in the initial and final assessments. In addition, this trend was consistent across the different age groups involved in the study. These findings could be related to the substantial proportion of women involved in this study, particularly in relation to depressive symptoms. Specifically, previous studies have reported gender differences in depression prevalence and response to therapeutic interventions, with women often experiencing higher rates of depression than men [15,16]. The predominance of women in our sample could have contributed to the overall pattern of mild depressive symptoms observed, potentially reflecting gender-specific factors that are not fully addressed by this study.

On the other hand, the relationship between musculoskeletal and neurological disabilities and depressive symptomatology has been the subject of research in various studies. For example, a study published by Chimenti et al [17] addresses how rheumatological diseases such as rheumatoid arthritis and spondyloarthritis may be strongly associated with the development of alterations in the cognitive behavioral sphere, particularly with the development of depression. This association is attributed to various factors, including increased pain, fatigue, reduced health-related quality of life, increased levels of physical disability, and higher health care costs. In addition, the possible role of proinflammatory cytokines in the development of central nervous system manifestations is explored, suggesting a link between inflammation and depressive symptoms in these conditions [17].

In another study conducted by Yalew et al [18], the magnitude of depression and associated risk factors were specifically examined in patients with musculoskeletal disorders treated in an outpatient physiotherapy department. A significant prevalence of potential depression was found among patients, with 57.1% of patients showing signs of potential depression. This study also investigated factors such as treatment duration, social support, and pain intensity, and how these related to the prevalence of depression in patients with musculoskeletal disorders [18].

Furthermore, several studies explore the relationship between neurological diseases and depressive symptomatology. One specific study focused on finding an association between neurological disorders and symptoms of anxiety and depression in a vulnerable population. In this study, a significant

relationship was found between various neurological pathologies and anxious and depressive symptoms. Disorders such as cerebrovascular diseases and epilepsy showed higher severity in these symptoms compared with other disorders such as headaches. Around 112 assessed patients had high scores on a psychological distress scale, indicating a high risk of developing anxiety and depression disorders. This study underscores the importance of a comprehensive assessment of patients with neurological disorders to identify and treat possible symptoms of anxiety and depression [19]. These studies highlight the importance of considering the psychological and emotional implications in patients with musculoskeletal and neurological disabilities and suggest the need for a comprehensive approach that addresses both physical symptoms and associated mood disorders.

Our analysis of scores on the BDI did not reveal statistically significant differences between initial and control assessments. This result suggests that the participants' mood remained relatively stable throughout the program despite receiving psychological sessions. This suggests that although participants received fewer sessions of psychological and emotional support, the program may have contributed to the stability of the participants' mood. Regarding the optimal therapeutic dose of therapy, Bruijniks et al [20] explored the effectiveness of cognitive-behavioral therapy and interpersonal therapy with different frequencies for treating depression. It is suggested that twice-weekly sessions may be more effective and lead to faster recovery from depressive symptoms than once-weekly sessions. This study suggests that a limited number of sessions, such as the 8 received by patients in our study, may not be sufficient to achieve significant changes in the mood of patients with depression.

Limitations

Although this study provides significant results and important implications, it also has several limitations that should be considered. First, the study only included participants who were referred and able to participate in a home-based rehabilitation program, which may introduce selection biases and sample heterogeneity. In addition, the study relied on self-reported measures, such as the BDI, which may be subject to social desirability biases. Furthermore, the study did not include a control group receiving standard care or compare the home-based rehabilitation program with other rehabilitation interventions, limiting the ability to determine the specific effects of the program. Finally, the study only assessed motor function and mood and did not explore other important outcomes such as quality of life or activities of daily living.

Prospects and Next Steps

Our study highlights the effectiveness of a home-based rehabilitation program in improving motor function, emphasizing the importance of a multidisciplinary and holistic approach to rehabilitation. The need for personalized care and intensive therapy to achieve better outcomes is emphasized. Future research should focus on evaluating the long-term effects of these programs, as well as exploring additional measures to assess improvements in motor function. It also proposes investigating the potential benefits of increasing the frequency or intensity of psychological and emotional support sessions within the program, which could further enhance the well-being of participants and reduce depressive symptoms. These suggestions aim at optimizing the rehabilitation program, considering both the physical and emotional aspects of recovery. Future research should also address the limitations described in the previous section and further investigate the effectiveness of home-based rehabilitation programs in larger and more diverse populations, using objective measures and comparing different rehabilitation approaches.

Conclusions

In conclusion, this study provides significant evidence that a home-based rehabilitation program is effective in improving motor function in individuals with neurological conditions and those with musculoskeletal conditions. The results demonstrate that participants experienced notable improvements in motor function and a reduction in the risk of falls, especially in the group with neurological conditions. This finding highlights the importance of a multidisciplinary and comprehensive approach to rehabilitation, encompassing both the physical and emotional aspects of recovery. Although no significant differences were found in depression levels, the study suggests the possibility of further enhancing these programs by intensifying sessions of psychological and emotional support. In summary, the study reinforces the relevance of personalized care and intensive therapy in rehabilitation and invites future research to evaluate the long-term effects of such programs and explore additional measures for a more comprehensive assessment of improvements in motor function.

Acknowledgments

The Comprehensive Rehabilitation Program is a government-funded initiative by the regional government of Magallanes and Chilean Antarctica. It aims to provide care and support to patients in Punta Arenas, Puerto Natales, and Porvenir who require physical, mental, or social rehabilitation. It has a multidisciplinary team of health care professionals who design and implement personalized rehabilitation plans to improve the quality of life of patients. It offers individual and group therapies, promoting social inclusion and interaction among patients. It is free of charge through medical referral and aims to be a fundamental tool in the recovery and reintegration of individuals into society.

Data Availability

Data are available on reasonable request by email to PB (pbarria@rehabilitamos.org).

Conflicts of Interest

None declared.

References

1. Disability.: World Health Organization; 2023 Mar 07. URL: https://www.who.int/News-Room/Fact-Sheets/Detail/Disability-and-Health [accessed 2024-08-28]
2. Disability. Centers for Disease Control and Prevention. 2023. URL: https://www.cdc.gov/ncbddd/disabilityandhealth/features/disability-health-data.html [accessed 2024-08-23]
3. Dow B, Black K, Bremner F, Fearn M. A comparison of a hospital-based and two home-based rehabilitation programmes. Disabil Rehabil 2007;29(8):635-641. [doi: 10.1080/09638280600902760] [Medline: 17453984]
4. von Koch L, Wottrich AW, Holmqvist LW. Rehabilitation in the home versus the hospital: the importance of context. Disabil Rehabil 1998;20(10):367-372. [doi: 10.3109/09638289809166095] [Medline: 9793750]
5. Anderson C, Rubenach S, Mhurchu CN, Clark M, Spencer C, Winsor A. Home or hospital for stroke rehabilitation? Results of a randomized controlled trial: I: health outcomes at 6 months. Stroke 2000;31(5):1024-1031. [doi: 10.1161/01.str.31.5.1024] [Medline: 10797161]
6. Fonseca J, Paulo R, Paola PS, Kelly KMDR, Eduardo F. Home-based physiotherapy programmes for individuals with neurological diseases: systematic review. Fisioterapia em Movimento 2019. [doi: 10.1590/1980-5918.032.ao28]
7. Saggini R, Veraldi R, Carmignano SM, Palermo T, Russo C, Barassi G, et al. Home rehabilitation system in chronic stroke: an observational study in central Italy. Neurol India 2021;69(5):1285-1292 [FREE Full text] [doi: 10.4103/0028-3886.329548] [Medline: 34747801]
8. Bickenbach J, Sabariego C, Stucki G. Beneficiaries of rehabilitation. Arch Phys Med Rehabil 2021;102(3):543-548 [FREE Full text] [doi: 10.1016/j.apmr.2020.09.392] [Medline: 33239179]
9. Jette AM. The importance of dose of a rehabilitation intervention. Phys Ther 2017;97(11):1043. [doi: 10.1093/ptj/pzx085] [Medline: 29099967]
10. Guichen L, Li X, Chen L. Personally tailored exercises for improving physical outcomes for older adults in the community: a systematic review. Arch Gerontol Geriatr 2022;101:104707. [doi: 10.1016/j.archger.2022.104707] [Medline: 35462312]
11. Bogle Thorbahn LD, Newton RA. Use of the Berg Balance Test to predict falls in elderly persons. Phys Ther 1996;76(6):576-583; discussion 584. [doi: 10.1093/ptj/76.6.576] [Medline: 8650273]
12. Lim LH, Lee HS, Song CS. Home-based rehabilitation programs on postural balance, walking, and quality of life in patients with stroke: a single-blind, randomized controlled trial. Medicine (Baltimore) 2021;100(35):e27154 [FREE Full text] [doi: 10.1097/MD.0000000000027154] [Medline: 34477171]
13. Mat S, Tan MP, Kamaruzzaman SB, Ng CT. Physical therapies for improving balance and reducing falls risk in osteoarthritis of the knee: a systematic review. Age Ageing 2015;44(1):16-24. [doi: 10.1093/ageing/afu112] [Medline: 25149678]
14. Hamed A, Bohm S, Mersmann F, Arampatzis A. Follow-up efficacy of physical exercise interventions on fall incidence and fall risk in healthy older adults: a systematic review and meta-analysis. Sports Med Open 2018;4(1):56 [FREE Full text] [doi: 10.1186/s40798-018-0170-z] [Medline: 30547249]
15. Girgus J, Yang K, Ferri C. The gender difference in depression: are elderly women at greater risk for depression than elderly men? Geriatrics (Basel) 2017;2(4):35 [FREE Full text] [doi: 10.3390/geriatrics2040035] [Medline: 31011045]
16. Otten D, Tibubos AN, Schomerus G, Brähler E, Binder H, Kruse J, et al. Similarities and differences of mental health in women and men: a systematic review of findings in three large German cohorts. Front Public Health 2021;9:553071 [FREE Full text] [doi: 10.3389/fpubh.2021.553071] [Medline: 33614574]
17. Chimenti MS, Fonti GL, Conigliaro P, Triggianese P, Bianciardi E, Coviello M, et al. The burden of depressive disorders in musculoskeletal diseases: is there an association between mood and inflammation? Ann Gen Psychiatry 2021;20(1):1 [FREE Full text] [doi: 10.1186/s12991-020-00322-2] [Medline: 33397417]
18. Yalew ES, Melese AZ, Guadie YG, Abich Y, Kassa T, Gashaw M. Magnitude of depression and associated risk factors among patients with musculoskeletal disorder treated in physiotherapy outpatient department in Amhara region comprehensive specialized hospital in Ethiopia: a prospective cross-sectional study. BMC Psychiatry 2023;23(1):189 [FREE Full text] [doi: 10.1186/s12888-023-04658-3] [Medline: 36949431]
19. Ávila Gámez LD, Duarte Tagles H, Flores Río de la Loza LJ, Ponce Serrano S, Tong Payán JM. Presencia de sintomatología ansiosa y depresiva en pacientes ambulatorios con patología neurológica. Salud Ment 2014;37(5):399-406 [FREE Full text] [doi: 10.17711/sm.0185-3325.2014.047]
20. Bruijniks SJE, Bosmans J, Peeters FPML, Hollon SD, van Oppen P, van den Boogaard M, et al. Frequency and change mechanisms of psychotherapy among depressed patients: study protocol for a multicenter randomized trial comparing twice-weekly versus once-weekly sessions of CBT and IPT. BMC Psychiatry 2015;15:137 [FREE Full text] [doi: 10.1186/s12888-015-0532-8] [Medline: 26122891]

Abbreviations

BDI: Beck Depression Inventory-II

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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

Byron Lai[1*], PhD; Danielle Wadsworth[2*], PhD; Katherine Spring[2,3*], PhD; Chloe S Jones[2*], MS; Madison Mintz[4*], BS; Laurie A Malone[4*], PhD, MPH; Yumi Kim[5*], PhD; Jereme Wilroy[5*], PhD; Holim Lee[5], MD

[1]Division of Pediatric Rehabilitation Medicine, University of Alabama at Birmingham, Birmingham, AL, United States

[2]Exercise Adherence and Obesity Prevention Laboratory, School of Kinesiology, Auburn University, Auburn, AL, United States

[3]Pennington Biomedical Research Center, Division of Population and Public Health Science, Pediatric Obesity and Health Behavior Laboratory, Baton Rouge, LA, United States

[4]Department of Occupational Therapy, School of Health Professions, University of Alabama at Birmingham, Birmingham, AL, United States

[5]Department of Physical Medicine & Rehabilitation, University of Alabama at Birmingham, Birmingham, AL, United States

[*]these authors contributed equally

Corresponding Author:
Byron Lai, PhD
Division of Pediatric Rehabilitation Medicine
University of Alabama at Birmingham
1720 University Blvd
Birmingham, AL, 35294
United States
Phone: 1 205 638 9790 ext 8
Email: blai@uabmc.edu

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

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

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.

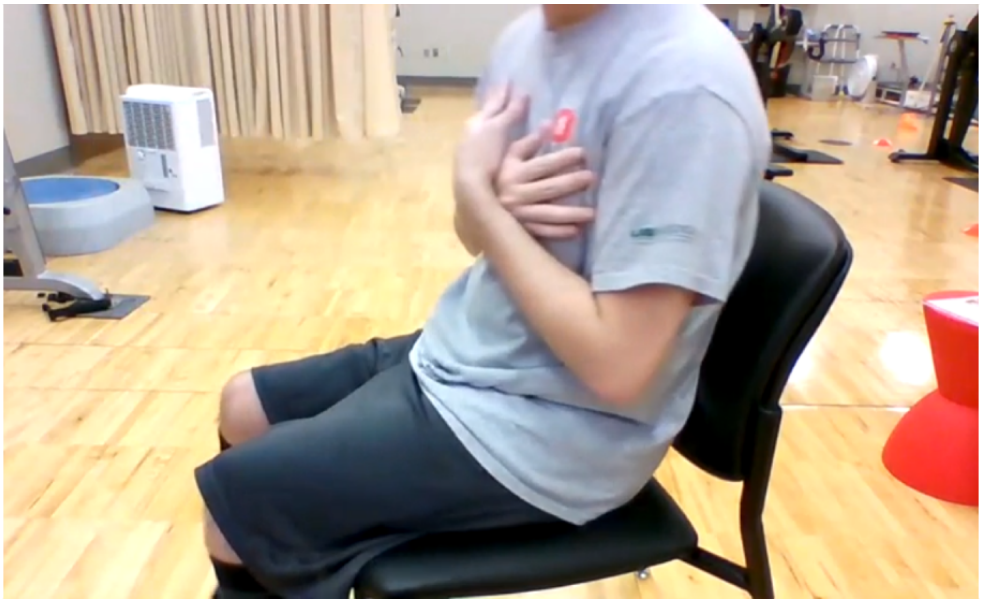
Hand Grip Strength Test (Physical Fitness)

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].

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

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).

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)

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.

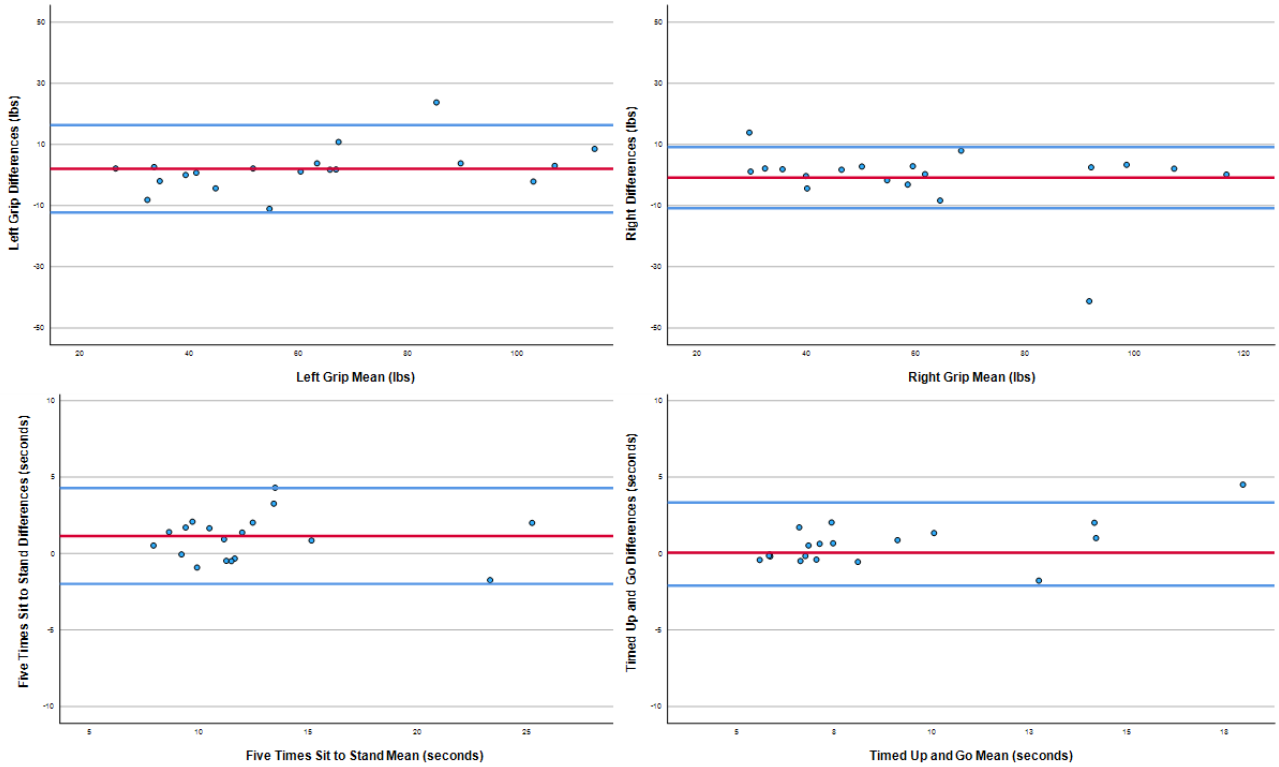


Table 3 displays the exploratory ICC-v analysis results between in-person assessments and teleassessments. Exploratory $ICC_{(2,1)}$ analyses demonstrated that the conversion factor (CF) of a 10.7 lap multiplier provided the highest ICC agreement value (Table 3). However, the HM6MWT 10.7 lap multiplier $ICC_{(2,1)}$, 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

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

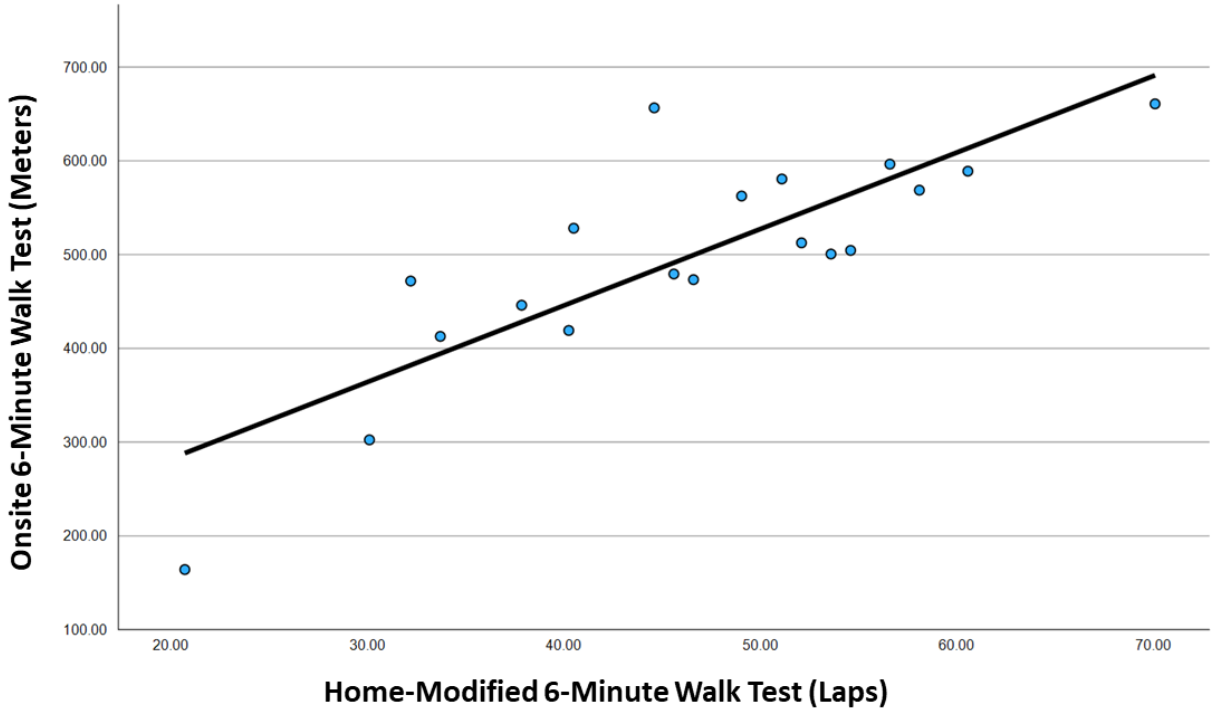
[a]ICC-v: intraclass correlation coefficient for validity.

[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.

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

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.

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]

References

1. Lai B, Cederberg K, Vanderbom KA, Bickel CS, Rimmer JH, Motl RW. Characteristics of adults with neurologic disability recruited for exercise trials: a secondary analysis. Adapt Phys Activ Q 2018 Oct 01;35(4):476-497. [doi: 10.1123/apaq.2017-0109] [Medline: 30382753]

2. Sheridan R, Martin-Kerry J, Hudson J, Parker A, Bower P, Knapp P. Why do patients take part in research? An overview of systematic reviews of psychosocial barriers and facilitators. Trials 2020 Mar 12;21(1):259 [FREE Full text] [doi: 10.1186/s13063-020-4197-3] [Medline: 32164790]
3. Whatnall MC, Hutchesson MJ, Sharkey T, Haslam RL, Bezzina A, Collins CE, et al. Recruiting and retaining young adults: what can we learn from behavioural interventions targeting nutrition, physical activity and/or obesity? A systematic review of the literature. Public Health Nutr 2021 Dec;24(17):5686-5703 [FREE Full text] [doi: 10.1017/S1368980021001129] [Medline: 33722332]
4. Waters LA, Galichet B, Owen N, Eakin E. Who participates in physical activity intervention trials? J Phys Act Health 2011 Jan;8(1):85-103. [doi: 10.1123/jpah.8.1.85] [Medline: 21297189]
5. Lai B, Young H, Bickel CS, Motl RW, Rimmer JH. Current trends in exercise intervention research, technology, and behavioral change strategies for people with disabilities. Am J Phys Med Rehabil 2017 Oct;96(10):748-761. [doi: 10.1097/PHM.0000000000000743] [Medline: 28398967]
6. Westbrook D, Kennerley H, Kirk J. Public health research: physical inactivity. In: Routledge Handbook of Adapted Physical Education. Oxfordshire, UK: Routledge; 2020:464-482.
7. Zhao M, Veeranki SP, Magnussen CG, Xi B. Recommended physical activity and all cause and cause specific mortality in US adults: prospective cohort study. BMJ 2020 Jul 01;370:m2031 [FREE Full text] [doi: 10.1136/bmj.m2031] [Medline: 32611588]
8. Carroll DD, Courtney-Long EA, Stevens AC, Sloan ML, Lullo C, Visser SN, Centers for Disease Control and Prevention (CDC). Vital signs: disability and physical activity--United States, 2009-2012. MMWR Morb Mortal Wkly Rep 2014 May 09;63(18):407-413 [FREE Full text] [Medline: 24807240]
9. Centers for Disease Control and Prevention (CDC). Physical activity among adults with a disability--United States, 2005. MMWR Morb Mortal Wkly Rep 2007 Oct 05;56(39):1021-1024 [FREE Full text] [Medline: 17914329]
10. Altman B, Bernstein A. Disability and Health in the United States, 2001-2005. Hyattsville, MD: National Center for Health Statistics; 2008.
11. Rimmer JH, Chen M, McCubbin JA, Drum C, Peterson J. Exercise intervention research on persons with disabilities: what we know and where we need to go. Am J Phys Med Rehabil 2010 Mar;89(3):249-263. [doi: 10.1097/PHM.0b013e3181c9fa9d] [Medline: 20068432]
12. U.S. Department of Health and Human Services. 2008 Physical Activity Guidelines for Americans: Be Active, Healthy, and Happy!. Washington, DC: U.S. Department of Health and Human Services; 2008.
13. Peyrusqué E, Granet J, Pageaux B, Buckinx F, Aubertin-Leheudre M. Assessing physical performance in older adults during isolation or lockdown periods: web-based video conferencing as a solution. J Nutr Health Aging 2022;26(1):52-56 [FREE Full text] [doi: 10.1007/s12603-021-1699-y] [Medline: 35067703]
14. Richardson BR, Truter P, Blumke R, Russell TG. Physiotherapy assessment and diagnosis of musculoskeletal disorders of the knee via telerehabilitation. J Telemed Telecare 2017 Jan;23(1):88-95. [doi: 10.1177/1357633X15627237] [Medline: 26985005]
15. Steele L, Lade H, McKenzie S, Russell TG. Assessment and diagnosis of musculoskeletal shoulder disorders over the internet. Int J Telemed Appl 2012;2012:945745 [FREE Full text] [doi: 10.1155/2012/945745] [Medline: 23193395]
16. Truter P, Russell T, Fary R. The validity of physical therapy assessment of low back pain via telerehabilitation in a clinical setting. Telemed J E Health 2014 Feb;20(2):161-167. [doi: 10.1089/tmj.2013.0088] [Medline: 24283249]
17. Blair CK, Harding E, Herman C, Boyce T, Demark-Wahnefried W, Davis S, et al. Remote assessment of functional mobility and strength in older cancer survivors: protocol for a validity and reliability study. JMIR Res Protoc 2020 Sep 01;9(9):e20834 [FREE Full text] [doi: 10.2196/20834] [Medline: 32769075]
18. Lawford BJ, Dobson F, Bennell KL, Merolli M, Graham B, Haber T, et al. Clinician-administered performance-based tests via telehealth in people with chronic lower limb musculoskeletal disorders: test-retest reliability and agreement with in-person assessment. J Telemed Telecare 2022 Nov 30:1357633X221137387. [doi: 10.1177/1357633X221137387] [Medline: 36451551]
19. Bird M, Peel F, Schmidt M, Fini NA, Ramage E, Sakakibara BM, et al. Mobility-focused physical outcome measures over telecommunication technology (Zoom): intra and interrater reliability trial. JMIR Rehabil Assist Technol 2022 Aug 22;9(3):e38101 [FREE Full text] [doi: 10.2196/38101] [Medline: 35994327]
20. Zischke C, Simas V, Hing W, Milne N, Spittle A, Pope R. The utility of physiotherapy assessments delivered by telehealth: a systematic review. J Glob Health 2021;11:04072 [FREE Full text] [doi: 10.7189/jogh.11.04072] [Medline: 34956637]
21. Brooks GC, Vittinghoff E, Iyer S, Tandon D, Kuhar P, Madsen KA, et al. Accuracy and usability of a self-administered 6-minute walk test smartphone application. Circ Heart Fail 2015 Sep;8(5):905-913 [FREE Full text] [doi: 10.1161/CIRCHEARTFAILURE.115.002062] [Medline: 26283292]
22. Pires IM, Denysyuk HV, Villasana MV, Sá J, Marques DL, Morgado JF, et al. Development technologies for the monitoring of six-minute walk test: a systematic review. Sensors (Basel) 2022 Jan 12;22(2):581 [FREE Full text] [doi: 10.3390/s22020581] [Medline: 35062542]

23. Pepera G, Karanasiou E, Blioumpa C, Antoniou V, Kalatzis K, Lanaras L, et al. Tele-assessment of functional capacity through the six-minute walk test in patients with diabetes mellitus type 2: validity and reliability of repeated measurements. Sensors (Basel) 2023 Jan 25;23(3):1354 [FREE Full text] [doi: 10.3390/s23031354] [Medline: 36772396]
24. Pelicioni PHS, Waters DL, Still A, Hale L. A pilot investigation of reliability and validity of balance and gait assessments using telehealth with healthy older adults. Exp Gerontol 2022 Jun 01;162:111747. [doi: 10.1016/j.exger.2022.111747] [Medline: 35227785]
25. Andrade FP, Ribeiro HS, Benvenutti H, de Oliveira SG, Thomé FS, Veronese FV, et al. Six-minute walk test may be a reliable predictor of peak oxygen uptake in patients undergoing hemodialysis. Ren Replace Ther 2023 Jan 19;9(1):6. [doi: 10.1186/s41100-023-00460-9] [Medline: 35227785]
26. Mizrahi D, Fardell JE, Cohn RJ, Partin RE, Howell CR, Hudson MM, et al. The 6-minute walk test is a good predictor of cardiorespiratory fitness in childhood cancer survivors when access to comprehensive testing is limited. Int J Cancer 2020 Aug 01;147(3):847-855 [FREE Full text] [doi: 10.1002/ijc.32819] [Medline: 31800093]
27. Dourado VZ, Nishiaka RK, Simões MSMP, Lauria VT, Tanni SE, Godoy I, et al. Classification of cardiorespiratory fitness using the six-minute walk test in adults: comparison with cardiopulmonary exercise testing. Pulmonology 2021;27(6):500-508 [FREE Full text] [doi: 10.1016/j.pulmoe.2021.03.006] [Medline: 33958319]
28. Nicola K, Waugh J, Charles E, Russell T. The feasibility and concurrent validity of performing the Movement Assessment Battery for Children - 2nd edition via telerehabilitation technology. Res Dev Disabil 2018 Jun;77:40-48. [doi: 10.1016/j.ridd.2018.04.001] [Medline: 29656273]
29. Martín-Díaz P, Carratalá-Tejada M, Molina-Rueda F, Cuesta-Gómez A. Reliability and agreement of the timed up and go test in children and teenagers with autism spectrum disorder. Eur J Pediatr 2023 Aug;182(8):3577-3585 [FREE Full text] [doi: 10.1007/s00431-023-05027-8] [Medline: 37227499]
30. Gortmaker SL, Lee R, Cradock AL, Sobol AM, Duncan DT, Wang YC. Disparities in youth physical activity in the United States: 2003-2006. Med Sci Sports Exerc 2012 May;44(5):888-893. [doi: 10.1249/MSS.0b013e31823fb254] [Medline: 22089478]
31. Sigmund E, De Ste Croix M, Miklánková L, Frömel K. Physical activity patterns of kindergarten children in comparison to teenagers and young adults. Eur J Public Health 2007 Dec;17(6):646-651. [doi: 10.1093/eurpub/ckm033] [Medline: 17434876]
32. Anderssen N, Jacobs DR, Sidney S, Bild DE, Sternfeld B, Slattery ML, et al. Change and secular trends in physical activity patterns in young adults: a seven-year longitudinal follow-up in the Coronary Artery Risk Development in Young Adults Study (CARDIA). Am J Epidemiol 1996 Feb 15;143(4):351-362. [doi: 10.1093/oxfordjournals.aje.a008749] [Medline: 8633619]
33. van Sluijs EMF, Ekelund U, Crochemore-Silva I, Guthold R, Ha A, Lubans D, et al. Physical activity behaviours in adolescence: current evidence and opportunities for intervention. Lancet 2021 Jul 31;398(10298):429-442 [FREE Full text] [doi: 10.1016/S0140-6736(21)01259-9] [Medline: 34302767]
34. Rimmer JA, Rowland JL. Physical activity for youth with disabilities: a critical need in an underserved population. Dev Neurorehabil 2008;11(2):141-148. [doi: 10.1080/17518420701688649] [Medline: 18415819]
35. Jung J, Leung W, Schram BM, Yun J. Meta-analysis of physical activity levels in youth with and without disabilities. Adapt Phys Activ Q 2018 Oct 01;35(4):381-402. [doi: 10.1123/apaq.2017-0123] [Medline: 30376716]
36. Lobenius-Palmér K, Sjöqvist B, Hurtig-Wennlöf A, Lundqvist L. Accelerometer-assessed physical activity and sedentary time in youth with disabilities. Adapt Phys Activ Q 2018 Jan 01;35(1):1-19 [FREE Full text] [doi: 10.1123/apaq.2015-0065] [Medline: 29072484]
37. Barnekow-Bergkvist M, Hedberg G, Janlert U, Jansson E. Physical activity pattern in men and women at the ages of 16 and 34 and development of physical activity from adolescence to adulthood. Scand J Med Sci Sports 1996 Dec;6(6):359-370. [doi: 10.1111/j.1600-0838.1996.tb00108.x] [Medline: 9046548]
38. Telama R, Yang X. Decline of physical activity from youth to young adulthood in Finland. Med Sci Sports Exerc 2000 Sep;32(9):1617-1622. [doi: 10.1097/00005768-200009000-00015] [Medline: 10994914]
39. Boreham C, Twisk J, Neville C, Savage M, Murray L, Gallagher A. Associations between physical fitness and activity patterns during adolescence and cardiovascular risk factors in young adulthood: the Northern Ireland Young Hearts Project. Int J Sports Med 2002 May;23(Suppl 1):S22-S26. [doi: 10.1055/s-2002-28457] [Medline: 12012258]
40. Yang X, Telama R, Viikari J, Raitakari OT. Risk of obesity in relation to physical activity tracking from youth to adulthood. Med Sci Sports Exerc 2006 May;38(5):919-925. [doi: 10.1249/01.mss.0000218121.19703.f7] [Medline: 16672846]
41. Morgan P, McGinley J. Gait function and decline in adults with cerebral palsy: a systematic review. Disabil Rehabil 2014;36(1):1-9. [doi: 10.3109/09638288.2013.775359] [Medline: 23594053]
42. Hanna SE, Rosenbaum PL, Bartlett DJ, Palisano RJ, Walter SD, Avery L, et al. Stability and decline in gross motor function among children and youth with cerebral palsy aged 2 to 21 years. Dev Med Child Neurol 2009 Apr;51(4):295-302 [FREE Full text] [doi: 10.1111/j.1469-8749.2008.03196.x] [Medline: 19391185]
43. Palisano RJ, Hanna SE, Rosenbaum PL, Tieman B. Probability of walking, wheeled mobility, and assisted mobility in children and adolescents with cerebral palsy. Dev Med Child Neurol 2010 Jan;52(1):66-71 [FREE Full text] [doi: 10.1111/j.1469-8749.2009.03454.x] [Medline: 19732118]

44. Day SM, Wu YW, Strauss DJ, Shavelle RM, Reynolds RJ. Change in ambulatory ability of adolescents and young adults with cerebral palsy. Dev Med Child Neurol 2007 Sep 20;49(9):647-653 [FREE Full text] [doi: 10.1111/j.1469-8749.2007.00647.x] [Medline: 17718819]
45. Bottos M, Feliciangeli A, Sciuto L, Gericke C, Vianello A. Functional status of adults with cerebral palsy and implications for treatment of children. Dev Med Child Neurol 2001 Aug;43(8):516-528 [FREE Full text] [doi: 10.1017/s0012162201000950] [Medline: 11508917]
46. Carty C, van der Ploeg HP, Biddle SJH, Bull F, Willumsen J, Lee L, et al. The First Global Physical Activity and Sedentary Behavior Guidelines for People Living With Disability. J Phys Act Health 2021 Jan 01;18(1):86-93 [FREE Full text] [doi: 10.1123/jpah.2020-0629] [Medline: 33395628]
47. UN SG Report on “Sport: a global accelerator of peace and sustainable development for all": report of the Secretary-General to the 75th Session of the General Assembly. United Nations Department of Economic and Social Affairs Social Inclusion. 2020. URL: https://www.un.org/development/desa/dspd/sport-development-peace/unsg-report2020.html [accessed 2024-01-05]
48. Bujang MA, Baharum N. A simplified guide to determination of sample size requirements for estimating the value of intraclass correlation coefficient: a review. Arch Orofac Sci 2017;12(1):1-11. [doi: 10.1007/springerreference_205392]
49. Lai B, Chiu C, Pounds E, Tracy T, Mehta T, Young H, et al. COVID-19 modifications for remote teleassessment and teletraining of a complementary alternative medicine intervention for people with multiple sclerosis: protocol for a randomized controlled trial. JMIR Res Protoc 2020 Jul 03;9(7):e18415 [FREE Full text] [doi: 10.2196/18415] [Medline: 32540838]
50. Harmsen WJ, Ribbers GM, Slaman J, Heijenbrok-Kal MH, Khajeh L, van Kooten F, et al. The six-minute walk test predicts cardiorespiratory fitness in individuals with aneurysmal subarachnoid hemorrhage. Top Stroke Rehabil 2017 May;24(4):250-255. [doi: 10.1080/10749357.2016.1260263] [Medline: 27915583]
51. Guclu-Gunduz A, Citaker S, Nazliel B, Irkec C. Upper extremity function and its relation with hand sensation and upper extremity strength in patients with multiple sclerosis. NeuroRehabilitation 2012 Jun 01;30(4):369-374. [doi: 10.3233/NRE-2012-0768] [Medline: 22672953]
52. Boissy P, Bourbonnais D, Carlotti MM, Gravel D, Arsenault BA. Maximal grip force in chronic stroke subjects and its relationship to global upper extremity function. Clin Rehabil 1999 Aug;13(4):354-362. [doi: 10.1191/026921599676433080] [Medline: 10460123]
53. Bertrand AM, Mercier C, Bourbonnais D, Desrosiers J, Gravel D. Reliability of maximal static strength measurements of the arms in subjects with hemiparesis. Clin Rehabil 2007 Mar;21(3):248-257. [doi: 10.1177/0269215506070792] [Medline: 17329282]
54. Aufsesser PM, Horvat M, Austin R. The reliability of hand held muscle testers with individuals with spinal cord injury. Clinical Kinesiol 2003;57(4):71.
55. Peek K. Muscle strength in adults with spinal cord injury: a systematic review of manual muscle testing, isokinetic and hand held dynamometry clinimetrics. JBI Database Syst Rev Implement Rep 2014;12(5):349-429. [doi: 10.11124/jbisrir-2014-1503]
56. Christopher A, Kraft E, Olenick H, Kiesling R, Doty A. The reliability and validity of the Timed Up and Go as a clinical tool in individuals with and without disabilities across a lifespan: a systematic review. Disabil Rehabil 2021 Jun;43(13):1799-1813. [doi: 10.1080/09638288.2019.1682066] [Medline: 31656104]
57. Halliday SJ, Wang L, Yu C, Vickers BP, Newman JH, Fremont RD, et al. Six-minute walk distance in healthy young adults. Respir Med 2020;165:105933 [FREE Full text] [doi: 10.1016/j.rmed.2020.105933] [Medline: 32308201]
58. López-Ortiz C, Gaebler-Spira DJ, Mckeeman SN, Mcnish RN, Green D. Dance and rehabilitation in cerebral palsy: a systematic search and review. Dev Med Child Neurol 2019 Apr;61(4):393-398 [FREE Full text] [doi: 10.1111/dmcn.14064] [Medline: 30350851]
59. Meislin MA, Wagner ER, Shin AY. A comparison of elbow range of motion measurements: smartphone-based digital photography versus goniometric measurements. J Hand Surg Am 2016 Apr;41(4):510-515.e1. [doi: 10.1016/j.jhsa.2016.01.006] [Medline: 26880499]
60. Podsiadlo D, Richardson S. J Am Geriatr Soc 1991 Feb;39(2):142-148. [doi: 10.1111/j.1532-5415.1991.tb01616.x] [Medline: 1991946]
61. Muñoz-Bermejo L, Adsuar JC, Mendoza-Muñoz M, Barrios-Fernández S, Garcia-Gordillo MA, Pérez-Gómez J, et al. Test-retest reliability of Five Times Sit to Stand Test (FTSST) in adults: a systematic review and meta-analysis. Biology (Basel) 2021 Jun 09;10(6):510 [FREE Full text] [doi: 10.3390/biology10060510] [Medline: 34207604]
62. Whitney SL, Wrisley DM, Marchetti GF, Gee MA, Redfern MS, Furman JM. Clinical measurement of sit-to-stand performance in people with balance disorders: validity of data for the Five-Times-Sit-to-Stand Test. Phys Ther 2005 Oct;85(10):1034-1045. [Medline: 16180952]
63. Mong Y, Teo TW, Ng SS. 5-Repetition sit-to-stand test in subjects with chronic stroke: reliability and validity. Arch Phys Med Rehabil 2010 Mar;91(3):407-413. [doi: 10.1016/j.apmr.2009.10.030] [Medline: 20298832]
64. Parmanto B, Lewis AN, Graham KM, Bertolet MH. Development of the Telehealth Usability Questionnaire (TUQ). Int J Telerehabil 2016;8(1):3-10 [FREE Full text] [doi: 10.5195/ijt.2016.6196] [Medline: 27563386]

65. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986 Feb 08;1(8476):307-310. [Medline: 2868172]
66. Koo TK, Li MY. A guideline of selecting and reporting intraclass correlation coefficients for reliability research. J Chiropr Med 2016 Jun;15(2):155-163 [FREE Full text] [doi: 10.1016/j.jcm.2016.02.012] [Medline: 27330520]
67. Krasny J, Jozwiak M, Rodby-Bousquet E. Comparison of the six-minute walk test performed over a 15 and 30 m course by children with cerebral palsy. BMC Musculoskelet Disord 2023 Jan 17;24(1):34 [FREE Full text] [doi: 10.1186/s12891-022-05944-z] [Medline: 36650438]

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

Zhaoying Li[1], MS; Yating Lei[2], MS; Quoc Bui[3], MD, MS; Olivia DePaul[4], OTD; Ginger E Nicol[5], MD; David C Mohr[6,7], PhD; Sunghoon I Lee[8], PhD; Mandy W M Fong[9], PhD; Christopher L Metts[10], MD; Stephanie E Tomazin[11], MPH; Alex W K Wong[11,12,13], PhD, DPhil

[1]Division of Occupational Science and Occupational Therapy, University of North Carolina School of Medicine, Chapel Hill, NC, United States
[2]Department of Occupational Therapy, New York University, New York, NY, United States
[3]Institute for Informatics, Data Science & Biostatistics, Washington University School of Medicine, St. Louis, MO, United States
[4]Memorial Hospital Belleville, Belleville, IL, United States
[5]Department of Psychiatry, Washington University School of Medicine, St. Louis, MO, United States
[6]Department of Preventive Medicine, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States
[7]Center for Behavioral Intervention Technologies, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States
[8]Manning College of Information and Computer Sciences, University of Massachusetts Amherst, Amherst, MA, United States
[9]Michigan Avenue Neuropsychologists, Chicago, IL, United States
[10]Department of Pathology and Laboratory Medicine, Medical University of South Carolina, Charleston, SC, United States
[11]Center for Rehabilitation Outcomes Research, Shirley Ryan AbilityLab, Chicago, IL, United States
[12]Department of Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States
[13]Department of Medical Social Sciences, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States

Corresponding Author:
Alex W K Wong, PhD, DPhil
Center for Rehabilitation Outcomes Research
Shirley Ryan AbilityLab
355 E. Erie Street
Chicago, IL, 60611
United States
Phone: 1 312 238 1742
Fax: 1 312 238 4572
Email: wwong@sralab.org

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.

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

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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

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

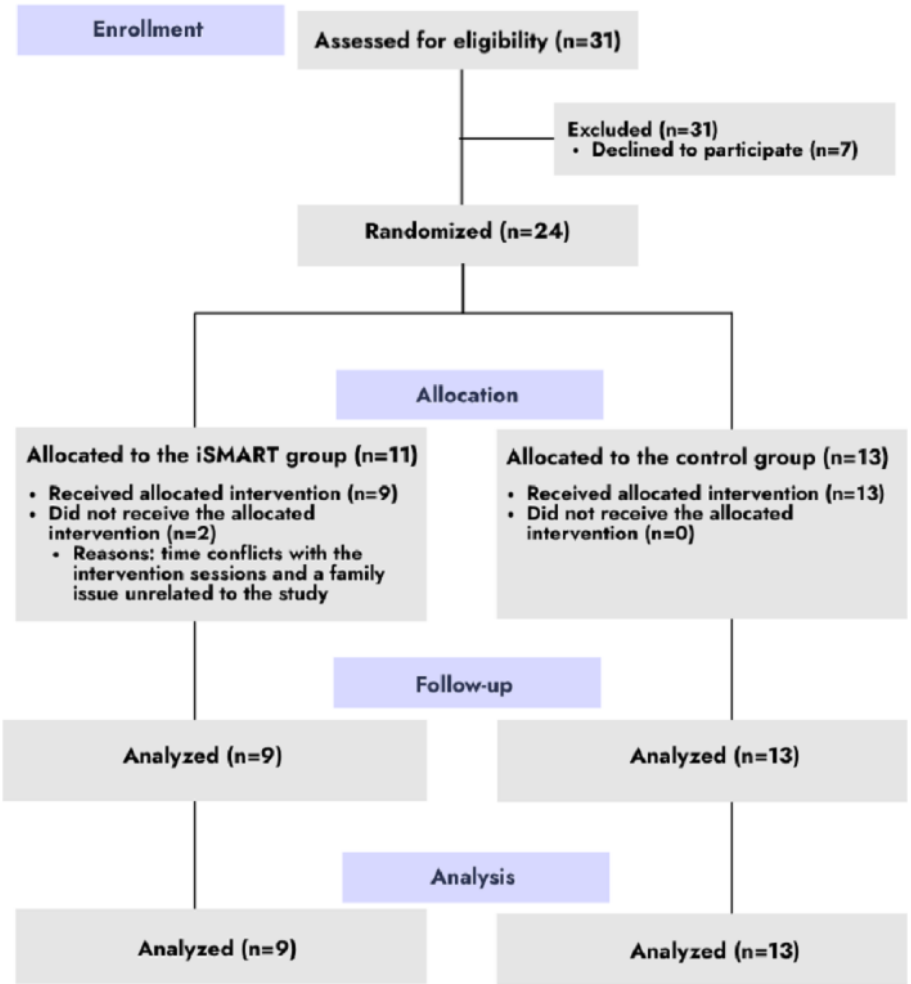
Design and Recruitment

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.



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.

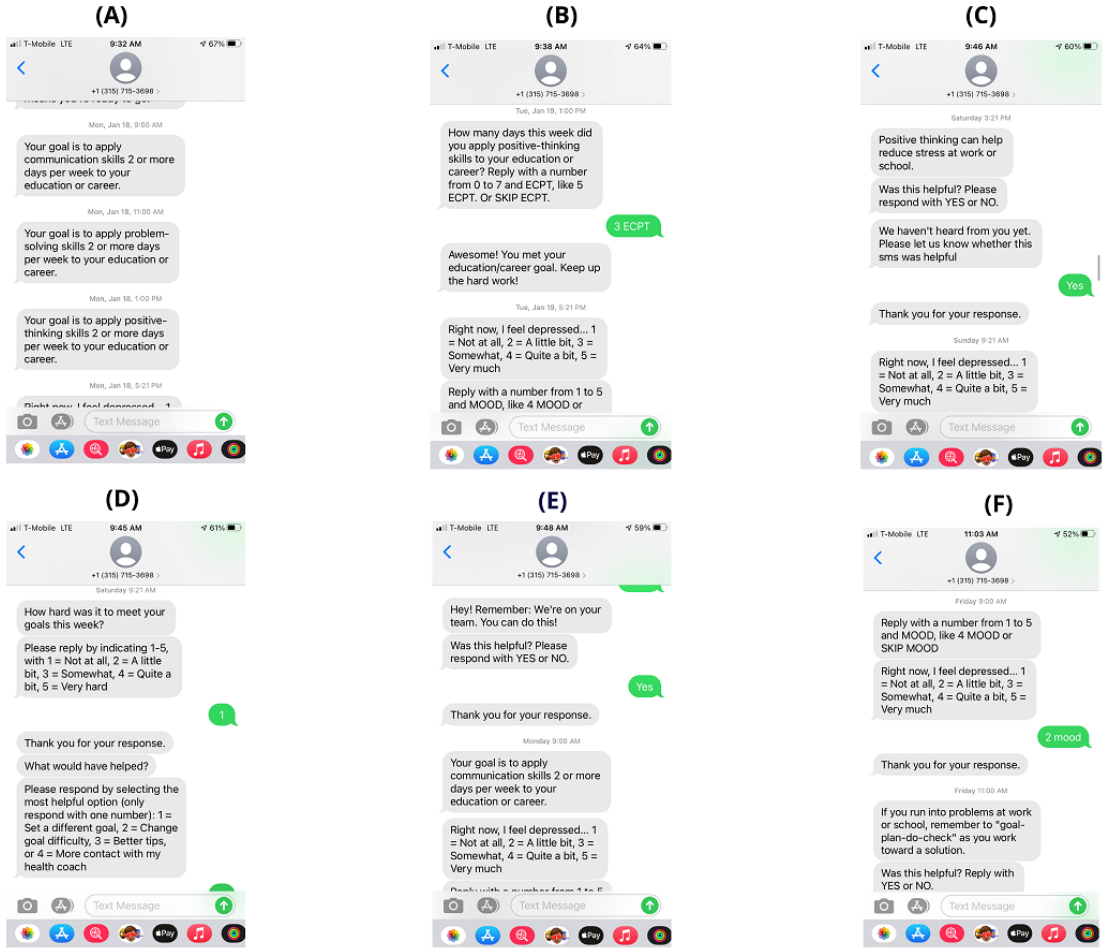
The iSMART Intervention

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.

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

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.

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

[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.

Figure 3. Changes in Participation Strategies Self-Efficacy Scale (PS-SES) scores after intervention. iSMART: interactive Self-Management Augmented by Rehabilitation Technologies.

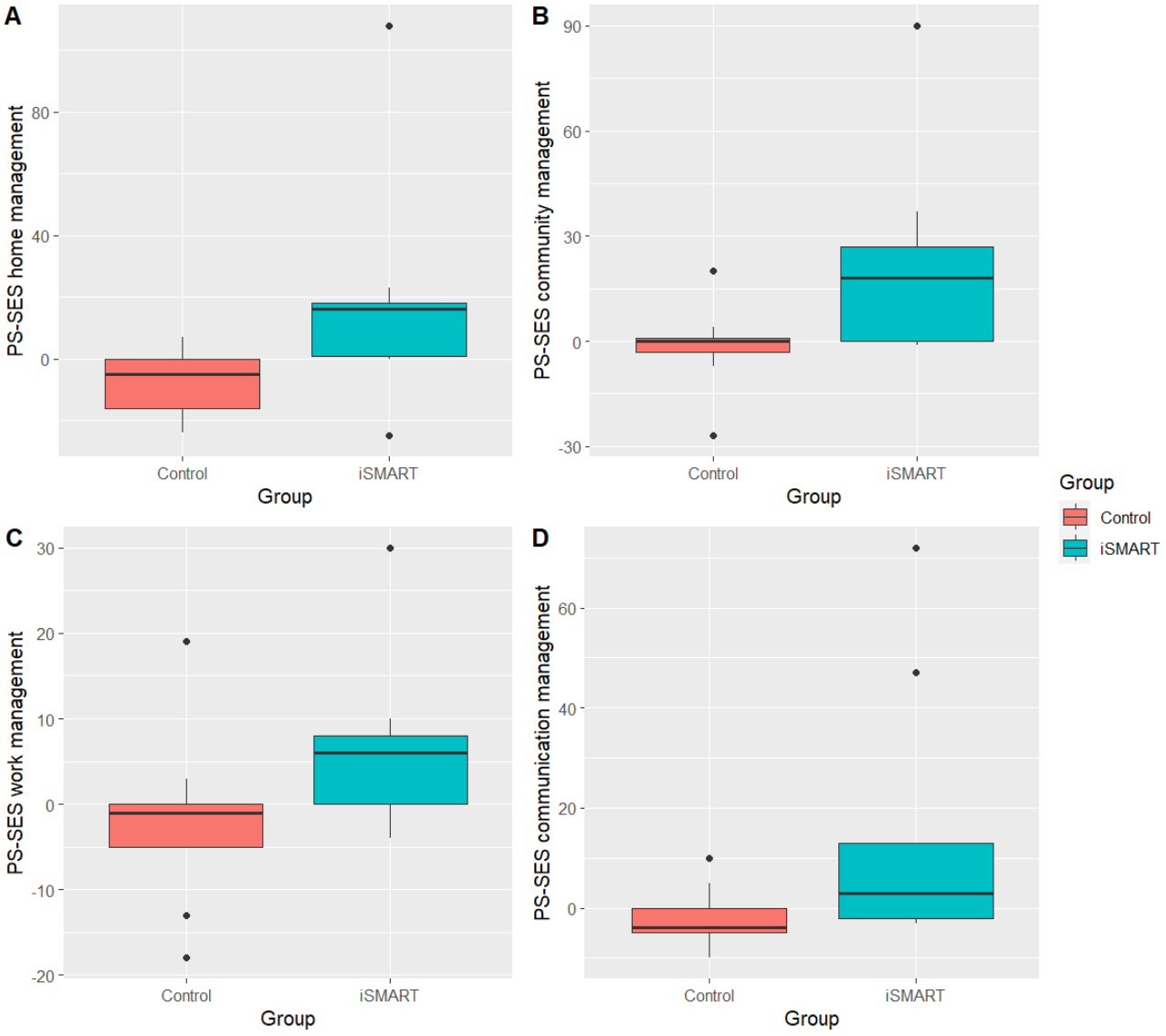


Figure 4. Changes in Patient-Reported Outcomes Measurement Information System's Self-Efficacy (PROMIS-SE) scores after intervention. iSMART: interactive Self-Management Augmented by Rehabilitation Technologies.

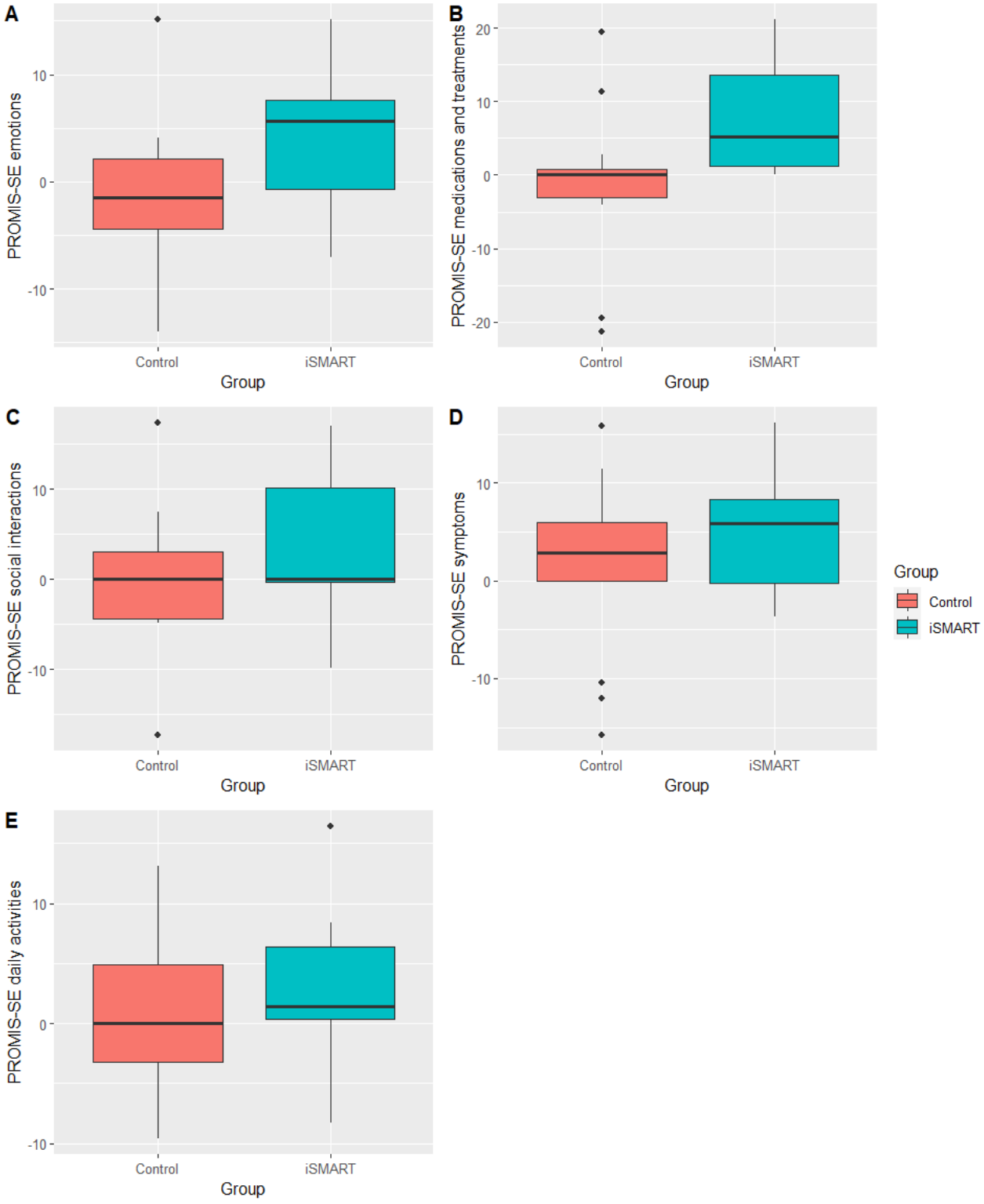


Table 3. Pre- and postintervention self-efficacy scores between the control and interactive Self-Management Augmented by Rehabilitation Technologies (iSMART) groups.

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

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

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]

References

1. Gassaway J, Horn SD, DeJong G, Smout RJ, Clark C, James R. Applying the clinical practice improvement approach to stroke rehabilitation: methods used and baseline results. Arch Phys Med Rehabil 2005 Dec;86(12 Suppl 2):S16-S33. [doi: 10.1016/j.apmr.2005.08.114] [Medline: 16373137]
2. Rochette A, Korner-Bitensky N, Bishop D, Teasell R, White CL, Bravo G, et al. The YOU CALL-WE CALL randomized clinical trial: impact of a multimodal support intervention after a mild stroke. Circ Cardiovasc Qual Outcomes 2013;6(6):674-679 [FREE Full text] [doi: 10.1161/CIRCOUTCOMES.113.000375] [Medline: 24221841]

3. Wolf TJ, Baum C, Conner LT. Changing face of stroke: implications for occupational therapy practice. Am J Occup Ther 2009;63(5):621-625 [FREE Full text] [doi: 10.5014/ajot.63.5.621] [Medline: 19785261]
4. Altieri M, Maestrini I, Mercurio A, Troisi P, Sgarlata E, Rea V, et al. Depression after minor stroke: prevalence and predictors. Eur J Neurol 2012;19(3):517-521. [doi: 10.1111/j.1468-1331.2011.03583.x] [Medline: 22175796]
5. Xie J, Wu EQ, Zheng ZJ, Croft JB, Greenlund KJ, Mensah GA, et al. Impact of stroke on health-related quality of life in the noninstitutionalized population in the United States. Stroke 2006;37(10):2567-2572 [FREE Full text] [doi: 10.1161/01.STR.0000240506.34616.10] [Medline: 16946158]
6. Rothwell PM, Giles MF, Chandratheva A, Marquardt L, Geraghty O, Redgrave JNE, et al. Effect of urgent treatment of transient ischaemic attack and minor stroke on early recurrent stroke (EXPRESS study): a prospective population-based sequential comparison. Lancet 2007;370(9596):1432-1442. [doi: 10.1016/S0140-6736(07)61448-2] [Medline: 17928046]
7. Mohan KM, Wolfe CDA, Rudd AG, Heuschmann PU, Kolominsky-Rabas PL, Grieve AP. Risk and cumulative risk of stroke recurrence: a systematic review and meta-analysis. Stroke 2011;42(5):1489-1494 [FREE Full text] [doi: 10.1161/STROKEAHA.110.602615] [Medline: 21454819]
8. Woodman P, Riazi A, Pereira C, Jones F. Social participation post stroke: a meta-ethnographic review of the experiences and views of community-dwelling stroke survivors. Disabil Rehabil 2014;36(24):2031-2043. [doi: 10.3109/09638288.2014.887796] [Medline: 24597937]
9. Mountain A, Lindsay MP, Teasell R, Salbach NM, de Jong A, Foley N, et al. Canadian stroke best practice recommendations: rehabilitation, recovery, and community participation following stroke. Part two: transitions and community participation following stroke. Int J Stroke 2020;15(7):789-806 [FREE Full text] [doi: 10.1177/1747493019897847] [Medline: 31983292]
10. Rochette A, Desrosiers J, Bravo G, St-Cyr-Tribble D, Bourget A. Changes in participation after a mild stroke: quantitative and qualitative perspectives. Top Stroke Rehabil 2007;14(3):59-68. [doi: 10.1310/tsr1403-59] [Medline: 17577968]
11. Wolf TJ, Baum CM, Lee D, Hammel J. The development of the Improving Participation after Stroke Self-management program (IPASS): an exploratory randomized clinical study. Top Stroke Rehabil 2016;23(4):284-292 [FREE Full text] [doi: 10.1080/10749357.2016.1155278] [Medline: 27077987]
12. Correia JC, Waqas A, Assal JP, Davies MJ, Somers F, Golay A, et al. Effectiveness of therapeutic patient education interventions for chronic diseases: a systematic review and meta-analyses of randomized controlled trials. Front Med (Lausanne) 2022;9:996528 [FREE Full text] [doi: 10.3389/fmed.2022.996528] [Medline: 36760883]
13. Lee D, Fischer H, Zera S, Robertson R, Hammel J. Examining a participation-focused stroke self-management intervention in a day rehabilitation setting: a quasi-experimental pilot study. Top Stroke Rehabil 2017;24(8):601-607. [doi: 10.1080/10749357.2017.1375222] [Medline: 28956721]
14. Damush TM, Ofner S, Yu Z, Plue L, Nicholas G, Williams LS. Implementation of a stroke self-management program: a randomized controlled pilot study of veterans with stroke. Transl Behav Med 2011;1(4):561-572 [FREE Full text] [doi: 10.1007/s13142-011-0070-y] [Medline: 24073080]
15. Jones F, Riazi A. Self-efficacy and self-management after stroke: a systematic review. Disabil Rehabil 2011;33(10):797-810. [doi: 10.3109/09638288.2010.511415] [Medline: 20795919]
16. Marks R, Allegrante JP, Lorig K. A review and synthesis of research evidence for self-efficacy-enhancing interventions for reducing chronic disability: implications for health education practice (part II). Health Promot Pract 2005;6(2):148-156. [doi: 10.1177/1524839904266792] [Medline: 15855284]
17. Free C, Phillips G, Galli L, Watson L, Felix L, Edwards P, et al. The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review. PLoS Med 2013;10(1):e1001362 [FREE Full text] [doi: 10.1371/journal.pmed.1001362] [Medline: 23349621]
18. Buhi ER, Trudnak TE, Martinasek MP, Oberne AB, Fuhrmann HJ, McDermott RJ. Mobile phone-based behavioural interventions for health: a systematic review. Health Educ J 2012;72(5):564-583. [doi: 10.1177/0017896912452071]
19. Lycett HJ, Raebel EM, Wildman EK, Guitart J, Kenny T, Sherlock JP, et al. Theory-based digital interventions to improve asthma self-management outcomes: systematic review. J Med Internet Res 2018;20(12):e293 [FREE Full text] [doi: 10.2196/jmir.9666] [Medline: 30541741]
20. Nahum-Shani I, Smith SN, Spring BJ, Collins LM, Witkiewitz K, Tewari A, et al. Just-in-Time Adaptive Interventions (JITAIs) in mobile health: key components and design principles for ongoing health behavior support. Ann Behav Med 2018;52(6):446-462 [FREE Full text] [doi: 10.1007/s12160-016-9830-8] [Medline: 27663578]
21. Lau SC, Bhattacharjya S, Fong MW, Nicol GE, Lenze EJ, Baum C, et al. Effectiveness of theory-based digital self-management interventions for improving depression, anxiety, fatigue and self-efficacy in people with neurological disorders: a systematic review and meta-analysis. J Telemed Telecare 2022;28(8):547-558 [FREE Full text] [doi: 10.1177/1357633X20955122] [Medline: 32954920]
22. Wong AWK, Fong MWM, Munsell EGS, Metts CL, Lee SI, Nicol GE, et al. Using intervention mapping and behavior change techniques to develop a digital intervention for self-management in stroke: development study. JMIR Hum Factors 2023;10:e45099 [FREE Full text] [doi: 10.2196/45099] [Medline: 37486748]
23. Brennan DM, Mawson S, Brownsell S. Telerehabilitation: enabling the remote delivery of healthcare, rehabilitation, and self management. Stud Health Technol Inform 2009;145:231-248. [Medline: 19592797]

24. Hall AK, Cole-Lewis H, Bernhardt JM. Mobile text messaging for health: a systematic review of reviews. Annu Rev Public Health 2015;36:393-415 [FREE Full text] [doi: 10.1146/annurev-publhealth-031914-122855] [Medline: 25785892]
25. Lejuez CW, Hopko DR, Acierno R, Daughters SB, Pagoto SL. Ten year revision of the brief behavioral activation treatment for depression: revised treatment manual. Behav Modif 2011;35(2):111-161. [doi: 10.1177/0145445510390929] [Medline: 21324944]
26. Frates EP, Moore MA, Lopez CN, McMahon GT. Coaching for behavior change in physiatry. Am J Phys Med Rehabil 2011;90(12):1074-1082. [doi: 10.1097/PHM.0b013e31822dea9a] [Medline: 22019966]
27. Brott T, Adams HP, Olinger CP, Marler JR, Barsan WG, Biller J, et al. Measurements of acute cerebral infarction: a clinical examination scale. Stroke 1989;20(7):864-870 [FREE Full text] [doi: 10.1161/01.str.20.7.864] [Medline: 2749846]
28. Kaplan E, Goodglass H, Weintraub S. Boston Naming Test. Austin, TX: Pro-ed; 2001.
29. Chiamulera C, Mantovani E, Tamburin S. Remote clinical trials: a timely opportunity for a virtual reality approach and its potential application in neurology. Br J Clin Pharmacol 2021;87(10):3639-3642 [FREE Full text] [doi: 10.1111/bcp.14922] [Medline: 34041779]
30. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research Electronic Data Capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
31. Bandura A. Social cognitive theory: an agentic perspective. Annu Rev Psychol 2001;52:1-26. [doi: 10.1146/annurev.psych.52.1.1] [Medline: 11148297]
32. Baum C, Christiansen CH, Bass JD. The Person-Environment-Occupaion-Performance (PEOP) model. In: Occupational Therapy: Performance, Participation, and Well-being, 4th Edition. Thorofare, NJ: SLACK Incorporated; 2014:49-55.
33. Tabak RG, Strickland JR, Stein RI, Dart H, Colditz GA, Kirk B, et al. Development of a scalable weight loss intervention for low-income workers through adaptation of interactive Obesity Treatment Approach (iOTA). BMC Public Health 2018;18(1):1265 [FREE Full text] [doi: 10.1186/s12889-018-6176-0] [Medline: 30445939]
34. Tabak RG, Strickland JR, Kirk B, Colvin R, Stein RI, Dart H, et al. Pilot test of an interactive obesity treatment approach among employed adults in a university medical billing office. Pilot Feasibility Stud 2020;6:57 [FREE Full text] [doi: 10.1186/s40814-020-00599-w] [Medline: 32355567]
35. Nicol G, Jansen M, Haddad R, Ricchio A, Yingling MD, Schweiger JA, et al. Use of an interactive obesity treatment approach in individuals with severe mental illness: feasibility, acceptability, and proposed engagement criteria. JMIR Form Res 2022;6(12):e38496 [FREE Full text] [doi: 10.2196/38496] [Medline: 36512399]
36. Bartholomew LK, Parcel GS, Kok G. Intervention mapping: a process for developing theory- and evidence-based health education programs. Health Educ Behav 1998;25(5):545-563. [doi: 10.1177/109019819802500502] [Medline: 9768376]
37. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci 2011;6:42 [FREE Full text] [doi: 10.1186/1748-5908-6-42] [Medline: 21513547]
38. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med 2013;46(1):81-95 [FREE Full text] [doi: 10.1007/s12160-013-9486-6] [Medline: 23512568]
39. Carey RN, Connell LE, Johnston M, Rothman AJ, de Bruin M, Kelly MP, et al. Behavior change techniques and their mechanisms of action: a synthesis of links described in published intervention literature. Ann Behav Med 2019;53(8):693-707 [FREE Full text] [doi: 10.1093/abm/kay078] [Medline: 30304386]
40. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, et al. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci 2017;12(1):108 [FREE Full text] [doi: 10.1186/s13012-017-0635-3] [Medline: 28851459]
41. Lee D, Fogg L, Baum CM, Wolf TJ, Hammel J. Validation of the Participation Strategies Self-Efficacy Scale (PS-SES). Disabil Rehabil 2018;40(1):110-115. [doi: 10.1080/09638288.2016.1242172] [Medline: 27793074]
42. Gruber-Baldini AL, Velozo C, Romero S, Shulman LM. Validation of the PROMIS® measures of self-efficacy for managing chronic conditions. Qual Life Res 2017;26(7):1915-1924 [FREE Full text] [doi: 10.1007/s11136-017-1527-3] [Medline: 28239781]
43. Cohen J. Statistical Power Analysis for the Behavioral Sciences. Hillsdale, NJ: L. Erlbaum Associates; 1988.
44. Kassambara A. Wilcoxon effect size. rstatix. 2019. URL: https://rpkgs.datanovia.com/rstatix/reference/wilcox_effsize.html [accessed 2023-11-05]
45. Schäfer T, Schwarz MA. The meaningfulness of effect sizes in psychological research: differences between sub-disciplines and the impact of potential biases. Front Psychol 2019;10:813 [FREE Full text] [doi: 10.3389/fpsyg.2019.00813] [Medline: 31031679]
46. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. Pilot Feasibility Stud 2016;2:64 [FREE Full text] [doi: 10.1186/s40814-016-0105-8] [Medline: 27965879]
47. Cuschieri S. The CONSORT statement. Saudi J Anaesth 2019;13(Suppl 1):S27-S30 [FREE Full text] [doi: 10.4103/sja.SJA_559_18] [Medline: 30930716]

48. Chai LK, Collins CE, May C, Ashman A, Holder C, Brown LJ, et al. Feasibility and efficacy of a web-based family telehealth nutrition intervention to improve child weight status and dietary intake: a pilot randomised controlled trial. J Telemed Telecare 2021;27(3):146-158. [doi: 10.1177/1357633X19865855] [Medline: 31364474]
49. Nhavoto JA, Grönlund Å, Klein GO. Mobile health treatment support intervention for HIV and tuberculosis in Mozambique: perspectives of patients and healthcare workers. PLoS One 2017;12(4):e0176051 [FREE Full text] [doi: 10.1371/journal.pone.0176051] [Medline: 28419149]
50. Suffoletto B, Wagner AK, Arenth PM, Calabria J, Kingsley E, Kristan J, et al. Mobile phone text messaging to assess symptoms after mild traumatic brain injury and provide self-care support: a pilot study. J Head Trauma Rehabil 2013;28(4):302-312. [doi: 10.1097/HTR.0b013e3182847468] [Medline: 23474882]
51. Guidetti S, Gustavsson M, Tham K, Andersson M, Fors U, Ytterberg C. F@ce: a team-based, person-centred intervention for rehabilitation after stroke supported by information and communication technology—a feasibility study. BMC Neurol 2020;20(1):387 [FREE Full text] [doi: 10.1186/s12883-020-01968-x] [Medline: 33096984]
52. Chau JPC, Lo SHS, Choi KC, Butt L, Zhao J, Thompson DR. Participation self-efficacy plays a mediation role in the association between mobility and social participation among stroke survivors. Heart Lung 2021;50(6):857-862. [doi: 10.1016/j.hrtlng.2021.07.002] [Medline: 34333221]
53. Kamwesiga JT, Eriksson GM, Tham K, Fors U, Ndiwalana A, von Koch L, et al. A feasibility study of a mobile phone supported family-centred ADL intervention, F@ce, after stroke in Uganda. Global Health 2018;14(1):82 [FREE Full text] [doi: 10.1186/s12992-018-0400-7] [Medline: 30111333]
54. Gupta SK. Intention-to-treat concept: a review. Perspect Clin Res 2011;2(3):109-112 [FREE Full text] [doi: 10.4103/2229-3485.83221] [Medline: 21897887]
55. Magasi S, Wong A, Gray DB, Hammel J, Baum C, Wang CC, et al. Theoretical foundations for the measurement of environmental factors and their impact on participation among people with disabilities. Arch Phys Med Rehabil 2015;96(4):569-577. [doi: 10.1016/j.apmr.2014.12.002] [Medline: 25813889]
56. Wong AWK, Ng S, Dashner J, Baum MC, Hammel J, Magasi S, et al. Relationships between environmental factors and participation in adults with traumatic brain injury, stroke, and spinal cord injury: a cross-sectional multi-center study. Qual Life Res 2017;26(10):2633-2645. [doi: 10.1007/s11136-017-1586-5] [Medline: 28444554]
57. Boyd H, McKernon S, Mullin B, Old A. Improving healthcare through the use of co-design. N Z Med J 2012;125(1357):76-87. [Medline: 22854362]
58. Sanz MF, Acha BV, García MF. Co-design for people-centred care digital solutions: a literature review. Int J Integr Care 2021;21(2):16 [FREE Full text] [doi: 10.5334/ijic.5573] [Medline: 33981193]
59. Syme SL. Social determinants of health: the community as an empowered partner. Prev Chronic Dis 2004;1(1):A02 [FREE Full text] [Medline: 15634364]
60. Farao J, Malila B, Conrad N, Mutsvangwa T, Rangaka MX, Douglas TS. A user-centred design framework for mHealth. PLoS One 2020;15(8):e0237910 [FREE Full text] [doi: 10.1371/journal.pone.0237910] [Medline: 32813711]
61. Collins LM, Murphy SA, Strecher V. The Multiphase Optimization Strategy (MOST) and the Sequential Multiple Assignment Randomized Trial (SMART): new methods for more potent eHealth interventions. Am J Prev Med 2007;32(5 Suppl):S112-S118 [FREE Full text] [doi: 10.1016/j.amepre.2007.01.022] [Medline: 17466815]
62. Spring B, Pfammatter AF, Marchese SH, Stump T, Pellegrini C, McFadden HG, et al. A factorial experiment to optimize remotely delivered behavioral treatment for obesity: results of the Opt-IN study. Obesity (Silver Spring) 2020;28(9):1652-1662 [FREE Full text] [doi: 10.1002/oby.22915] [Medline: 32656994]
63. Dionne-Odom JN, Wells RD, Guastaferro K, Azuero A, Hendricks BA, Currie ER, et al. An early palliative care telehealth coaching intervention to enhance advanced cancer family caregivers' decision support skills: the CASCADE pilot factorial trial. J Pain Symptom Manage 2022;63(1):11-22 [FREE Full text] [doi: 10.1016/j.jpainsymman.2021.07.023] [Medline: 34343621]
64. Phillips SM, Penedo FJ, Collins LM, Solk P, Siddique J, Song J, et al. Optimization of a technology-supported physical activity promotion intervention for breast cancer survivors: results from Fit2Thrive. Cancer 2022;128(5):1122-1132 [FREE Full text] [doi: 10.1002/cncr.34012] [Medline: 34812521]

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

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

Kirsten Elisabeth Smayda[1*], BA, BM, MM, PhD; Sarah Hodsdon Cooper[1*], BA; Katie Leyden[2], BA; Jackie Ulaszek[2], MSc; Nicole Ferko[3], MSc; Annamaria Dobrin[3], MBDC

[1]MedRhythms, Portland, ME, United States

[2]Bold Insight, Downers Grove, IL, United States

[3]Eversana, Burlington, ON, Canada

[*]these authors contributed equally

Corresponding Author:
Kirsten Elisabeth Smayda, BA, BM, MM, PhD
MedRhythms
183 Middle St.
Portland, ME, 04101
United States
Phone: 1 2072332373
Email: ksmayda@medrhythms.com

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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*

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.

The original corresponding author was Sarah Hodsdon Cooper:

Sarah Hodsdon Cooper, BA
MedRhythms
183 Middle Street
Portland, ME, 04101
United States
Phone: 1 207 233 2373
Email: secooper@medrhythms.com

Has been updated to Kirsten Elisabeth Smayda:

Kirsten Elisabeth Smayda, BA, BM, MM, PhD
MedRhythms
183 Middle Street
Portland, ME, 04101
United States
Phone: 1 207 233 2373
Email: ksmayda@medrhythms.com

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

Xiaofeng Nan[1], CPO; Tuğba Kuru Çolak[2], PhD; Burçin Akçay[3], PhD; Hua Xie[4], CPO; Liwei Zhao[5], CPO; Maksym Borysov[6], CPO, PT

[1]Nan Xiaofeng's Spinal Orthopedic Workshop, Xi'an Shaanxi, China

[2]Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, Marmara University, İstanbul, Turkey

[3]Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, Bandırma Onyedi Eylül University, Balıkesir, Turkey

[4]Schroth Health Technology, Chongqing, China

[5]National Research Centre for Rehabilitation Technical Aids, Schroth Health Technology, Beijing, China

[6]Orttech Plus Rehabilitation Service, Kharkiv, Ukraine

Corresponding Author:
Xiaofeng Nan, CPO
Nan Xiaofeng's Spinal Orthopedic Workshop
Room 806, Unit 2, Zhongmao Square (15th floor), Beilin District
Xi'an Shaanxi, 710068
China
Phone: 86 189 9124 1048
Fax: 86 189 9124 1048
Email: xiaofeng.nann@gmail.com

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.

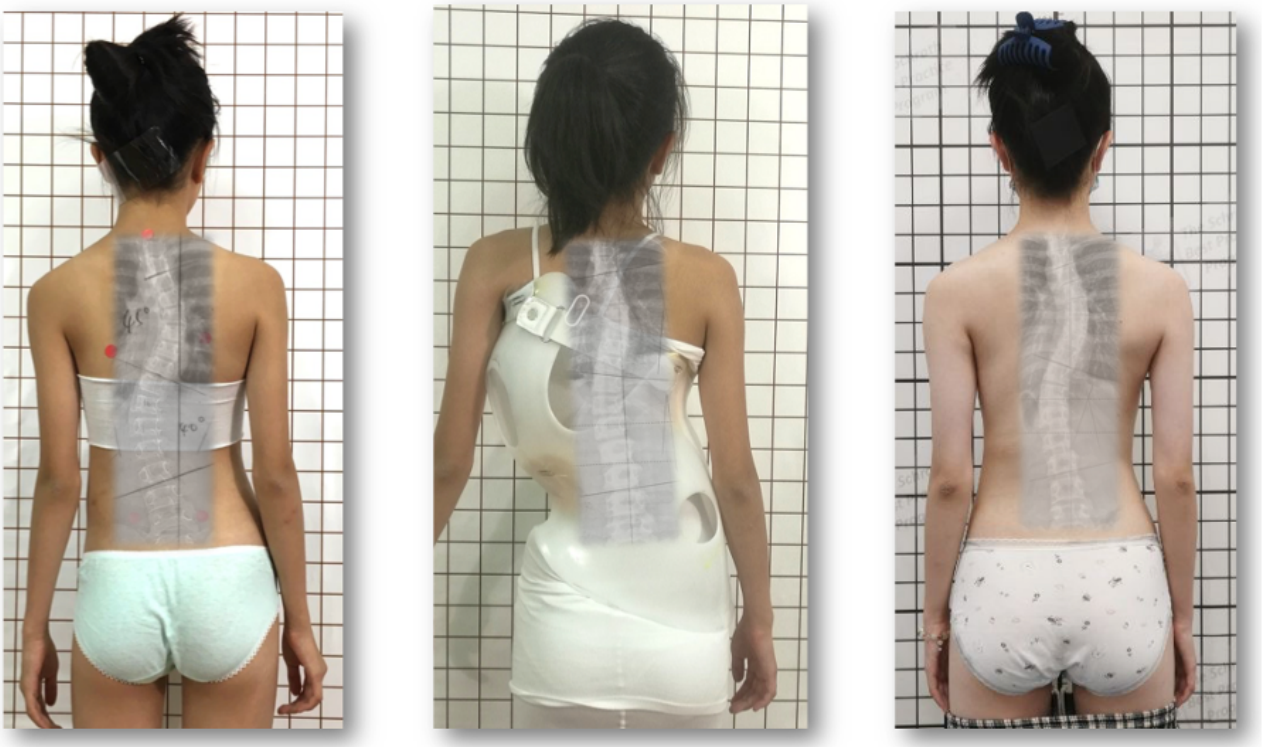
According to the current guidelines, it is recommended that patients with Risser stage 0-3 and a scoliosis progression risk of more than 60% according to the Lonstein and Carlson [22] formula should start bracing treatment. In this study, risk of progression was calculated and brace treatment was recommended 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).

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).

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

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).

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.

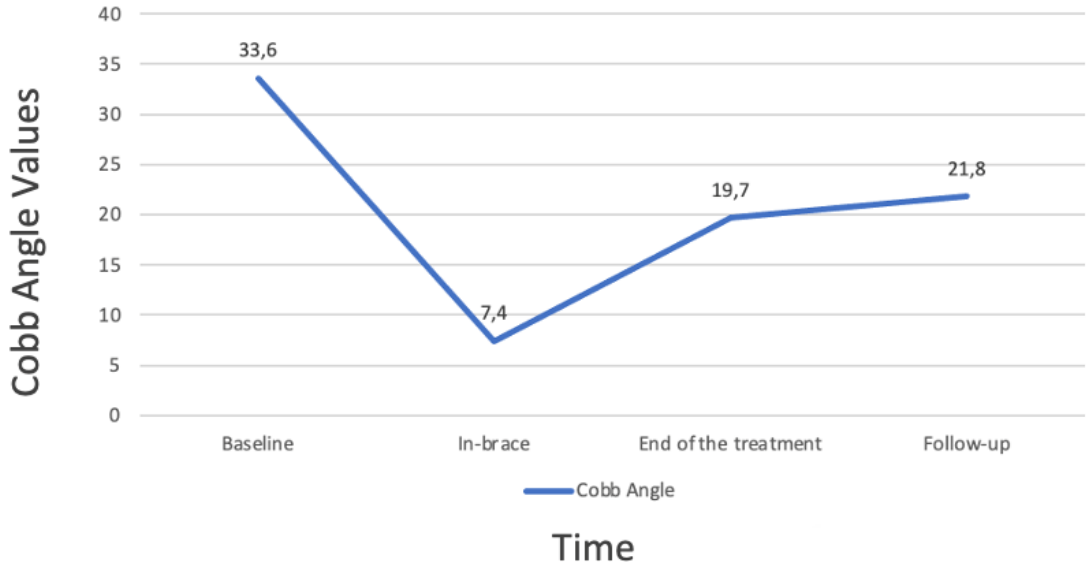


Table 2. Changes in the Cobb angle and angles of trunk rotation (ATR).

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

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.

References

1. Asher MA, Burton DC. Adolescent idiopathic scoliosis: natural history and long term treatment effects. Scoliosis 2006 Mar 31;1(1):2 [FREE Full text] [doi: 10.1186/1748-7161-1-2] [Medline: 16759428]
2. Goldberg CJ, Moore DP, Fogarty EE, Dowling FE. Adolescent idiopathic scoliosis: natural history and prognosis. Stud Health Technol Inform 2002;91:59-63. [Medline: 15457694]
3. Kruzel K, Moramarco M. Idiopathic Scoliosis. In: Moramarco M, Borysov M, Ng SY, Weiss HR, editors. Schroth's Textbook of Scoliosis and other Spinal Deformities. Newcastle upon Tyne: Cambridge Scholars Publishing; 2020:380-400.
4. Weinstein SL, Dolan LA, Spratt KF, Peterson KK, Spoonamore MJ, Ponseti IV. Health and function of patients with untreated idiopathic scoliosis: a 50-year natural history study. JAMA 2003 Feb 05;289(5):559-567. [doi: 10.1001/jama.289.5.559] [Medline: 12578488]
5. Seleviciene V, Cesnaviciute A, Strukcinskiene B, Marcinowicz L, Strazdiene N, Genowska A. Physiotherapeutic scoliosis-specific exercise methodologies used for conservative treatment of adolescent idiopathic scoliosis, and their effectiveness: an extended literature review of current research and practice. Int J Environ Res Public Health 2022 Jul 28;19(15) [FREE Full text] [doi: 10.3390/ijerph19159240] [Medline: 35954620]

6. Kuru T, Yeldan İ, Dereli EE, Özdinçler AR, Dikici F, Çolak İ. The efficacy of three-dimensional Schroth exercises in adolescent idiopathic scoliosis: a randomised controlled clinical trial. Clin Rehabil 2016 Feb;30(2):181-190. [doi: 10.1177/0269215515575745] [Medline: 25780260]
7. Monticone M, Ambrosini E, Cazzaniga D, Rocca B, Ferrante S. Active self-correction and task-oriented exercises reduce spinal deformity and improve quality of life in subjects with mild adolescent idiopathic scoliosis. Results of a randomised controlled trial. Eur Spine J 2014 Jun;23(6):1204-1214. [doi: 10.1007/s00586-014-3241-y] [Medline: 24682356]
8. Anwer S, Alghadir A, Abu Shaphe M, Anwar D. Effects of exercise on spinal deformities and quality of life in patients with adolescent idiopathic scoliosis. Biomed Res Int 2015;2015:123848 [FREE Full text] [doi: 10.1155/2015/123848] [Medline: 26583083]
9. Nachemson AL, Peterson LE. Effectiveness of treatment with a brace in girls who have adolescent idiopathic scoliosis. A prospective, controlled study based on data from the Brace Study of the Scoliosis Research Society. J Bone Joint Surg Am 1995 Jun;77(6):815-822. [doi: 10.2106/00004623-199506000-00001] [Medline: 7782353]
10. Weinstein SL, Dolan LA, Wright JG, Dobbs MB. Effects of bracing in adolescents with idiopathic scoliosis. N Engl J Med 2013 Oct 17;369(16):1512-1521 [FREE Full text] [doi: 10.1056/NEJMoa1307337] [Medline: 24047455]
11. Weiss H, Weiss GM. Brace treatment during pubertal growth spurt in girls with idiopathic scoliosis (IS): a prospective trial comparing two different concepts. Pediatr Rehabil 2005;8(3):199-206. [doi: 10.1080/13638490400022212] [Medline: 16087554]
12. Weiss H, Nan X, Potts MA. Is there an indication for surgery in patients with spinal deformities? - A critical appraisal. S Afr J Physiother 2021;77(2):1569 [FREE Full text] [doi: 10.4102/sajp.v77i2.1569] [Medline: 34859161]
13. Bettany-Saltikov J, Weiss H, Chockalingam N, Taranu R, Srinivas S, Hogg J, et al. Surgical versus non-surgical interventions in people with adolescent idiopathic scoliosis. Cochrane Database Syst Rev 2015 Apr 24(4):CD010663 [FREE Full text] [doi: 10.1002/14651858.CD010663.pub2] [Medline: 25908428]
14. Sy N, Bettany-Saltikov J, Moramarco M. Evidence for conservative treatment of adolescent idiopathic scoliosis - Update 2015 (Mini-Review). Curr Pediatr Rev 2016;12(1):6-11. [doi: 10.2174/1573396312666151117120056] [Medline: 26573167]
15. Weiss H, Çolak TK, Lay M, Borysov M. Brace treatment for patients with scoliosis: state of the art. S Afr J Physiother 2021;77(2):1573 [FREE Full text] [doi: 10.4102/sajp.v77i2.1573] [Medline: 34859162]
16. Hawary RE, Zaaroor-Regev D, Floman Y, Lonner BS, Alkhalife YI, Betz RR. Brace treatment in adolescent idiopathic scoliosis: risk factors for failure-a literature review. Spine J 2019 Dec;19(12):1917-1925 [FREE Full text] [doi: 10.1016/j.spinee.2019.07.008] [Medline: 31325626]
17. Addai D, Zarkos J, Bowey AJ. Current concepts in the diagnosis and management of adolescent idiopathic scoliosis. Childs Nerv Syst 2020 Jun;36(6):1111-1119 [FREE Full text] [doi: 10.1007/s00381-020-04608-4] [Medline: 32314025]
18. Weiss H, Lay M, Seibel S, Kleban A. [Is it possible to improve treatment safety in the brace treatment of scoliosis patients by using standardized CAD algorithms?]. Orthopade 2021 Jun 06;50(6):435-445 [FREE Full text] [doi: 10.1007/s00132-020-04000-9] [Medline: 33025038]
19. Weiss H, Turnbull D, Seibel S, Kleban A. First end-result of a prospective cohort with AIS treated with a CAD Chêneau style brace. J Phys Ther Sci 2019 Dec;31(12):983-991 [FREE Full text] [doi: 10.1589/jpts.31.983] [Medline: 32038069]
20. Tournavitis N, Çolak TK, Voutsas C. Effect of Chêneau style braces on vertebral wedging amongst individuals with adolescent idiopathic scoliosis. S Afr J Physiother 2021;77(2):1617 [FREE Full text] [doi: 10.4102/sajp.v77i2.1617] [Medline: 34966856]
21. Richards BS, Bernstein RM, D'Amato CR, Thompson GH. Standardization of criteria for adolescent idiopathic scoliosis brace studies: SRS Committee on Bracing and Nonoperative Management. Spine (Phila Pa 1976) 2005 Sep 15;30(18):2068-75; discussion 2076. [doi: 10.1097/01.brs.0000178819.90239.d0] [Medline: 16166897]
22. Lonstein JE, Carlson JM. The prediction of curve progression in untreated idiopathic scoliosis during growth. J Bone Joint Surg Am 1984 Sep;66(7):1061-1071. [Medline: 6480635]
23. Negrini S, Donzelli S, Aulisa AG, Czaprowski D, Schreiber S, de Mauroy JC, et al. 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. Scoliosis Spinal Disord 2018;13:3 [FREE Full text] [doi: 10.1186/s13013-017-0145-8] [Medline: 29435499]
24. Weiss H. "Brace technology" thematic series - the Gensingen brace™ in the treatment of scoliosis. Scoliosis 2010 Oct 13;5:22 [FREE Full text] [doi: 10.1186/1748-7161-5-22] [Medline: 20942970]
25. Reem J, Carney J, Stanley M, Cassidy J. Risser sign inter-rater and intra-rater agreement: is the Risser sign reliable? Skeletal Radiol 2009 Apr;38(4):371-375. [doi: 10.1007/s00256-008-0603-8] [Medline: 19002685]
26. Akçay B, Çolak TK, Apti A, Çolak İ, Kızıltaş. The reliability of the augmented Lehnert-Schroth and Rigo classification in scoliosis management. S Afr J Physiother 2021;77(2):1568 [FREE Full text] [doi: 10.4102/sajp.v77i2.1568] [Medline: 34859160]
27. Cobb J. Outline for the study of scoliosis. Instructional Course Lectures 1948.
28. Bunnell WP. An objective criterion for scoliosis screening. J Bone Joint Surg Am 1984 Dec;66(9):1381-1387. [Medline: 6501335]

29. SOSORT guideline committee, Weiss H, Negrini S, Rigo M, Kotwicki T, Hawes MC, et al. Indications for conservative management of scoliosis (guidelines). Scoliosis 2006 May 08;1:5 [FREE Full text] [doi: 10.1186/1748-7161-1-5] [Medline: 16759357]
30. Dereli EE, Gong S, Çolak TK, Turnbull D. Guidelines for the conservative treatment of spinal deformities - Questionnaire for a Delphi consensus. S Afr J Physiother 2021;77(2):1587 [FREE Full text] [doi: 10.4102/sajp.v77i2.1587] [Medline: 34957343]
31. Weiss H, Lehnert-Schroth C, Moramarco M, Moramarco K. Schroth Therapy Advancements in Conservative Scoliosis Treatment (3rd Edition). Saarbrücken, Germany: LAP LAMBERT Academic Publishing; 2022.
32. Kuru Çolak T, Akçay B, Apti A, Çolak İ. The effectiveness of the Schroth Best Practice Program and Chêneau-Type Brace treatment in adolescent idiopathic scoliosis: long-term follow-up evaluation results. Children (Basel) 2023 Feb 16;10(2) [FREE Full text] [doi: 10.3390/children10020386] [Medline: 36832515]
33. De Giorgi S, Piazzolla A, Tafuri S, Borracci C, Martucci A, De Giorgi G. Chêneau brace for adolescent idiopathic scoliosis: long-term results. Can it prevent surgery? Eur Spine J 2013 Nov;22 Suppl 6(Suppl 6):S815-S822 [FREE Full text] [doi: 10.1007/s00586-013-3020-1] [Medline: 24043341]
34. Weinstein SL, Dolan LA, Wright JG, Dobbs MB. Effects of bracing in adolescents with idiopathic scoliosis. N Engl J Med 2013 Oct 17;369(16):1512-1521 [FREE Full text] [doi: 10.1056/NEJMoa1307337] [Medline: 24047455]
35. Fang M, Huang X, Wang W, Li Y, Xiang G, Yan G, et al. The efficacy of Schroth exercises combined with the Chêneau brace for the treatment of adolescent idiopathic scoliosis: a retrospective controlled study. Disabil Rehabil 2022 Sep;44(18):5060-5068. [doi: 10.1080/09638288.2021.1922521] [Medline: 33984249]
36. Landauer F, Wimmer C, Behensky H. Estimating the final outcome of brace treatment for idiopathic thoracic scoliosis at 6-month follow-up. Pediatr Rehabil 2003;6(3-4):201-207. [doi: 10.1080/13638490310001636817] [Medline: 14713586]
37. van den Bogaart M, van Royen BJ, Haanstra TM, de Kleuver M, Faraj SSA. Predictive factors for brace treatment outcome in adolescent idiopathic scoliosis: a best-evidence synthesis. Eur Spine J 2019 Mar;28(3):511-525. [doi: 10.1007/s00586-018-05870-6] [Medline: 30607519]
38. Aulisa AG, Guzzanti V, Falciglia F, Galli M, Pizzetti P, Aulisa L. Curve progression after long-term brace treatment in adolescent idiopathic scoliosis: comparative results between over and under 30 Cobb degrees - SOSORT 2017 award winner. Scoliosis Spinal Disord 2017;12:36 [FREE Full text] [doi: 10.1186/s13013-017-0142-y] [Medline: 29094108]
39. Aulisa AG, Guzzanti V, Falciglia F, Giordano M, Galli M, Aulisa L. Brace treatment of Idiopathic Scoliosis is effective for a curve over 40 degrees, but is the evaluation of Cobb angle the only parameter for the indication of treatment? Eur J Phys Rehabil Med 2019 Apr;55(2):231-240 [FREE Full text] [doi: 10.23736/S1973-9087.18.04782-2] [Medline: 29517186]

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

Vitaliy Trofimchuk[1], PhD; Bolatbek Dossanov[1], PhD; Vassiliy Lozovoy[1], DSc; Sergey Khmyzov[2], DSc; Assem Dossanova[1], PhD; Aleksandr Angelov[1], MMedSci; Andrey Pashenko[2], PhD; Olzhas Zhukenov[1], MMedSci

[1]Department of Pediatrician Surgery, Non-Profit Joint Stock Company Astana Medical University, Astana, Kazakhstan

[2]Department of Pathology of the Spine and Joints of Children, Sitenko Institute of Spine and Joint Pathology, Kharkiv, Ukraine

Corresponding Author:
Vitaliy Trofimchuk, PhD
Department of Pediatrician Surgery
Non-Profit Joint Stock Company Astana Medical University
Beibitshilik St 49/A
Astana, 010000
Kazakhstan
Phone: 7 701 473 6786
Email: vatrofi86@gmail.com

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.

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.

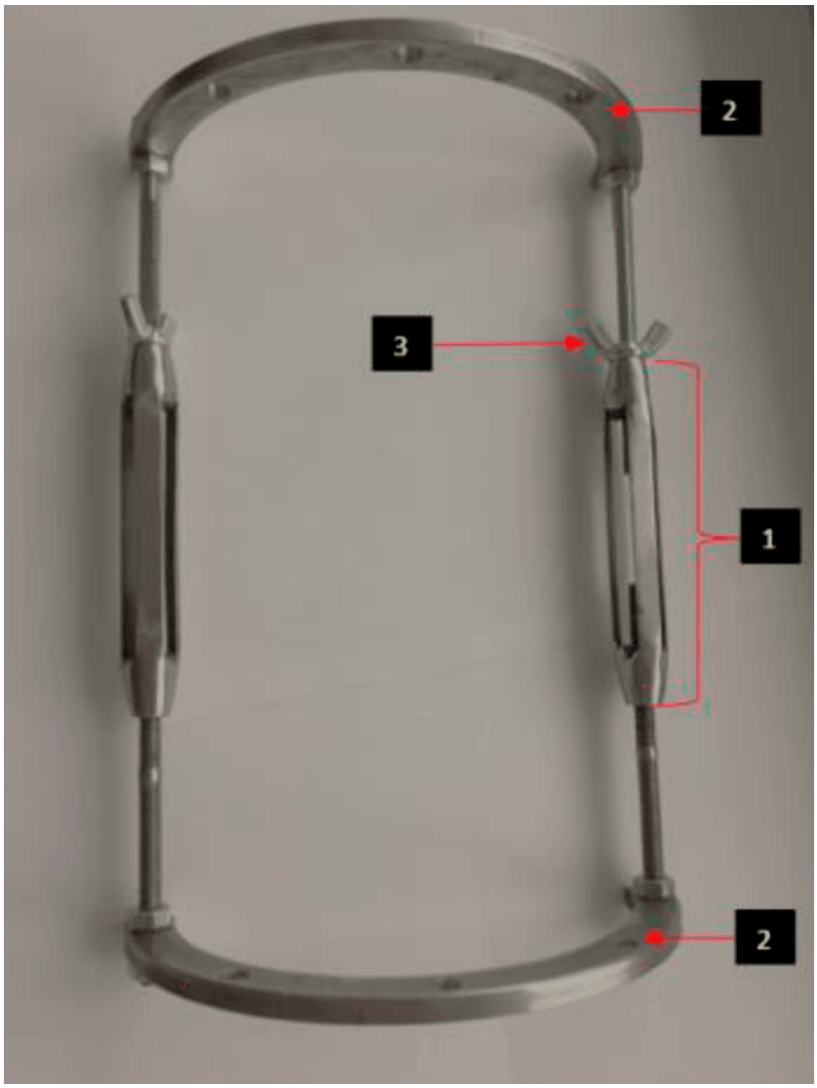
Clinical Examination

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.



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).

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.

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.

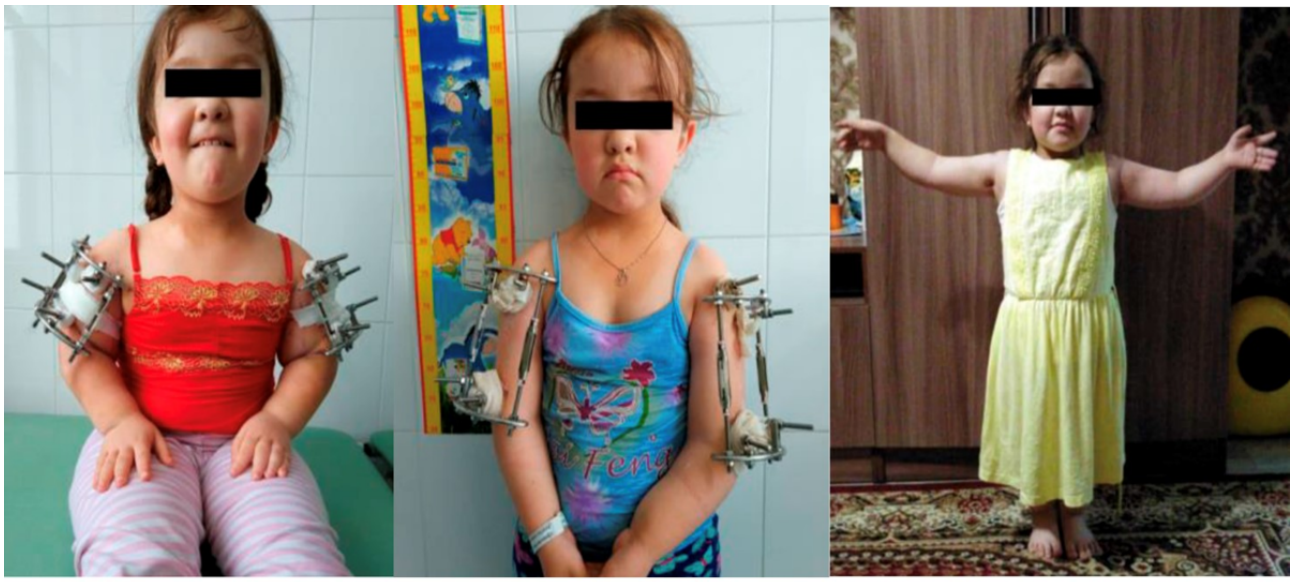
Table 2. Results of transosseous osteosynthesis using the circular multiaxis system and PedsQL[a] v4.0 questionnaire scores completed by patients and their parents in the control group (N=9).

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.

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).



a b c

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

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.

References

1. Pauli RM. Achondroplasia: a comprehensive clinical review. Orphanet J Rare Dis 2019 Jan 03;14(1):1 [FREE Full text] [doi: 10.1186/s13023-018-0972-6] [Medline: 30606190]
2. Ornitz DM, Legeai-Mallet L. Achondroplasia: Development, pathogenesis, and therapy. Dev Dyn 2017 Apr 02;246(4):291-309 [FREE Full text] [doi: 10.1002/dvdy.24479] [Medline: 27987249]
3. Legeai-Mallet L, Savarirayan R. Novel therapeutic approaches for the treatment of achondroplasia. Bone 2020 Dec;141:115579 [FREE Full text] [doi: 10.1016/j.bone.2020.115579] [Medline: 32795681]

4. Wrobel W, Pach E, Ben-Skowronek I. Advantages and disadvantages of different treatment methods in achondroplasia: a review. Int J Mol Sci 2021 May 25;22(11):5573 [FREE Full text] [doi: 10.3390/ijms22115573] [Medline: 34070375]
5. Foreman PK, van Kessel F, van Hoorn R, van den Bosch J, Shediac R, Landis S. Birth prevalence of achondroplasia: A systematic literature review and meta-analysis. Am J Med Genet A 2020 Oct 17;182(10):2297-2316 [FREE Full text] [doi: 10.1002/ajmg.a.61787] [Medline: 32803853]
6. Daugherty A. Achondroplasia: etiology, clinical Presentation, and management. Neonatal Netw 2017 Nov 01;36(6):337-342. [doi: 10.1891/0730-0832.36.6.337] [Medline: 29185944]
7. Witt S, Kolb B, Bloemeke J, Mohnike K, Bullinger M, Quitmann J. Quality of life of children with achondroplasia and their parents - a German cross-sectional study. Orphanet J Rare Dis 2019 Aug 09;14(1):194 [FREE Full text] [doi: 10.1186/s13023-019-1171-9] [Medline: 31399110]
8. Lorne H, Newman CJ, Unger S. Is height important for quality of life in children with skeletal dysplasias? Eur J Med Genet 2020 Apr;63(4):103816. [doi: 10.1016/j.ejmg.2019.103816] [Medline: 31811945]
9. Menshchikova T, Aranovich A. Lengthening of the shins in 6-9 years old patients with achondroplasia as the first stage of growth correction. Genius Orthop 2021;27(3):366-371. [doi: 10.18019/1028-4427-2021-27-3-366-371]
10. Dyachkova G, Klimov O, Aranovich A, Dyachkov K. New possibilities of studying the distraction regenerate according to X-ray data. Genius Orthop 2015;3:60-66. [doi: 10.18019/1028-4427-2015-3-60-66]
11. Dossanov B, Trofimchuk V, Lozovoy V, Khmyzov S, Dossanova A, Zhukenov O, et al. Evaluating the results of long tubular bone distraction with an advanced rod monolateral external fixator for achondroplasia. Sci Rep 2021 Jul 19;11(1):14727 [FREE Full text] [doi: 10.1038/s41598-021-94146-z] [Medline: 34282216]
12. Chilbule S, Dutt V, Madhuri V. Limb lengthening in achondroplasia. Indian J Orthop 2016;50(4):397-405 [FREE Full text] [doi: 10.4103/0019-5413.185604] [Medline: 27512222]
13. Donaldson J, Aftab S, Bradish C. Achondroplasia and limb lengthening: Results in a UK cohort and review of the literature. J Orthop 2015 Mar;12(1):31-34 [FREE Full text] [doi: 10.1016/j.jor.2015.01.001] [Medline: 25829758]
14. Ko KR, Shim JS, Chung CH, Kim JH. Surgical results of limb lengthening at the femur, tibia, and humerus in patients with achondroplasia. Clin Orthop Surg 2019 Jun;11(2):226-232 [FREE Full text] [doi: 10.4055/cios.2019.11.2.226] [Medline: 31156776]
15. Constantinides C, Landis SH, Jarrett J, Quinn J, Ireland PJ. Quality of life, physical functioning, and psychosocial function among patients with achondroplasia a targeted literature review. Disabil Rehabil 2022 Oct 17;44(21):6166-6178. [doi: 10.1080/09638288.2021.1963853] [Medline: 34403286]
16. Diachkova G, Aranovich A, Diachkov K, Klimov O, Novikov K, Sutyagin I. Orthopaedic, psychological, social and philosophical aspects of achondroplasia patients treated with the Ilizarov method. Geni Ortop 2018 Dec;24(4):465-473. [doi: 10.18019/1028-4427-2018-24-4-465-473]
17. Belokrylov A. Features of application of the Ilizarov device for replacement of bone tissue defects in children. Orthoped Traumatol Pediatr Reconstr Surg 2020;8:8-10 [FREE Full text]
18. Pesenti S, Iobst C, Launay F. Evaluation of the external fixator TrueLok Hexapod System for tibial deformity correction in children. Orthop Traumatol Surg Res 2017 Sep;103(5):761-764 [FREE Full text] [doi: 10.1016/j.otsr.2017.03.015] [Medline: 28428035]
19. Hosny GA. Limb lengthening history, evolution, complications and current concepts. J Orthop Traumatol 2020 Mar 05;21(1):3 [FREE Full text] [doi: 10.1186/s10195-019-0541-3] [Medline: 32140790]
20. Arenas-Miquelez A, Arbeloa-Gutierrez L, Amaya M, Vázquez B, De Pablos Fernández J. Upper limb lengthening in achondroplasia using unilateral external fixation. J Pediatr Orthop 2021 Apr 01;41(4):e328-e336. [doi: 10.1097/BPO.0000000000001767] [Medline: 33560708]
21. De Agostinis M. Re-design of a uniplanar, monolateral external fixator. Proc Inst Mech Eng H 2018 May 09;232(5):446-457. [doi: 10.1177/0954411918762021] [Medline: 29521169]
22. Denisova R, Alekseeva E, Albitsky V, Vinyarskaya S, Bzarova T, Lositsin A. Reliability, validity and sensitivity of the Russian versions of the PedsQL Generic Core Scale and PedsQL Rheumatology Module questionnaires. Curr Pediatr 2009;8(1):40 [FREE Full text]
23. Garra G, Singer AJ, Taira BR, Chohan J, Cardoz H, Chisena E, et al. Validation of the Wong-Baker FACES Pain Rating Scale in pediatric emergency department patients. Acad Emerg Med 2010 Jan 04;17(1):50-54 [FREE Full text] [doi: 10.1111/j.1553-2712.2009.00620.x] [Medline: 20003121]
24. Khlopova A, Shcherbakova I. Conditions for the applicability of Student's t-test in medicine. Bull Med Internet Conf 2014;4(11):1276-1278 [FREE Full text]
25. Paley D. PRECICE intramedullary limb lengthening system. Expert Rev Med Devices 2015 May 18;12(3):231-249. [doi: 10.1586/17434440.2015.1005604] [Medline: 25692375]
26. Four segment lengthening. Achondroplasia. Paley Orthopedic & Spine Institute. URL: http://tinyurl.com/7v3kczpm [accessed 2022-09-13]
27. Paley Orthopedic & Spine Institute. URL: http://tinyurl.com/z7x49949 [accessed 2020-09-12]
28. Herzenberg JE, Standard SC, Conway JD. Lengthening Over Nails (LON): femur and tibia. In: Advanced Techniques in Limb Reconstruction Surgery. Berlin, Germany: Springer; 2015.

29. Rozbruch S, Fragomen A. Hybrid lengthening techniques: Lengthening and Then Nailing (LATN) and Lengthening and Then Plating (LAP). In: Advanced Techniques in Limb Reconstruction Surgery. Berlin, Germany: Springer; 2015:85-99.

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

Sarah EP Munce[1,2,3,4], PhD

[1]KITE Research Institute, Toronto Rehabilitation Institute-University Health Network, Toronto, ON, Canada
[2]Occupational Science & Occupational Therapy, University of Toronto, Toronto, ON, Canada
[3]Rehabilitation Sciences Institute, University of Toronto, Toronto, ON, Canada
[4]Institute of Health Policy, Management & Evaluation, University of Toronto, Toronto, ON, Canada

Corresponding Author:
Sarah EP Munce, PhD
KITE Research Institute
Toronto Rehabilitation Institute-University Health Network
345 Rumsey Road
Toronto, ON, M4G 1R7
Canada
Phone: 1 416 597 3422
Email: Sarah.Munce@uhn.ca

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

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*.

References

1. Rehabilitation. World Health Organization. 2023 Jan 30. URL: https://www.who.int/news-room/fact-sheets/detail/rehabilitation [accessed 2023-12-15]
2. Munce S, Andreoli A, Bayley M, Guo M, Inness EL, Kua A, et al. Clinicians' experiences of implementing a telerehabilitation toolkit during the COVID-19 pandemic: qualitative descriptive study. JMIR Rehabil Assist Technol 2023 Mar 10;10:e44591 [FREE Full text] [doi: 10.2196/44591] [Medline: 36897634]
3. Peretti A, Amenta F, Tayebati SK, Nittari G, Mahdi SS. Telerehabilitation: review of the state-of-the-art and areas of application. JMIR Rehabil Assist Technol 2017 Jul 21;4(2):e7. [doi: 10.2196/rehab.7511] [Medline: 28733271]
4. Anderson S. "A lifelong journal": two billion people need rehabilitation globally. Health Policy Watch. 2023 Jul 10. URL: https://healthpolicy-watch.news/a-lifelong-journey-2-billion-people-need-rehabilitation-globally/ [accessed 2023-12-22]
5. What are the article types for JMIR Publications journals? JMIR Publications Knowledge Base and Help Center. 2024 Feb 06. URL: https://support.jmir.org/hc/en-us/articles/115004950787-What-are-the-article-types-for-JMIR-Publications-journals [accessed 2024-02-19]
6. Munce SEP, Guetterman TC, Jaglal SB. Using the exploratory sequential design for complex intervention development: example of the development of a self-management program for spinal cord injury. J Mix Methods Res 2020 Apr 13;15(1):37-60. [doi: 10.1177/1558689820901936]

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A Participatory Model for Cocreating Accessible Rehabilitation Technology for Stroke Survivors: User-Centered Design Approach

Andrew Kerr[1,*], PhD; Madeleine Grealy[2,*], PhD; Milena Slachetka[1,*], BSc; Chioma Obinuchi Wodu[1,*], BSc; Gillian Sweeney[1,*], PhD; Fiona Boyd[1,*], MEng; David Colville, MA, MSc; Philip Rowe[1,*], PhD

[1]

[2]

[*]these authors contributed equally

Corresponding Author:
Andrew Kerr, PhD

Abstract

Background: Globally, 1 in 3 people live with health conditions that could be improved with rehabilitation. Ideally, this is provided by trained professionals delivering evidence-based dose, intensity, and content of rehabilitation for optimal recovery. The widely acknowledged inability of global health care providers to deliver recommended levels of rehabilitation creates an opportunity for technological innovation. Design processes that lack close consideration of users' needs and budgets, however, mean that many rehabilitation technologies are neither useful nor used. To address this problem, our multidisciplinary research group have established a cocreation center for rehabilitation technology that places the end user at the center of the innovation process.

Objective: This study aims to present the participatory cocreation model that has been developed from our center and illustrate the approach with 2 cases studies.

Methods: The model is built around user participation in an intensive rehabilitation program (2-hour sessions, 2 - 5 times per week, and 8-week duration), supervised by qualified therapists but delivered exclusively through commercial and prototype technology. This provides participants (chronic stroke survivors with movement and/or speech disability) with a rich experience of rehabilitation technology, enabling them to provide truly informed feedback, as well as creating an observatory for the research team. This process is supported by short-term focus groups for specific product development and a longer-term advisory group to consider broader issues of adoption and translation into everyday health care.

Results: Our model has been active for 3 years with 92 (92%) out of 100 participants completing the program. Five new technologies have evolved from the process with further ideas logged for future development. In addition, it has led to a set of cocreated protocols for technology-enriched rehabilitation, including recruitment, outcome measures, and intervention structure, which has allowed us to replicate this approach in an acute hospital ward.

Conclusions: Suboptimal rehabilitation limits recovery from health conditions. Technology offers the potential support to increase access to recommended levels of rehabilitation but needs to be designed to suit end users and not just their impairment. Our cocreation model, built around participation in an intensive, technology-based program, has produced new accessible technology and demonstrated the feasibility of our overall approach to providing the rehabilitation that people need, for as long as needed.

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KEYWORDS

rehabilitation; rehabilitative; rehab; rehabilitation technology; accessibility; accessible; stroke; design; participatory; participatory design; participatory designs; participatory model; participatory models; user-centred; user-centered; user-focused; digital health; digital technology; digital intervention; digital interventions; participatory medicine; technology

Introduction

Across the world, 1 in 3 people live with a health condition that could benefit from rehabilitation [1]. Delivering effective levels of rehabilitation to meet this global demand is beyond the reach of most, if not all, state-run health services, not least because of the inadequate workforce [2,3]. This means that most people will either receive suboptimal rehabilitation or no rehabilitation at all. Consequently, recovery from disabling conditions such as stroke is not simply a function of severity but will depend on an individual's capacity to access additional rehabilitation. Technology has reached the point of maturity where could it help address this large unmet need in an equitable manner. Rehabilitation technology, such as virtual reality and robotics,

has been shown to improve function across a range of conditions, for example, stroke [4] and Parkinson disease [5], as well as age-related disability [6]. Access to this technology, however, has been described as poor or nonexistent in the public sector of many countries, including the United Kingdom [7].

Besides the initial challenge of access, the subsequent abandonment of prescribed technology (rehabilitation and assistive) is common; for example, Sugawara et al [8] reported that more than 50% of upper-limb prostheses were not used after prescription. Many reasons are given for the nonuse of technology in rehabilitation. Sweeney et al [7] found reasons that stem from both therapists (eg, lack of training) and patients (eg, poor motivation). To overcome these barriers and increase the use of technology in rehabilitation, a number of recommendations have been proposed, including improved usability, clinical evidence of effectiveness, value for money, and conforming to self-management programs [9].

These recommendations require the involvement of end users throughout the design process, for the people in need of rehabilitation to be cocreators of the technology and be involved at different stages in the development process both as determiners and evaluators of these technologies.

Cocreation is a relatively new approach in health care. The idea originated in marketing and management [10], driven by the desire for bottom-up economics and greater personalization. The collaborative approach quickly spread into other domains including health care, where it has been used to develop services such as rehabilitation [11] and the design of assistive devices [12]. Irrespective of the field of study, cocreation is the practice of identifying and empowering relevant stakeholders (user groups) to collaborate in the process of finding solutions to a problem affecting the group. Its application in health care has been described using different terms such as co-design and coproduction [13]. The common idea behind cocreation is the involvement and partnership between the researcher or designer and the end users of the product, services, or intervention in generating concepts and evaluating products [14] .

While cocreation can address many of the user-based issues identified with rehabilitation technology (usability, access, and adherence) [11], a potential weakness is the imbalance between designers and users in their knowledge and experience. Such an imbalance may be reflected in the outcomes. Users' knowledge of rehabilitation technology is likely limited in the range of technology and limited to their day-to-day experience of using them as part of a rehabilitation program. A participatory approach [15] would allow users to gain the necessary knowledge to make meaningful contributions to the design process.

In 2021, our research group set up a cocreation center for rehabilitation technology [16], aiming to develop accessible rehabilitation using a cocreation approach that is informed by users who have completed, or are completing, an 8-week, technology-based rehabilitation program [16,17]. This paper describes the formal and informal cocreation processes that developed from our center and presents 2 cases studies to demonstrate how specific devices have benefited from our participatory cocreation approach.

Methods

Participants

Details of our research center (participants, intervention, staff, and outcome measures) are provided in previous publications [16,17]. In the interests of clarity, they are briefly described here. Participants living with disabilities caused by stroke (mobility, communication, and cognition) were invited to attend an 8-week rehabilitation program at the University of Strathclyde. Participants were recruited through invitations distributed by a medical charity: Chest Heart and Stroke Scotland. Interested individuals attended an initial meeting to assess eligibility (more than a year since a stroke diagnosis; well enough, and able, to attend at least twice a week; and had a physical and/or communication or cognitive disability resulting from stroke), and their baseline measures were recorded.

Ethical Considerations

The study was approved by the University of Strathclyde ethics board (UEC20/08) and all participants provided informed consent process. Participant data were anonymized, and there was no compensation for study participation.

Intervention

A goal-setting interview and baseline measures of mobility, communication, and cognition helped our research therapists (physiotherapist and occupational therapist) to design an intensive, personalized rehabilitation program. The programs were delivered exclusively through technology (eg, treadmills, power-assisted exercise machines, tablet apps, virtual reality, upper-limb robots, balance-training systems, and functional electrical stimulation) but supervised in small (n=5 - 10) circuit-based classes by at least 1 therapist. Each session was 2 hours long, for which participants can attend daily but must agree to attend at least 2 sessions a week for the 8-week period. We called the program Technology Enriched Rehabilitation Gym (TERG) to encapsulate training with technology designed to address the range of impairments resulting from stroke.

Outcome Measures

Standard, validated measures of mobility (eg, Berg Balance Scale and the Ten Meter Walk Test) and global impact (Stroke Impact Scale) were recorded immediately before and after the program. These have been well described in our other publications, including pilot data on outcomes [17].

Cocreation Activities

Our cocreation activities were aimed at either the development of specific devices or informing the strategy for implementing the TERG model into practice. For device development, short-term, purposively selected focus groups were formed from individuals (n=5-8) currently attending the TERG to provide focused user feedback on the device. The number of focus groups varied (typically 3 - 5) and could have extended into future groups, in which case individuals were invited to continue contributing.

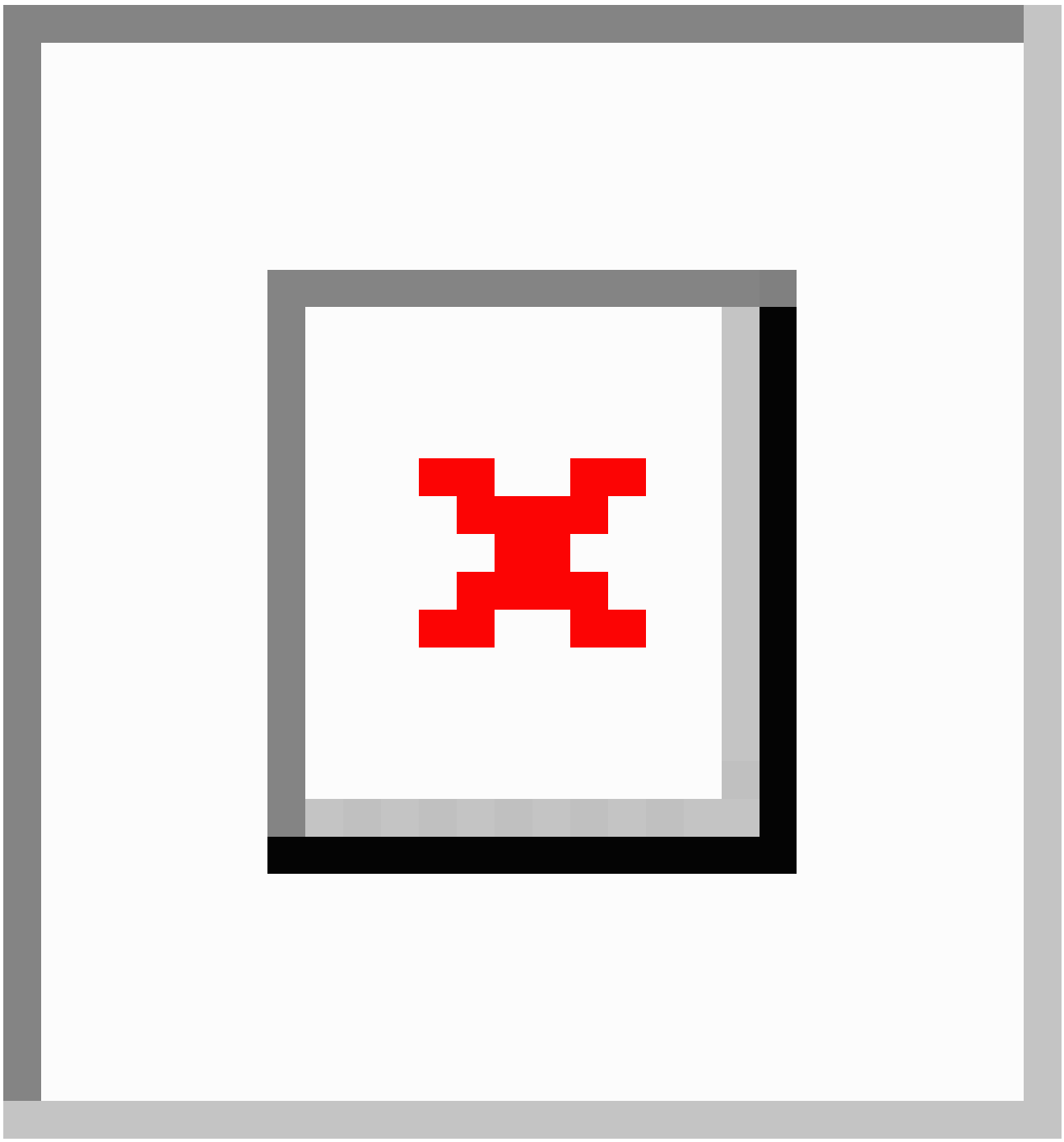
Translating and integrating our TERG model into everyday rehabilitation practice is the long-term aim of our center. To

achieve this, we have formed a User Advisory Group that meets formally 3 times a year and provides feedback on specific plans and ideas around implementation in community and hospital settings.

The activities described so far represent formal methods of cocreation. The opportunity to observe and work closely with these heterogeneous users as they carry out their technology-based rehabilitation provided our multidisciplinary research group (therapists, engineers, and scientists) with a rich dataset of daily informal observations on how users interact with technology and how this evolves over the course of 8 weeks as users learn and improve. These informal observations were documented in the laboratory book and reviewed by the team at the end of each group. This more informal mechanism has arguably provided a greater volume of feedback on devices and led to several new ideas that are currently being explored. A graphical overview of the whole cocreation model is presented in Figure 1.

To illustrate how the model functions practically, we present 2 case studies in the following section.

Figure 1. Overview of the participatory cocreation process showing the core 8-week program and related focus and user groups. TERG: Technology Enriched Rehabilitation Gym.



Results

Overview

Our participatory model of cocreation has been active for almost 3 years (from September 2021 until June 2024), with 92 (92%) out of 100 recruited participants fully completing the 8-week program. Feedback from these individuals has contributed to the design process of 5 rehabilitation technologies, with further concepts logged for future development. Case studies for 2 of these technologies are presented below. Critically, participant feedback, along with data on feasibility (safety and adherence) and impact on function, has also produced a set of cocreated protocols for technology-enriched rehabilitation, including recruitment, outcome measures, and intervention parameters. This has allowed us to replicate our approach in an acute hospital ward.

Case Study 1: Design of a Low-Cost Hand Device for People With Hemiplegia

The aim was to design a technology that could improve the hand flexibility and function of people with moderate-to-high levels of spasticity that was accessible in community settings (low cost, easy to use, and did not require professional supervision) including low-income countries, was comfortable, and supported self-management.

The design process followed the UK Design Council's Double Diamond model [18], which promotes divergent (creating a range of solutions) and convergent (narrowing solutions down through a set of criteria) thinking. The model supports a cocreation approach with users (in this case, rehabilitation professionals and stroke survivors) contributing to the discovery and delivery phases of this iterative design model through observations of technology interactions, focus groups, and interviews.

The design process started by observing stroke survivors participating in the TERG model and engaging them in discussions related to hand rehabilitation. This early discovery phase provided general design criteria (comfort and ease of use) and important features that were further refined by a focus group of rehabilitation engineers (n=8) to ensure feasibility in terms of manufacturing. Three potential designs were then presented to 2 user groups: (1) rehabilitation professionals (physiotherapists and occupational therapists; n=9) experienced in this area and (2) stroke survivors (n=6), to reduce this list to a single design that was the most appropriate to solving the problem.

A semistructured interview (choice of in person or virtual) was conducted by a researcher (COW) for each participant, during which 3D models of the 3 concepts were presented to generate opinions on key attributes (usability, comfort, and effectiveness). The interviews were recorded, transcribed, and anonymized. Thematic analysis was then used to identify common themes in the resulting data and used to reduce the list of devices to a single preferred device that would be built for further hands-on evaluation.

A prototype of the final choice has been tested for feasibility and acceptability by a new group of stroke survivor attending the center. The device is currently going through further refinement as part of a process to prepare it for commercialization.

Case Study 2: Design of a Rehabilitation Dosage and Intensity Monitoring System

This case study aimed to develop a system for monitoring rehabilitation dosage and intensity to allow stroke survivors and clinicians to gauge activity against the *National Clinical Guidelines for Stroke* [19]. The system tracks and logs the dosage and intensity of rehabilitation activities users partake in throughout their time at the cocreation center for rehabilitation technology, thereby supporting users in their recovery process. Central to its foundation was a co-design process, meticulously planned over a year through 4 focus groups. This methodological approach ensured the inclusion of direct feedback from participants, fostering a rapport that enriched the design process with iterative refinements and consistent insights.

Analysis from these sessions revealed a notable gap in the transition from prescribed to self-managed rehabilitation, often leading to reduced engagement. Yet, it also highlighted a persistent motivation among individuals to pursue adequate rehabilitation, particularly when supported by peers. This insight steered the development toward leveraging peer support to bolster self-rehabilitation motivation. Consequently, the project led to the collaborative design of a system that should not only facilitate home- and community-based stroke rehabilitation but also improve the engagement and motivation of a person to complete their rehabilitation exercises.

Using these insights, the project embarked on the development of a mobile app with accompanying hardware to support home- and community-based stroke rehabilitation. This development process also used gamification principles to make said rehabilitation activities more engaging, with a strong emphasis on social involvement and accessible peer support. Further on in the design and development process, the involvement of stakeholders from the stroke community, participants of the cocreation model, health care professionals, and researchers ensured that the device not only met the unique needs of its users but also aligned with evidence-based rehabilitation principles.

Discussion

Principal Findings

We have described our participatory approach to the cocreation of rehabilitation technology and presented 2 case studies to illustrate the process and highlight the potential benefits of this approach. Our model expands the concept of cocreation beyond surveys, questionnaires, and interviews or focus groups [20]. Contributions from end users are enriched by their participation in an 8-week, technology-based rehabilitation program. Feedback is consequently highly informed, detailed, and authentic with the opportunity to compare technologies. This in-depth feedback is critical for designing technology that is fit for the "real world" [9].

The participatory nature of our model has also created an ideal observatory for engineers (biomedical and design) to collect data on the interactions between stroke survivors and rehabilitation technology. This has led to a number of new device concepts being drafted and adjustments to commercial technology, for example, alterations to hand grips and equipment portability, which have been accepted by our industrial partners. A surprising outcome from these observations and informal discussions with participants has been the desire to integrate technology, for example, balance and speech therapy training, and track these activities on a common platform. This is now a focused area of our activity.

Case study 1 demonstrates that our cocreation method can complement standard design models such as the UK Design Council's Double Diamond model [21]. Similarly, case study 2 followed the Medical Research Council framework for the design of complex medical interventions and devices [22]. Our model ensures that the users' voice strongly influences each phase of these innovation frameworks and guidelines and fulfills explicit requirements to engage stakeholders (Medical Research Council framework) and involve users [21].

Limitations

In presenting this model, we recognize that there are some limitations. First, the volunteers attending our center may be more motivated and generally more positive toward rehabilitation than the average stroke survivor, since they have actively sought the opportunity for more rehabilitation. Their opinions may therefore be biased and not entirely generalizable. To address this potential bias, we have recently started a version of our center in a hospital setting where all eligible patients with stroke are offered the opportunity to experience technology-enriched rehabilitation.

The process may also raise issues around intellectual property, since a number of people contribute to technology development. This requires the involvement of an experienced research office and a legal framework that recognizes and protects different contributions.

Finally, we recognize that our model is not implementable in most engineering departments and industrial settings due to a lack of resource (equipment and therapy staff). This places greater importance on the need for collaboration across the rehabilitation engineering sector.

Conclusion

There is an urgent need to develop rehabilitation technology that is fit for purpose and capable of supporting the recommended levels of rehabilitation. Our multidisciplinary group has developed a model of cocreation where stroke survivors with related disabilities participate in a technology-enriched rehabilitation program that captures meaningful feedback and contributions from end users on specific device development, including new concepts, as well as developing a model that can be widely adopted in everyday practice. We have presented this novel model for developing rehabilitation technology for discussion and included 2 illustrative case studies.

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Conflicts of Interest

None declared.

References

1. Cieza A, Causey K, Kamenov K, Hanson SW, Chatterji S, Vos T. Global estimates of the need for rehabilitation based on the Global Burden of Disease Study 2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet 2021 Dec 19;396(10267):2006-2017. [doi: 10.1016/S0140-6736(20)32340-0] [Medline: 33275908]
2. Gupta N, Castillo-Laborde C, Landry MD. Health-related rehabilitation services: assessing the global supply of and need for human resources. BMC Health Serv Res 2011 Oct 17;11:276. [doi: 10.1186/1472-6963-11-276] [Medline: 22004560]
3. Gimigliano F, Negrini S. The World Health Organization "Rehabilitation 2030: a call for action.". Eur J Phys Rehabil Med 2017 Apr;53(2):155-168. [doi: 10.23736/S1973-9087.17.04746-3] [Medline: 28382807]
4. Wu J, Cheng H, Zhang J, Yang S, Cai S. Robot-assisted therapy for upper extremity motor impairment after stroke: a systematic review and meta-analysis. Phys Ther 2021 Apr 4;101(4):pzab010. [doi: 10.1093/ptj/pzab010] [Medline: 33454787]
5. Kwon SH, Park JK, Koh YH. A systematic review and meta-analysis on the effect of virtual reality-based rehabilitation for people with Parkinson's disease. J Neuroeng Rehabil 2023 Jul 20;20(1):94. [doi: 10.1186/s12984-023-01219-3] [Medline: 37475014]
6. Mitzner TL, Sanford JA, Rogers WA. Closing the capacity-ability gap: using technology to support aging with disability. Innov Aging 2018 Apr 27;2(1):igy008. [doi: 10.1093/geroni/igy008] [Medline: 30480132]
7. Sweeney G, Barber M, Kerr A. Exploration of barriers and enablers for evidence-based interventions for upper limb rehabilitation following a stroke: use of constraint induced movement therapy and robot assisted therapy in NHS Scotland. Br J Occup Ther 2020 Nov;83(11):690-700. [doi: 10.1177/0308022620909023]

8. Sugawara AT, Ramos VD, Alfieri FM, Battistella LR. Abandonment of assistive products: assessing abandonment levels and factors that impact on it. Disabil Rehabil Assist Technol 2018 Oct;13(7):716-723. [doi: 10.1080/17483107.2018.1425748] [Medline: 29334475]
9. Kerr A, Smith M, Reid L, Baillie L. Adoption of stroke rehabilitation technologies by the user community: qualitative study. JMIR Rehabil Assist Technol 2018 Aug 17;5(2):e15. [doi: 10.2196/rehab.9219] [Medline: 30120086]
10. Prahalad CK, Ramaswamy V. The Future of Competition: Co-Creating Unique Value With Customers: Harvard Business School Press; 2004.
11. Dobe J, Gustafsson L, Walder K. Co-creation and stroke rehabilitation: a scoping review. Disabil Rehabil 2023 Feb;45(3):562-574. [doi: 10.1080/09638288.2022.2032411] [Medline: 35113754]
12. Lamontagne ME, Pellichero A, Tostain V, et al. The REHAB-LAB model for individualized assistive device co-creation and production. Assist Technol 2024 Mar 3;36(2):154-163. [doi: 10.1080/10400435.2023.2229880] [Medline: 37463509]
13. Palmer VJ, Weavell W, Callander R, et al. The participatory zeitgeist: an explanatory theoretical model of change in an era of coproduction and codesign in healthcare improvement. Med Humanit 2019 Sep;45(3):247-257. [doi: 10.1136/medhum-2017-011398] [Medline: 29954854]
14. Ogrin R, Dickins M, Johnstone G, Mortimer D, Iezzi A, Lowthian J. Co-creation of services to maintain independence and optimise well-being: learnings from Australia's Older Women Living Alone (OWLA) project. Health Soc Care Community 2020 Mar;28(2):494-504. [doi: 10.1111/hsc.12882] [Medline: 31663214]
15. Leask CF, Sandlund M, Skelton DA, et al. Framework, principles and recommendations for utilising participatory methodologies in the co-creation and evaluation of public health interventions. Res Involv Engagem 2019 Jan;5:2. [doi: 10.1186/s40900-018-0136-9] [Medline: 30652027]
16. Kerr A, Grealy MA, Kuschmann A, Rutherford R, Rowe P. A co-creation centre for accessible rehabilitation technology. Front Rehabil Sci 2021 Jan 7;2:820929. [doi: 10.3389/fresc.2021.820929] [Medline: 36188853]
17. Kerr A, Keogh M, Slachetka M, Grealy M, Rowe P. An intensive exercise program using a technology-enriched rehabilitation gym for the recovery of function in people with chronic stroke: usability study. JMIR Rehabil Assist Technol 2023 Jul 21;10:e46619. [doi: 10.2196/46619] [Medline: 37477954]
18. Eleven lessons: managing design in eleven global brands. a study of the design process. Design Council. 2007 Jan 20. URL: https://www.designcouncil.org.uk/fileadmin/uploads/dc/Documents/ElevenLessons_Design_Council%2520%25282%2529.pdf [accessed 2024-08-19]
19. National Clinical Guideline for Stroke for the United Kingdom and Ireland: Sentinel Stroke National Audit Programme (SSNAP); 2023. URL: https://www.strokeguideline.org/app/uploads/2023/04/National-Clinical-Guideline-for-Stroke-2023.pdf?_gl=1*1iti3p2*_up*MQ..*_ga*MjAzOTcxMzI1My4xNzI0MDk3NjUx*_ga_EE3BZMVLRT*MTcyNDA5NzY1MC4xLjEuMTcyNDA5NzY1OC4wLjAuMA [accessed 2024-08-19]
20. Karahasanović A, Brandtzæg PB, Heim J, et al. Co-creation and user-generated content–elderly people's user requirements. Comput Hum Behav 2009 May;25(3):655-678. [doi: 10.1016/j.chb.2008.08.012]
21. The Double Diamond. Design Council. 2023. URL: https://www.designcouncil.org.uk/our-resources/the-double-diamond [accessed 2024-02-07]
22. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ 2021 Sep 30;374:2061. [doi: 10.1136/bmj.n2061] [Medline: 34593508]

Abbreviations

TERG: Technology Enriched Rehabilitation Gym

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