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Original Paper

The Effect of Mobile Care Delivery on Clinically Meaningful Outcomes, Satisfaction, and Engagement Among Physical Therapy Patients: Observational Retrospective Study

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Abstract

Background: Musculoskeletal care is now delivered via mobile apps as a health care benefit. Although preliminary evidence shows that the clinical outcomes of mobile musculoskeletal care are comparable with those of in-person care, no research has examined the features of app-based care that secure these outcomes.

Objective: Drawing on the literature around in-person physical therapy, this study examines how patient-provider relationships and program engagement in app-based physical therapy affect clinically meaningful improvements in pain, function, and patient satisfaction. It then evaluates the effects of patient-provider relationships forged through in-app messages or video visits and timely, direct access to care on patients' engagement in their recovery.

Methods: We conducted an observational, retrospective study of 814 pre- and postsurveyed participants enrolled in a mobile app physical therapy program where physical therapists prescribed workouts, education, and therapeutic activities after a video evaluation from February 2019 to December 2020. We estimated generalized linear models with logit functions to evaluate the effect of program engagement on clinical outcomes, minimal clinically important differences (MCIDs) in pain (ΔVisual Analogue Scale ≤−1.5) and function (ΔPatient Specific Functional Scale ≥1.3), and the effects of patient-provider relationships and clinical outcomes on patient satisfaction—participant reported likelihood to recommend the program (Net Promoter Scores of 9-10). We estimated Poisson generalized linear models to evaluate the effects of stronger patient-provider relationships and timely access to physical therapy within 24 hours on engagement including the number of weekly workouts and weeks in the program.

Results: The odds that participants (N=814) had a pain MCID increased by 13% (odds ratio [OR] 1.13, 95% CI 1.04-1.23; *P*=.003) with each weekly workout and the odds of a function MCID by 4% (OR 1.04, 95% CI 1.00-1.08; *P*=.03) with each week in the program. Participants with MCIDs in function and large changes in pain (Δ Visual Analogue Scale ≤−3.5) were 1.85 (95% CI 1.17-2.93; *P*=.01) and 2.84 times (95% CI 1.68-4.78; *P*<.001) more satisfied, respectively. Those with video follow-up visits were 2 to 3 times (*P*=.01) more satisfied. Each physical therapist's message increased weekly workouts by 11% (OR 1.11, 95% CI 1.07-1.16; *P*<.001). Video follow-up visits increased weekly workouts by at least 16% (OR 1.16, 95% CI 1.04-1.29; *P*=.01) and weeks in the program at least 8% (OR 1.08, 95% CI 1.01-1.14; *P*=.02). Access was associated with a 14% increase (OR 1.14, 95% CI 1.05-1.24; *P*=.003) in weekly workouts.

Conclusions: Similar to in-person care, program engagement positively affects clinical outcomes, and strong patient-provider relationships positively affect satisfaction. In app-based physical therapy, clinical outcomes positively affect patient satisfaction. Timely access to care and strong patient-provider relationships, particularly those forged through video visits, affect engagement.

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KEYWORDS

physical therapy; mobile apps; engagement; health care delivery

Introduction

Background

Physical therapists, providers with highly specialized knowledge in managing musculoskeletal conditions [1-3], now deliver care directly through mobile apps. In a digital environment, physical therapists evaluate and diagnose patients on demand to ensure they receive appropriate care. Rather than prescribing opioids [4-7] or administering unnecessary imaging [8-19], physical therapists can prescribe exercise and education, which are key components of evidence-based care in physical therapy, as a first line of defense [11-13].

Increasing evidence supports that physical therapy via a mobile app delivers pain and functional outcomes comparable with those of in-person care [14-16]. However, this literature does not explore what drives clinically meaningful outcomes in pain, function, and patient satisfaction—the foundational measures of evidence-based physical therapy— in a digital setting [17].

In brick-and-mortar physical therapy clinics, “adherence” to a course of provider-prescribed care drives clinical outcomes [18]. Consistent at-home exercise, which is among the most supported physical therapy interventions, as well as completion of prescribed or insurance-allowed visits are assessed by physical therapists to measure adherence [17,19,20].

Physical therapy delivered through a mobile app may not be structured similarly to in-person physical therapy with a specific number of weekly visits. In the program examined in this paper, care delivery focused on immediate access to care, ad hoc follow-up video visits, and direct, asynchronous communication between patients and their designated therapists. After an initial synchronous video evaluation, physical therapists designed recovery programs to accord with patients’ goals and altered these programs in response to synchronous and asynchronous feedback from patients. Physical therapists guided their patients through phases of their recovery in real time based on their activity levels, feedback to exercises, and changes in pain and function levels throughout an episode of care.

Owing to the real-time nature of physical therapy in this setting, we take a broader view of adherence and measure it as program engagement defined by 2 measures: the number of patient-recorded in-app–prescribed therapeutic weekly workouts and the number of weeks participants are active in the program. We first tested the hypothesis that clinical outcomes (clinically meaningful pain reduction and functional improvement) were positively associated with program engagement.

In concert with driving clinical outcomes by leveraging the best available evidence, evidence-based care is patient-centered, which is measured by patient satisfaction [21]. Some evidence indicates that patient satisfaction with in-person physical therapy is based on office experiences such as wait times and friendly exchanges between patients, physical therapists, and office staff [22-24], whereas digital care removes such experiences. However, care delivered through an app can nurture relationships between physical therapists and patients through in-app chat and face-to-face video visits. We tested the hypothesis that the strength of patient-provider relationships [25,26] measured by the frequency of digital communication with providers (number of days providers send weekly in-app chat messages and number of synchronous follow-up video visits) is positively associated with patient satisfaction.

There is inconsistent evidence in the literature about how patients’ clinical outcomes affect patient satisfaction with physical therapy [27]. By removing some of the subjective aspects of care (eg, appointment wait times, office cleanliness, friendliness of staff), clinical outcomes may take on new significance for patient satisfaction in a digital setting. Therefore, we also tested the hypothesis that patient satisfaction is associated with the clinical outcomes of the program itself.

There are explicit trade-offs between care delivered through a mobile app versus in-person office visits. On the one hand, regular face-to-face visits may better strengthen patient–provider relationships than app-based video visits and chats. On the other hand, patients who arrive at in-person physical therapy only after referral, ineffective self-management, or alternative therapies (eg, acupuncture and massage), may be less motivated to engage in their treatment than those who can directly access care the same day via an app. Although we cannot interrogate these trade-offs in this paper, our secondary purpose is to understand if the strength of digital patient-provider relationships and immediate access to care via a mobile physical therapy program affects how readily participants engage in their own recovery.

In traditional clinical settings, provider communication with patients affects their adherence to treatment [28], which, in turn, affects whether patients experience meaningful clinical outcomes. Interpersonal connections with providers often motivate patients to adhere to prescribed care [24,29]. Patients’ relationships with their providers are strengthened the more they interact [25,26]. The content of communication also matters; positive feedback from providers is associated with exercise adherence [20]. The providers in this study were trained to positively reinforce exercise adherence via in-app chat and video visits. We hypothesize that the frequency of patient-provider digital communication is associated with physical therapy program engagement as measured by longer episodes of care and more weekly workouts.

There is also evidence that early, direct access to physical therapy can affect clinical outcomes by treating conditions before they become more chronic and difficult to treat [30-32]. This effect may be behavioral in the sense that patients who are motivated and able to expediently address an issue are more likely to engage and do the hard work to get better, that is, to exercise [33]. By reducing barriers to access physical therapy, patients, regardless of their chronicity, who are motivated to initiate physical therapy can promptly do so, and this motivation may express itself in better engagement than those who wait longer for initial video evaluations [34]. We tested the hypothesis that access to initial evaluations with physical therapists within 24 hours is associated with greater program engagement.

Objective

Our goal in this study is to examine the aspects of patient-provider relationships and program engagement that are associated with clinically important differences in pain and function along with patient satisfaction in physical therapy delivered via a mobile app. The secondary purpose of this study is to understand how 2 aspects of mobile app–based care delivery—relationships built on in-app interactions and immediate access to care—affect patient behaviors that are clinically meaningful: consistently working out and sticking with the program.

Methods

Study Design

We conducted an observational, longitudinal, retrospective study using data collected from commercial users of a physical therapy program delivered via a mobile app offered as a health benefit with no cost or copay to privately insured employees by their employers [35]. The study used health care operations data, not originally collected for research purposes, which were deidentified for analysis. Participants registered and checked for program eligibility through a landing page created specifically for their employer and accessible through employers' benefits portals. Once eligibility was verified, participants were given a passphrase to download the app, read and accept in-app informed consent, and complete a mandatory in-app baseline survey. Each survey response was associated with an individual participant's account. The Western Institutional Review Board granted an exemption from human subject research for the study's protocol.

We used established patient-reported outcome measures, including the Patient Specific Functional Scale (PSFS), Visual Analogue Scale (VAS), and Global Rate of Change (GROC), which were delivered asynchronously [36]. Our internal user experience team developed the layout and functionality of the surveys. Both the baseline and final surveys surfaced questions in the same order for all participants. Before launching the program on February 15, 2019, we deployed the surveys to other populations of patients treated in the program. The survey results from this trial period demonstrated that they consistently agreed with the patients' subjective reports.

The baseline survey had an average of 4 questions across 5 screens. All the questions in the baseline survey were required to be answered. The final survey had an average of 4.5 questions across 4 screens, with responses to all but one open-ended question required. Participants could go back during their surveys and edit responses on previous pages, but they could not review their responses as a summary or alter their surveys after submission.

Intervention

To enroll in the program, participants created an account in a mobile app and entered demographic information (age and gender), their chief complaint, and provided pain and function ratings in an in-app baseline survey. The participants were matched with a therapist licensed in their state to schedule an initial video evaluation visit. The program's therapists were trained in evidence-based approaches to evaluate, diagnose, and treat patients on demand via a mobile app.

During the evaluation, physical therapists conducted an in-depth interview and performed a physical exam over secure in-app video to establish a functional baseline and arrive at a diagnosis. On the basis of the participant's diagnosis and treatment goals, physical therapists then prescribed a course of care accessible through the app. Therapists also assigned educational content specific to patients' conditions, therapeutic activities (eg, icing or going for a walk), and asynchronous digital physical assessments. Physical therapists modified their patients' care plans in response to direct feedback from patients via in-app chat, regular pain and function surveys, or follow-up video visits.

All activities in the program were collected and quantified, including completion of prescribed in-app exercises and therapeutic activities, in-app chats with physical therapists, and subsequent video visits. At the end of the program, participants were asked to complete a final survey, which included final measures of pain and function.

Participants

We included participants in the study who enrolled after the launch of the program on February 15, 2019, and completed the program by December 31, 2020, if they were (1) aged ≥18 years; and (2) presented with a musculoskeletal condition such as low back pain, neck pain, arthritis, sprains, strains, or similar overuse injuries that would benefit from physical therapy or presented for postoperative rehabilitation; and (3) completed a participant survey of clinical outcomes at the end of their episode of care or reported reliable pain and function metrics toward the end of care in weekly surveys. We excluded participants if they (1) did not meet the inclusion criteria and (2) endorsed symptoms or multiple conditions during the initial video evaluation that physical therapists determined would preclude the use of app-based physical therapy as a first line of treatment and required referral for an in-person physical exam (eg, fractures, cervical central cord lesion, subarachnoid hemorrhage or ischemic stroke, unexplained weight gain or loss, fatigue and malaise, among other conditions).

Participants in our sample were not automatically excluded if they endorsed symptoms found on the Optimal Screening for Prediction of Referral and Outcome-Review of Systems (OSPRO-ROS) tool [37]. Rather, physical therapists assessed the appropriateness of app-based physical therapy given patients' explanations of their symptoms and the ongoing management of those conditions by a physician.

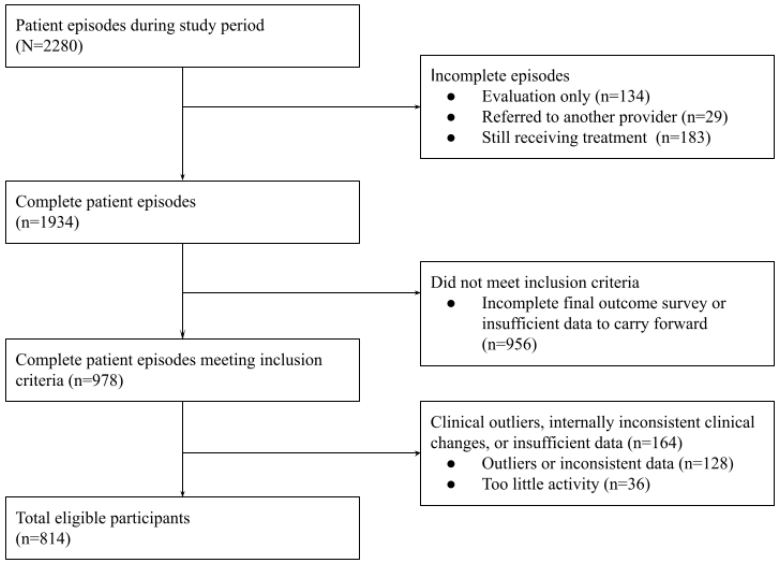
During the study period, 945 participants completed the program and a final outcome survey. Participants typically completed the voluntary final survey within 2 weeks of finishing the program and were neither incentivized nor reminded to do so. We carried forward 33 pain and function observations that participants reported in weekly in-app pain and function surveys if participants reported them less than 3 weeks before completing the program and more than 2 weeks after starting the program. Weekly pain and function surveys were not implemented until September 23, 2020, and participants responded more readily

to these earlier in their recovery, resulting in few responses to carry forward. We also imputed 32 values for missing satisfaction scores using the modal responses of similar participants with similar earlier in-episode satisfaction scores. The average time between baseline and outcome responses collected during either the final survey or last weekly pain and function surveys was approximately 44 days.

To eliminate outliers, we calculated the standardized individual difference by dividing participant-level pre–post outcome differences by the SD of those differences and eliminating observations above and below 1% of the distribution for both clinical outcomes [38]. If participants reported differences in pain or functional scores outside of these thresholds, they were excluded. This procedure eliminated 128 outliers. Most of these outliers (all but 29) had inconsistent data where participants reported improvement on the GROC final survey question (GROC>0) but reported that either their pain or function worsened and were moving in opposing directions.

A total of 36 participants had too little activity to make reliable conclusions about the program's outcomes (no workouts and <2 weeks in the program) and were excluded from the analysis. This left a total of 814 eligible participants included in the study (Figure 1). We estimated models with and without outlier removal, with 2.5% outlier elimination, as well as with and without carrying forward the final pain and function observations and obtained similar results.

Figure 1. Study participation flow diagram.



Measurements

Clinical Outcomes

In the baseline and end-of-program surveys, participants rated their maximum pain levels over the last 24 hours using the VAS [39] on a scale from 0 ("no pain") to 10 ("worst pain imaginable"). Participants rated their level of functional impairment on a scale from 0 ("completely unable to perform") to 10 ("able to perform normally") for up to 3 different self-identified activities impacted by their condition using the PSFS [36,39,40]. We used the functional measure for the activity participants mentioned first because this is likely the daily activity that they struggle with most. We also modeled the average score across the PSFS activities, which yielded similar results, but resulted in a greater number of outliers. In the app, participants saw these scales as a slider that ranged continuously from 0 to 10.

We created 2 binary variables for minimal clinically important differences (MCID) in pain (VAS) and function (PSFS): a value of 1 was assigned to participants' episodes with changes in their pain ≤−1.5 points and ≥1.3 points in their functional ability [36]. Otherwise, a value of 0 was assigned.

We also created binary variables equal to 1 for large changes in pain (ΔVAS≤−3.5) and function (ΔPSFS≥2.7) and 0 otherwise based on thresholds identified in the literature [36]. We did this because, at the outset of the study, we did not know if different thresholds of change in clinical outcomes might affect satisfaction because clinical outcomes are not observed to affect satisfaction in the literature evaluating in-person physical therapy. We found that thresholds for moderate changes in pain (−3<ΔVAS≤−3) or function (2.7<ΔPSFS≥2.3) contained relatively few observations (61 observations for those with moderate pain changes and 36 for those with moderate function changes) and did not affect satisfaction; therefore, we decided to test the effects of MCIDs on pain and function and large changes in these clinical outcomes, retaining the smallest change necessary to affect satisfaction [36].

Satisfaction

Satisfaction with the program was measured by a final survey question that was used to calculate the Net Promoter Score (NPS) by asking participants to answer: "How likely is it that you will recommend the program to a friend or colleague?" on a scale from 0 "Not at all Likely" to 10 "Extremely Likely." NPS defines categories of respondents as "Detractors" (0-6), "Passives" (7-8), and "Promoters" (9-10) [41,42]. Owing to the lack of variation in this variable, we chose to investigate the correlates of being a promoter. We created a binary variable equal to 1 if participants scored the NPS question with a score of 9 or 10 and 0 otherwise.

Program Engagement

Two variables measured program engagement: (1) the number of in-app workouts per week and (2) the duration of the program in weeks. The duration of the program was calculated as the difference between the time participants started the program after their initial evaluation to the end of the program, which was defined as the time when patients were either discharged directly by their provider or were inactive for 2 weeks, whichever came first.

Patient-Provider Relationships

During the program, physical therapists communicated asynchronously with participants through in-app chat to assess their progress and provide guidance. Physical therapists and participants also scheduled synchronous follow-up video visits. Patient-provider communications are used to measure the strength of these relationships and are captured by (1) the number of unique days a provider sends a message to participants through in-app chat per week and (2) a categorical variable for the number of video follow-up visits after participants' initial video evaluations. The categories for follow-up visits included (1) no visits, (2) 1 to 2 visits, (3) 3 to 4 visits, and (4) 5 or more visits. The category for "no visits" was omitted from our models to serve as a comparator.

Access

Prompt access to care was measured in days to the initial video evaluation after enrolling in the program. A binary variable was created with 1 assigned to those who accessed care within 24 hours, and 0 assigned to those who accessed care after 24 hours.

Controls

Chronicity, baseline pain and function levels, comorbid conditions, and adverse symptoms can affect participants' recovery [14]. We controlled for comorbid conditions including hypertension, diabetes, cardiovascular disease, a family or personal history of cancer, or other conditions, including behavioral health conditions. We also controlled for adverse symptoms found on the OSPRO-ROS [37], such as night sweats, headaches, lightheadedness, or abnormal sensations.

We controlled for baseline pain and function. Baseline pain was categorized as little to no pain (VAS≤1), mild pain (3.4≤VAS>1), moderate pain (7.4≤VAS>3.4), and severe pain (VAS>7.4) based on cut points identified in the literature [43]. Severe baseline pain (other categories were omitted) as well as continuous baseline pain and function scores served as controls in our models because, in our clinical practice, we observed that patients with poorer scores on baseline pain and function face larger physical and behavioral health obstacles to recovery than patients with better scores, who also have less room to improve [44,45]. We present controls in the results when they are statistically significant (P<.05).

Statistical Analysis Plan

To test our hypotheses, we estimated generalized linear models (GLMs). GLMs for MCIDs in pain, function, and satisfaction were estimated using the binomial family of exponential dispersion models and a logit link function, which is equivalent to a logistic regression model fit by maximum likelihood estimation. GLMs for the number of workouts per week and number of weeks in the program were estimated using the Poisson family of exponential dispersion models and a log link function. We interpreted our results by evaluating changes in the odds of an outcome, which were calculated by exponentiating the coefficients from the model, and by subtracting 1 from the odds to better interpret odds that were less than one (negative coefficients).

Results

Overview

Table 1 presents the demographic and clinical profiles of the participants in the sample at baseline. Nearly half (387/814, 47.5%) of the participants were female and aged approximately 41 years, on average. Furthermore, 26.2% (214/814) were aged ≥50 years when musculoskeletal symptoms present with greater frequency, limiting productivity while working [46]. The participants were treated for various musculoskeletal conditions. No single anatomical region captured most of the participants' diagnosed conditions.

Table 2 presents descriptive statistics for outcomes and predictors in the analysis. Mean VAS was 1.7 (SD 1.9) at program completion compared with 4.4 (SD 2.2) at baseline (Table 1). Approximately 66.8% (544/814) experienced an MCID in pain (VAS Δ≤–1.5) with 35.5% (289/814) experiencing a large pain change (VAS Δ≤–3.5) [36]. Mean PSFS was 7.8 (SD 2.4) post treatment, compared with 5.2 (SD 3) at baseline (Table 1), with nearly 63.7% (519/814) reporting an MCID in function (PSFS Δ≥1.3) and 51.7% (421/814) a large change (PSFS Δ≥2.7) [36]. Participants were highly satisfied with an average 9.3 on the NPS question. The average participant logged 2.8 workouts per week over an average duration of 9.1 weeks in the program.

On average, providers frequently communicated with the participants. About one-third (257/814, 31.6%) of the participants completed 3 or more additional video visits beyond the initial evaluation. In between visits, physical therapists checked in with participants about 1.8 days per week via in-app chat. Provider chat messages consisted of single messages or in-depth live chat conversations with participants. Approximately 52.8% (430/814) of the participants completed their initial video consultation within 24 hours of registering for the program. Multimedia Appendix 1 provides a heatmap of significant Pearson correlations between the variables included in the analysis.

Table 1. Baseline participant characteristics (N=814).

Characteristics	Values
Demographics	
Female, n (%)	387 (47.5)
Age (years)	
Value, mean (SD)	40.85 (11.9)
≥50, n (%)	214 (26.3)
Anatomical region, n (%)	
Low back pain	172 (21.1)
Shoulder	132 (16.2)
Knee	118 (14.5)
Neck	104 (12.8)
Upper body, elbow, wrist, hand, or arm	84 (10.2)
Lower body, ankle, foot or leg	83 (10.3)
Hip	70 (8.6)
Back or spine	46 (5.7)
Other	5 (0.6)
Clinical baseline, mean (SD)	
Pain baseline (VAS[a])	4.4 (2.2)
Function baseline (PSFS[b])	5.2 (3.0)
Baseline pain level categories, n (%)	
Little to no pain (VAS≤1)	61 (7.5)
Mild pain (3.4≤VAS>1)	218 (26.8)
Moderate (7.4≤VAS>3.4)	475 (58.4)
Severe pain (VAS>7.4)	60 (7.4)
Chronicity, n (%)	
Chronic (>3 months)	497 (61.1)
Subacute (1-3 months)	128 (15.7)
Acute (<1 month)	189 (23.2)
Comorbid conditions and adverse symptoms, n (%)	
Reported comorbid conditions	383 (47.1)
Reported adverse symptoms	281 (34.5)

[a]VAS: Visual Analogue Scale.

[b]PSFS: Patient Specific Functional Scale.

Table 2. Descriptive statistics for outcomes and predictors (N=814).

Variables	Values
Clinical outcomes	
Pain outcome (VAS[a]), mean (SD)	1.7 (1.9)
Pain changes, n (%)	
Pain MCID[b] (ΔVAS≤−1.5)	544 (66.8)
Large pain MCID (ΔVAS≤−3.5)	289 (35.5)
Function Outcome (PSFS[c]), mean (SD)	7.8 (2.365)
Function changes, n (%)	
Function MCID (ΔPSFS≥1.3)	519 (63.8)
Large function MCID (ΔPSFS≥2.7)	421 (51.7)
Satisfaction	
Likelihood to recommend, mean (SD)	9.3 (1.5)
Promoters, n (%)	674 (82.8)
Program engagement, mean (SD)	
Number of workouts per week	2.8 (2.2)
Weeks in program	9.1 (5.4)
Patient-provider communication	
Days messaged by physical therapist per week, mean (SD)	1.8 (1.1)
Follow-up visits, n (%)	
None	232 (28.5)
1-2	325 (39.9)
3-4	180 (22.1)
≥5	77 (9.5)
Access, n (%)	
24 hours to first visit	430 (52.8)

[a]VAS: Visual Analogue Scale.

[b]MCID: minimal clinically important difference.

[c]PSFS: Patient Specific Functional Scale.

Clinical Outcomes

Figure 2 demonstrates that as weekly workouts increased, pain decreased. In Table 3, we see that after controlling for significant baseline characteristics, the odds of having an MCID in pain increased by 1.13 (P=.003) times for each additional weekly workout a participant completed. There were no significant direct effects of access or the strength of patient-provider relationships as proxied by patient-provider communication on MCIDs in pain or function.

Participants' baseline chronicity and pain affected the odds of having an MCID in pain. We observed a 46% (P<.001) reduction in the odds of having an MCID in pain among participants with chronic conditions compared to those with conditions that troubled them for less than 3 months. Those with severe pain saw a 70% (P=.01) reduction in the odds of having an MCID in pain compared to those with less severe pain levels. However, the odds of having an MCID in pain increased by 80% (P<.001) for each additional unit in reported baseline pain; those with higher pain, all else being equal, had more room to improve their pain.

Figure 3 illustrates the positive relationship between functional improvements and weeks in the program. Table 3 further shows that program engagement also increased the odds of having an MCID in function, but only as measured by weeks in the program and not the number of workouts per week. We observed a 4% (P=.03) increase in the odds of having an MCID in function with each additional week a participant spent in the program.

Participants' age, chronicity, and baseline pain severity and function affected the odds that the participants saw an MCID in function. The odds of completing the program with an MCID in function were 53% (P<.001) lower for participants aged ≥50 years than those of younger participants. Similar to the results for pain, the odds of having an MCID in function were 50% (P<.001) lower for participants with chronic conditions compared to their counterparts with acute and subacute

conditions. The odds of having an MCID in function were also 71% (*P*<.001) lower for participants with severe pain compared to those with moderate, mild, or little to no pain. With each additional unit of reported baseline function, the odds of having an MCID in function decreased by 42% (*P*<.001); better functioning patients had less room for improvement.

Figure 2. Distribution of pain change by number of workouts. VAS: Visual Analogue Scale.

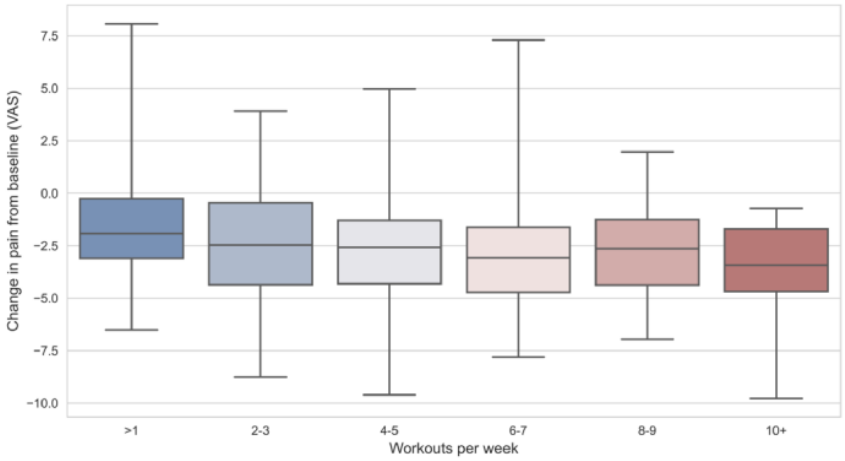


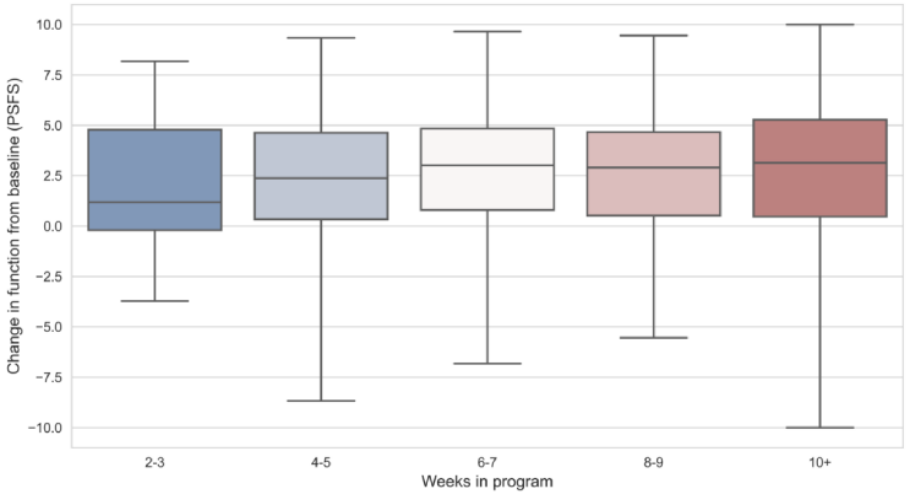
Table 3. Odds ratios (ORs) for generalized linear models of program engagement and baseline controls on clinical outcomes (814 observations)[a].

Variables	OR (95% CI)	*P* value
Pain MCID[b]		
Intercept	0.13 (0.07-0.24)	<.001
Program engagement		
Number of workouts per week	1.13 (1.04-1.23)	.003
Controls		
Age ≥50 years	0.56 (0.38-0.83)	.003
Chronic condition	0.54 (0.38-0.77)	<.001
Severe pain	0.30 (0.12-0.74)	.01
Baseline pain	1.80 (1.63-2.00)	<.001
Function MCID		
Intercept	89.24 (43.52-182.98)	<.001
Program engagement		
Number of weeks in program	1.04 (1.00-1.08)	.03
Controls		
Age ≥50 years	0.47 (0.31-0.72)	<.001
Chronic condition	0.50 (0.35-0.74)	<.001
Severe pain	0.29 (0.14-0.57)	<.001
Baseline function	0.58 (0.54-0.63)	<.001

[a]Comorbid conditions, adverse symptoms, and access were not significant, and there was no direct relationship between provider communication and outcomes.

[b]MCID: minimal clinically important difference.

Figure 3. Distribution of functional change by weeks in program. PSFS: Patient Specific Functional Scale.



Satisfaction

Table 4 presents the results of our GLM for satisfaction, which was measured using a binary variable for whether a participant was a "promoter" of the program. Satisfaction was positively related to video follow-up visits by providers (increasing odds of being a promoter 2 to 3 times). The odds of being a promoter were 85% (P<.001) higher if participants had an MCID in function. However, improvements in pain only significantly affected the odds of being a promoter if participants experienced large pain changes. Participants with large changes in pain had nearly 3 times the odds (odds ratio 2.84, 95% CI 1.68-4.78; P<.001) of being a promoter of the program compared to those with smaller or no pain changes.

Table 4. Odds ratios (ORs) for generalized linear models of strength of patient–provider relationships, clinical outcomes, and baseline controls on satisfaction (814 observations)[a].

Variables	OR (95% CI)	*P* value
Promoter (likelihood to recommend ≥9)		
Intercept	1.47 (0.56-3.84)	.43
Patient–provider communication		
1-2 follow-up visits	2.06 (1.33-3.20)	<.001
3-4 follow-up visits	2.17 (1.27-3.70)	.01
≥5 follow-up visits	3.32 (1.42-7.79)	.01
Pain and function changes		
Function MCID[b]	1.85 (1.17-2.93)	.01
Large pain MCID	2.84 (1.68-4.78)	<.001
Controls		
Female	2.23 (1.48-3.34)	<.001
Baseline function	1.09 (1.01-1.17)	.03
Baseline pain	0.85 (0.22-0.95)	.004

[a]A total of 32 imputed values (782 original).

[b]MCID: minimal clinically important difference.

Program Engagement

Patient-Provider Relationships

Table 5 presents results for program engagement measured by number of workouts per week and weeks in the program. Each additional weekly message a physical therapist sent to participants increased the number of workouts per week by 11% (P<.001). Follow-up visits also directly affected the number of weekly workouts that participants completed. In Figure 4, we demonstrate the relationship between the frequency of video follow-up visits and number of weekly workouts.

The results in Table 5 show that, compared with participants who did not have follow-up visits, those with 1 to 2 follow-up video visits had 16% (P=.01) more workouts per week and those with 3 to 4 follow-up visits had 32% (P<.001) more workouts per week. This effect tapered off and was no longer significant for participants with 5 or more follow-up visits. These results indicate that there may be a sweet spot for on-screen facetime

between patients and providers to build a strong, motivating relationship.

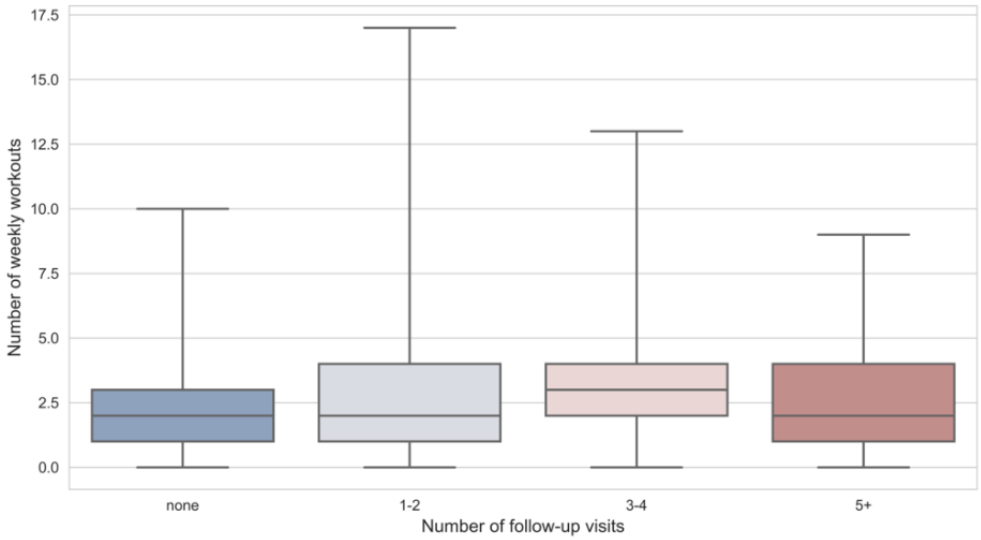
Table 5. Odds ratios (ORs) for generalized linear models of strength of patient–provider relationships, access, and baseline controls on program engagement (814 observations).

Variables	OR (95% CI)	*P* value
Number of workouts per week		
Intercept	2.04 (1.68-2.47)	<.001
Patient-provider communication		
1-2 follow-up visits	1.16 (1.04-1.29)	.01
3-4 follow-up visits	1.32 (1.17-1.49)	<.001
≥5 follow-up visits	1.06 (0.90 to 1.25)	.49
Days messaged by physical therapist per week	1.11 (1.07-1.16)	<.001
Access		
24 h to first visit	1.14 (1.05-1.24)	.003
Controls		
Age ≥50 years	1.25 (1.14-1.37)	<.001
Adverse symptoms	0.87 (0.79-0.95)	.002
Severe pain (VAS[a]>7.4)	0.76 (0.63-0.92)	.01
Baseline pain (VAS)	1.02 (1.00-1.05)	.049
Baseline function (PSFS[b])	0.96 (0.95-0.98)	<.001
Number of weeks in program		
Intercept	9.57 (8.80-10.40)	<.001
Patient-provider communication		
1-2 follow-up visits	1.08 (1.01-1.14)	.02
3-4 follow-up visits	1.28 (1.19-1.36)	<.001
≥5 follow-up visits	1.91 (1.77-2.05)	<.001
Days messaged by physical therapist per week	0.85 (0.83-0.87)	<.001
Controls		
Age ≥50 years	1.11 (1.05-1.16)	<.001
Chronic Condition (>3 months)	1.13 (1.08-1.18)	<.001
Adverse symptoms	1.11 (1.06-1.17)	<.001
Baseline function (PSFS)	0.99 (0.98-0.99)	<.001

[a]VAS: Visual Analogue Scale.

[b]PSFS: Patient Specific Functional Scale.

Figure 4. Distribution of number of workouts per week by number of follow-up visits.



Access

Table 5 also shows that participants had greater odds of completing more workouts per week if they accessed physical therapy quickly through an initial video evaluation within 24 hours. Participants who saw their physical therapist within 24 hours finished 14% (P=.003) more weekly workouts than those who waited longer for visits.

We included significant controls for age, adverse symptoms, pain severity, and baseline pain and function scores. Interestingly, participants aged ≥50 years had about 25% (P<.001) more weekly workouts than their younger counterparts. These participants may have had more time to work out (eg, fewer small children at home) or they may have been more motivated to work out to ease persistent conditions.

Participants who concurrently experienced adverse symptoms found on the OSPRO-ROS did approximately 13% (P=.002) fewer weekly workouts compared with those who did not present with these symptoms. Those with severe pain also had fewer weekly workouts, despite an inverse relationship between worse baseline pain and function scores and program engagement via working out.

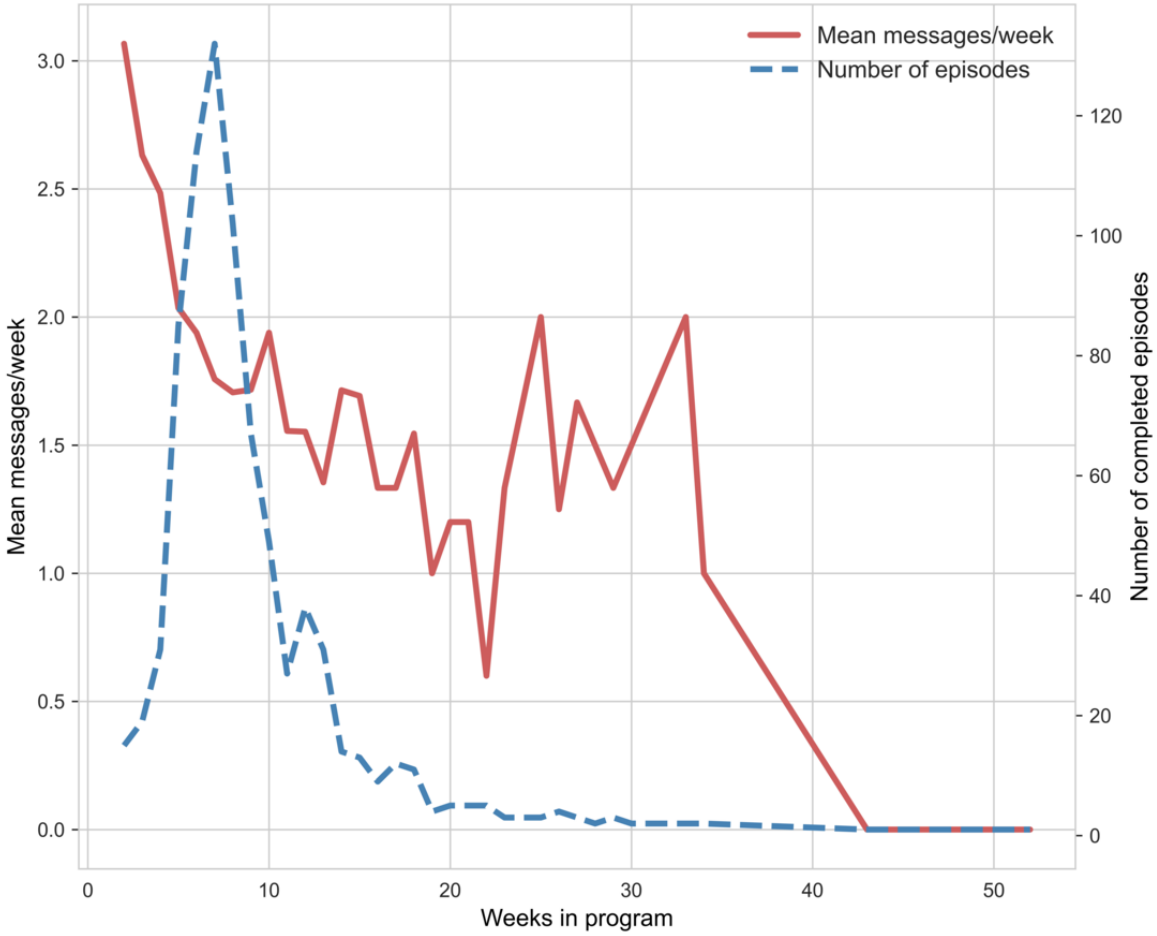
Table 5 additionally shows the effect of patient–provider relationships on the number of weeks participants remained in the program. Although program duration is not the ideal measurement of engagement, it further validates our findings on how patient–provider communication may strengthen relationships and its association with program engagement and meaningful functional outcomes.

Table 5 shows a negative association between the number of weekly physical therapists' messages and weeks in the program. Each additional weekly message sent by a physical therapist to the participants was associated with a 15% decrease in the number of weeks in the program (P<.001). As depicted in Figure 5, this may be because of unsuccessful attempts to reach out to participants who achieved their program goals, but had not communicated with their physical therapists who, therefore, delayed formal discharge.

Additional video follow-up visits were positively associated with program duration. Compared with participants who did not have follow-up visits, Table 5 shows that those with 1 to 2 follow-up video visits had 8% (P=.02) more weeks in their episodes, those with 3 to 4 follow-up visits had 28% (P<.001) more weeks, and those with ≥5 follow-up visits spent 91% (P<.001) more weeks in the program. Program access within 24 hours was not significantly correlated with the program duration.

Participants who were aged ≥50 years (P<.001) with chronic conditions (P<.001) and adverse symptoms (P<.001) all had greater odds of having longer episodes than their younger counterparts without chronic conditions or adverse symptoms. Those with higher functionality at baseline had shorter episodes (P<.001). Multimedia Appendix 2 illustrates all models with the main effects only.

Figure 5. Mean physical therapist messages per week by distribution of program durations in weeks.



Discussion

Principal Findings

This study builds on prior studies that show that mobile app–based physical therapy delivers similar outcomes to in-person care [16,47,48]. Similar to in-person physical therapy, clinical outcomes for physical therapy delivered via a mobile app were positively associated with program engagement [17-20]. Meaningful changes in pain were positively correlated with participants performing the most clinically relevant activity: consistently exercising.

However, the mechanism driving clinically meaningful changes in function requires a different form of engagement: time in the program. Exercise-induced analgesia is well documented in the literature, although the mechanism remains unclear [49,50]. We speculate that patients may associate exercise with pain reduction because they perceive a change in tissue status after stretching and movement. They may report they feel "looser" or "more flexible" immediately after exercise and associate that as a positive result. Changes in function may occur gradually, with incremental improvements not perceived until they hit a specific functional threshold, resulting in a change in task performance, such as more easily picking up their child or walking down the stairs. As changes in function are likely grounded in changes in strength, range of motion, motor planning, or motor control, several weeks of consistent exercise may be required to achieve meaningful functional improvement. Future research should explore the causal mechanisms underlying functional improvement versus pain reduction.

Unlike traditional physical therapy, we observed that clinical outcomes were more closely associated with satisfaction. A minimal amount of functional change had a large effect on participants' willingness to recommend the program under study. However, it took large changes in pain to influence participants to recommend the program to their friends and family.

Perceptions of functional changes may differ from perceptions of pain change. In our clinical practice, most patients during intake come to us "because they don't want to hurt anymore" and expect pain to be eliminated. Patients may have more relative, vague expectations around functional recovery unless they cannot perform activities required for their livelihood. Patients often struggle to pinpoint goals for functional improvement. Pain alone may not be enough for patients to stop doing something altogether or they may not have a requisite daily task that they can no longer perform (eg, they must be able to lift 50 pounds for their job; they cannot pick up their child). This means that the elimination of pain (a hard outcome to achieve) must be met to be satisfied, but a lower level of functional improvement may yield satisfaction. Future research should unpack perceptions around changes in pain and function throughout recovery.

Physical therapy delivered via a mobile app resembles in-person physical therapy in that it depends on strong relationships between patients and providers to be successful. Frequent, albeit not weekly, video follow-up visits were positively associated with satisfaction, the completion of more weekly workouts, and persistence in the program, which were the key ingredients for recovery. Asynchronous messaging may also help strengthen patient–provider relationships because weekly workouts increased with each day per week that providers messaged participants. However, provider messaging may have a negative effect if used to chase unresponsive participants later in the program. Provider messages also did not have a significant effect on satisfaction, whereas video visits did.

Frequent, face-to-face interactions between providers and participants may keep participants motivated and remain active in the program until they see significant improvements. Future research should further explore how digital communication can build stronger therapeutic alliances between physical therapists and patients in a digital setting [22,29].

Unlike traditional in-person physical therapy, mobile physical therapy has the potential to reduce time to care [51,52], with significant effects on program engagement (number of weekly workouts). Patients who seek care can access it immediately, which may have a motivating effect to help them initiate behavioral changes that alleviate pain and restore functionality [34,53]. Direct access removes a barrier to traditional physical therapy, which is often delayed while patients traverse a costly referral process or receive inappropriate care from other providers who do not practice evidence-based care [54]. The experience of being passed from one provider to another is time consuming, frustrating, and may negatively impact patients' motivation toward recovery. Given the evidence that mobile apps can provide prompt access to care that yields results comparable with in-person care, apps may also deliver better and more cost-effective results than the typical care pathway that begins with a physician [1-3,47,54]. Care delivered via mobile apps also removes barriers to recovery that can make initiating traditional physical therapy inconvenient, including appointment scheduling and travel [55].

We cannot eliminate the possibility that participants who access care sooner are more intrinsically motivated or have fewer barriers to exercising than those who delay their appointments. The delivery of care in a digital environment is a promising area for future research to understand how providers can optimize care to ensure better clinical outcomes and patient satisfaction.

Limitations

We did not find any direct relationship between clinical outcomes and access to care or patient-provider communication that indicates strong ties. Rather, access and relationships between physical therapists and patients that were strengthened by digital communication were associated with patient behaviors that were then followed by significant recovery outcomes. Future work should aim to understand the causal relationships between the design of mobile app physical therapy programs in terms of access, indicators of different qualities of patient-provider relationships, and the recovery behavior of participants.

This study is inherently limited as an observational study of an employer-based population. The voluntary nature of, and lack of compensation for, completing the final survey meant that our sample size was reduced, potentially biasing our results. The results may not be generalizable to a broader population of employees, retirees, or children. Our study also lacked a control group. Future research should compare meaningful clinical outcomes, satisfaction, and program engagement of mobile app–based physical therapy to in-person physical therapy in a controlled clinical trial. Randomized control trials or other suitable experimental methods should be used to unpack causality around patient-provider communication and relational indicators, access to care, and program engagement.

Conclusions

Physical therapy delivered via a mobile app may be more likely to result in clinically important changes in pain and function if it engages patients by directly connecting them with physical therapists and by facilitating strong relationships with their providers. Synchronous communication, in particular video visits, may help physical therapists foster strong relationships that personalize app-based care and build in accountability and encouragement so that patients engage in recovery and, concomitantly, enjoy clinically important improvements in pain and function. In app-based physical therapy, clinical outcomes may be more closely associated with patient satisfaction, independent of patients' relationships with their providers, than what is observed in studies evaluating in-person physical therapy.

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Conflicts of Interest

LB and TN are both employed shareholders of Omada Health Inc.

Multimedia Appendix 1
Heatmap of significant Pearson correlations (P<.05).
[PNG File , 218 KB - rehab_v9i1e31349_app1.png]

Multimedia Appendix 2
Models with main effects only.
[PDF File (Adobe PDF File), 62 KB - rehab_v9i1e31349_app2.pdf]

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Abbreviations

GLM: generalized linear model
GROC: Global Rate of Change
MCID: minimal clinically important difference
NPS: Net Promoter Score
OSPRO-ROS: Optimal Screening for Prediction of Referral and Outcome-Review of Systems
PSFS: Patient Specific Functional Scale
VAS: Visual Analogue Scale

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Original Paper

Smart Assistive Technology for Cooking for People With Cognitive Impairments Following a Traumatic Brain Injury: User Experience Study

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Abstract

Background: User experience (UX), including usability, should be formally assessed multiple times throughout the development process to optimize the acceptability and integration of a new technology before implementing it within the home environment of people living with cognitive impairments.

Objective: The aim of this study is to identify UX issues, notably usability issues, and factors to consider for the future implementation of the COOK (Cognitive Orthosis for Cooking) within the home of individuals with traumatic brain injury (TBI) to identify modifications to improve the technology.

Methods: This study comprised two rounds of UX evaluations, including extensive usability testing, which were completed in a laboratory context: 3 sessions with 5 experts and, after improvement of COOK, 2 sessions with 10 participants with TBI. Each session included the use of scenarios and questionnaires on UX and usability.

Results: Both rounds demonstrated good usability outcomes and hedonic qualities. Various usability issues were identified by participants, such as navigation inconsistencies, technical bugs, and the need for more feedback. Factors to consider in the future implementation of COOK were also mentioned by participants with TBI, including environmental (eg, space available and presence of pets) and personal factors (eg, level of comfort with technology, presence of visual deficits, and preferences).

Conclusions: By evaluating UX, including usability, various times throughout the development process and including experts and end users, our research team was able to develop a technology that was perceived as usable, pleasant, and well-designed. This research is an example of how and when people with cognitive impairments (ie, people with TBI) can be involved in evaluating the UX of new technology.

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KEYWORDS

usability testing and evaluation; user experience; qualitative methods; assistive technologies; rehabilitation; patient safety

Introduction

Background

Individuals who sustain a traumatic brain injury (TBI) will have to live for numerous years with physical impairments, emotional problems, and cognitive deficits (eg, memory, attention, and executive functions) [1]. These deficits, especially cognitive impairments, may limit their independence and safety in completing everyday activities within their home and community, including instrumental activities of daily living such as meal preparation [2-4]. Indeed, meal preparation involves the coordination of complex tasks using high-level cognitive abilities such as planning, working memory, multitasking, and problem solving, which can be affected in people with TBI [5]. As technology evolves, the use of assistive technology for cognition (ATC) is becoming increasingly attractive to support the functioning of people with TBI [6-9]. For example, De Joode et al [10] demonstrated that a PDA could be as effective as a traditional paper-and-pencil method in achieving personalized goals. Wang et al [11] also compared 2 prompting methods (paper vs via an ATC) during a meal preparation task and showed that prompts provided via an ATC were generally more efficient and appreciated by participants. Therefore, ATCs are a promising avenue for developing and implementing home support interventions for people with cognitive impairments following a TBI. However, to our knowledge, other than the Cueing Kitchen [12,13], which is installed in a laboratory setting, no ATC has been specifically developed to support this population both in terms of safety and independence in meal preparation. The current use of technology to support meal preparation includes the use of reminders and step-by-step instructions [8,14].

In recent years, our interdisciplinary research team (including experts in computer sciences, engineering, occupational therapy, physiotherapy, speech-language pathology, neuropsychology, and evaluative and implementation research) closely collaborated with people who sustained a severe TBI (principal end users), their families, and the team of care (specialized educators, occupational therapists, social workers, and managers) to design an ATC named the COOK (Cognitive Orthosis for Cooking) [15]. Using a user-centered design [16], this cooking assistant was initially developed for 3 persons living with a severe TBI in an alternative housing unit with 24-hour supervision to promote their autonomy and resume meaningful activity (ie, meal preparation) [15,17]. Our research team ultimately aimed to expand its potential to a broader population with TBI (eg, those living in their own apartments in the community). The aim of this paper is to present an overview of the usability evaluation completed throughout the process of developing this technology.

The Cognitive Assistant—COOK

COOK is a web application that was developed to work on any device with a tactile screen (eg, electronic tablet or computer). For this project, a Dell XPS 18 portable all-in-one desktop computer was used. COOK consists of two systems that work in complementarity: (1) a cognitive support module that guides the user through the interface on the screen (see Figure 1 for an example) and (2) the self-monitoring security system (SSS), which is connected to a smart stove. The cognitive support module encompasses cognitive interventions and functionalities configured by occupational therapists based on their evaluation of the person and the type of intervention approach he or she needs during meal preparation (eg, rehabilitation or compensatory). This can include such things as reminders to reduce distractors and optimize the cooking environment, adapted recipes, food storage charts, timers, and notes. The SSS works with connected sensors installed in the kitchen environment and the smart stove to follow kitchen-related activity and detect at-risk situations (eg, forgetting to turn off a burner). When such situations are detected, the user is warned via the interface and, if he or she does not correct the situation, the stove is automatically shut down. To ensure safety, the use of COOK is required to activate and use the stove. COOK can also be set up according to the user's needs and preferences. Finally, an interface is available for caregivers to monitor the stove and SSS state (eg, activated or shut down following an at-risk situation). For this study, COOK was installed in a laboratory setting organized as an apartment, including a living room, a bathroom, a main door, and a fully functional kitchen equipped with a smart stove (Figures 2 and 3).

Figure 1. Screenshot of COOK (Cognitive Orthosis for Cooking). (1) Time and date, reminder for another task (eg, washing machine) and timers for the burner and the oven; (2) return to the home page; (3) toolbox (including stress management, notes, and personalized objectives), culinary information (eg, food storage charts, idea of spices, and recommended internal cooking temperatures), and safety rules; (4) exit; (5) steps of the meal preparation task, including goal formulation, planning, conducting the task and self-assessment, and breaks.

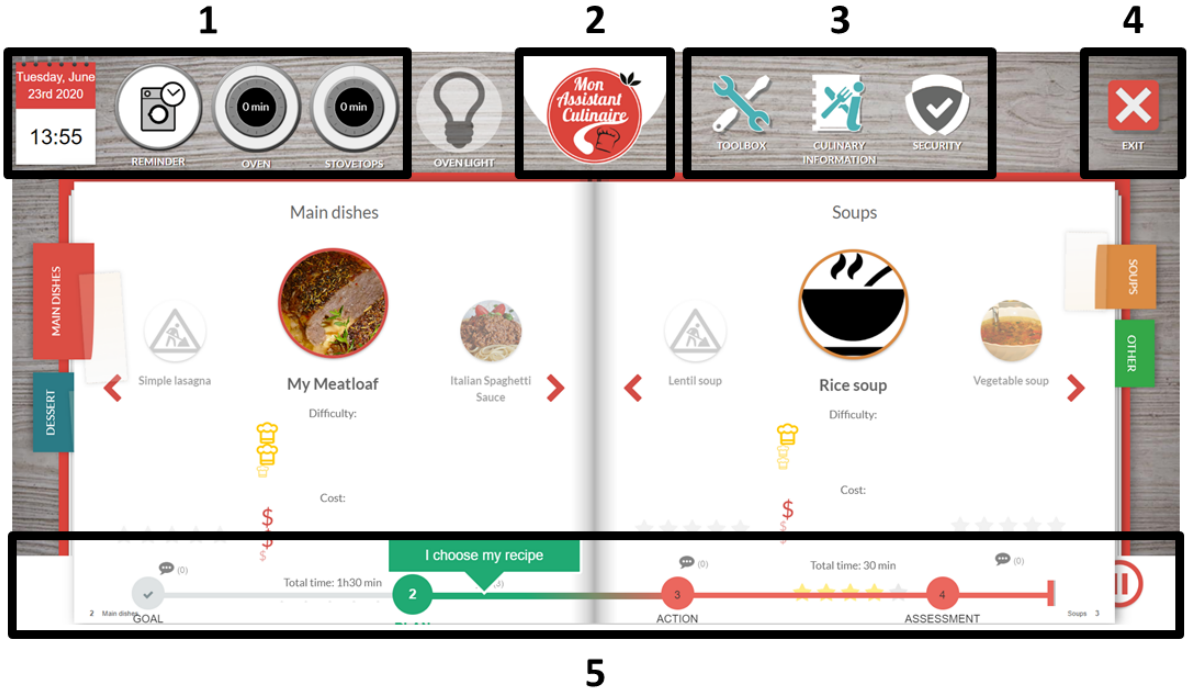


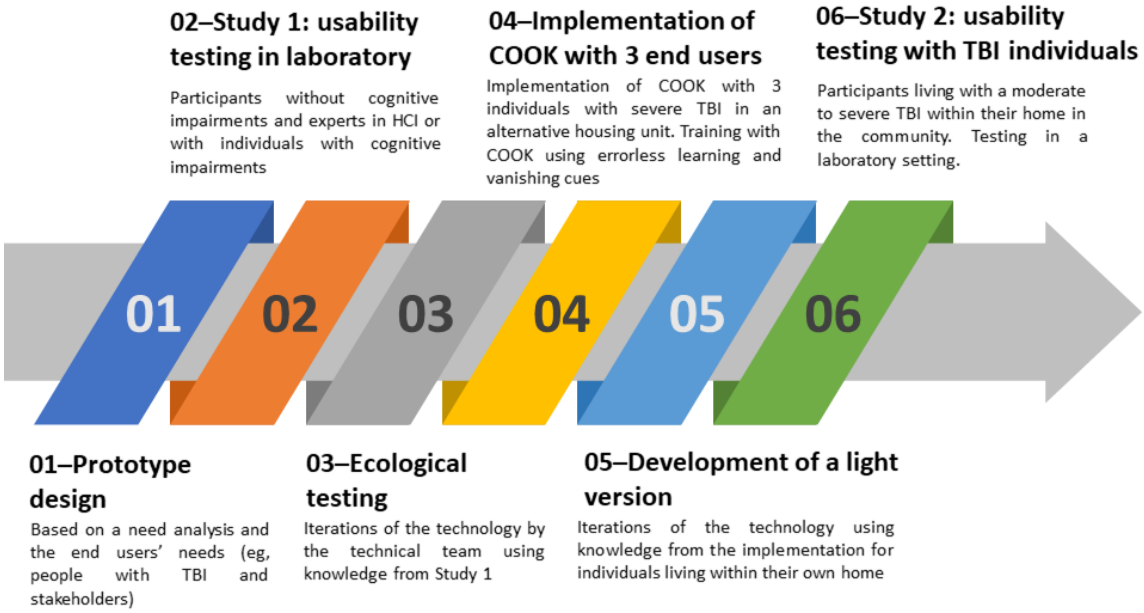
Figure 2. Installation of COOK (Cognitive Orthosis for Cooking) in the laboratory setting.

Figure 3. Installation of COOK (Cognitive Orthosis for Cooking) in the laboratory setting.

User Experience Evaluation

Previous studies have demonstrated that poor user experience (UX), including poor usability (eg, lack of knowledge and training or improper design according to the user's needs), was associated with nonadoption of ATCs [18]. Therefore, it was essential to formally evaluate UX at various time points in the development of COOK to develop a more *usable* product [19,20]. UX results from interactions among the user (eg, needs and expectations), the system (eg, functionalities and usability), and the context, and thus considers *hedonic* qualities (eg, pleasure and emotions) [21,22]. Usability, which is an important element contributing to a good UX, refers to the degree to which users are able to attain their goals with efficacy, efficiency, and satisfaction in a specific context using an ATC [23]. As presented in Figure 4, our research team completed 6 broad steps, of which 2 are further explained in this paper (steps 2 and 6). Step 4, which comprises the implementation of COOK with 3 individuals living with a severe TBI in an alternative housing unit and UX evaluation within this real-world environment, is described elsewhere [15].

Figure 4. Steps of development and usability tests of the cognitive assistant (COOK). COOK: Cognitive Orthosis for Cooking; HCI: human–computer interaction; TBI: traumatic brain injury.



More specifically, this project aims to (1) document UX issues, particularly usability issues, that could interfere with the use of COOK by individuals living with TBI; (2) identify modifications to improve the technology; and (3) explore factors to consider in the future implementation of COOK within the homes of individuals with TBI.

Methods

Study 1: Experts' Perspective on UX

Overview

The first study (step 2 in Figure 4) focused on testing the functionalities of the cooking assistant early in its development process to improve its UX. Considering the end users' cognitive impairments (eg, limited cognitive load, learning potential, and memory deficits), they are more likely to replicate their mistakes and not be able to correct themselves over time if in contact with a preliminary version of the technology. Therefore, it was preferred to not involve the 3 participants with TBI who participated in step 4 at this step of the development process to reduce risks of integrating faulty ways of using COOK and becoming frustrated as a result. Instead, only individuals with expertise in human-computer interaction (HCI) or with clinical experience with future end users (ie, people living with TBI) were involved in this preliminary step of development as they could provide extensive feedback and potential solutions to the identified UX issues and help our research team reduce bugs and limit future major necessary modifications that could interfere with the further steps in the development process. In the same vein, no caregivers or health providers were included at this step of the project, although they could participate in step 4. This study was approved by the research ethics committee of the Centre Intégré Universitaire en Santé et Services Sociaux of Estrie–Centre hospitalier universitaire de Sherbrooke (CRIR-897-113), and all participants provided their informed consent. A total of three usability tests were conducted in study 1: tests for version 2.1, version 2.2, and a preliminary version of the SSS.

Participants

Using convenience sampling, 8 French-speaking individuals with expertise in HCI or clinical experience with clients with cognitive impairments were recruited to participate in at least 1 of the 3 UX tests. Participants were recruited from collaborators involved in other projects conducted at the research laboratory. A clinician specialized in visual impairments was also recruited to obtain her perspective on the visual accessibility of COOK. Among the group of 8 participants, a sample of 5 (63%) participants for each test was considered enough to uncover most UX issues, notably usability issues [24]. Before each UX evaluation, the participants had to complete a 7-point Likert scale, where 1 corresponded to *never* and 7 to *all the time*, to measure the extent to which they used electronic tablets on a monthly basis and the number of meals prepared during a week (ie, cooking habits).

Task and Procedure

Overview

The UX evaluation was completed with 3 tests (1 each) for versions 2.1 and 2.2 and the SSS. Each test included three steps: (1) a general presentation of COOK (including the context of the project and its future use), (2) scenarios simulating the use of the technology during an activity (eg, meal preparation or meal planning, depending on the version tested), and (3) administration of 2 questionnaires measuring usability with the System Usability Scale (SUS) [25-27] and UX from a more global perspective with the AttrakDiff scale [28,29]. All the UX tests were completed between January 2016 and December 2016 and were audiotaped. Each test was completed with the participant, an evaluator, and an observer who took notes.

After the presentation of the cooking assistant, participants were invited to follow scenarios simulating different tasks that could be achieved using COOK. During each simulation, participants were asked to think aloud and describe their thoughts and judgments, explain their understanding of the task and the technology, and comment on the ease of use and potential UX issues and usability issues in particular. As recommended to design technologies, open-ended questions, such as "You seemed surprised, what led you to feel like this?" and "How did you know that you had to...?" were also asked to help participants further express their thoughts and actions [30]. All comments from participants were systematically transcribed using observer notes and records, and then deductively regrouped by functionalities and usability issues (eg, size of labels and understanding of messages provided by the technology) to identify the number of times each comment emerged. At this point of development, it was preferred to provide the development team with an exhaustive and detailed list of comments mentioned by the participants to facilitate modifications of the technology. Following UX evaluation, grouped comments were translated into requests, prioritized, and transmitted to the development team to improve the cooking assistant.

Scenarios varied depending on the version assessed in UX evaluation.

Version 2.1

Participants were invited to simulate 2 activities of meal preparation (ie, with and without a recipe) and explore functionalities that were developed to help end users follow through the task (eg, timers, culinary information, breaks, and self-assessment).

Version 2.2

Participants were invited to simulate a meal preparation activity (ie, with a recipe) to explore new functionalities that had been added in version 2.2 (eg, voice command and vocal synthesis). Participants were also asked to plan meals using COOK.

SSS Module

Participants were invited to try the SSS safety rules using 8 scenarios. For 75% (6/8) of the scenarios, participants had to simulate the use of the stove during a meal preparation task while their actions were being supervised by the security system.

Each of these scenarios was designed such that a security rule would be triggered. Participants were then asked to react to the various warnings and information transmitted by sound (voice synthesis) and text (pop-up) modalities. In the last 2 scenarios, participants played the role of a caregiver who received notifications about the status of the SSS via a screen in another room. A member of the research team played the role of the person using the stove and needing assistance to restart it after it had been turned off by the SSS.

Measures

The following two questionnaires were used: the SUS and the AttrakDiff scale.

The SUS is a highly robust and versatile tool developed by Brooke [25] to evaluate perceived and subjective usability [26]. This questionnaire consists of 10 statements that are scored on a 5-point Likert scale of agreement, with 1 corresponding to *totally disagree* and 5 to *totally agree*. The total score varies between 0 and 100, with higher scores corresponding to stronger usability. The total score can then be qualified using the adjective rating scale (eg, awful, okay, and excellent) to provide a better understanding of the usability value [26,31]. A French translation of the scale was developed by our team and used as no validated version in French was available at the time of the study.

The AttrakDiff is a standardized questionnaire that includes 4 scales with 7 items, totaling to 28 items that evaluate the pragmatic and hedonic qualities of a system [32]. The scales evaluated in the AttrakDiff are the pragmatic quality, hedonic-stimulation quality, hedonic-identity quality, and global attraction. For each scale, an average score varying between –3 and 3 was calculated, where a higher score was associated with positive UX. For this study, the AttrakDiff was an interesting choice to measure UX as it allows comparisons between different versions of a specific product, thus highlighting the potential impact of modifications of COOK on the end users' experience. The French version of the AttrakDiff was used in this study [28].

Study 2: People With TBI's Perspective on UX

Overview

In accordance with our goal of expanding the potential use of COOK to a broader population with TBI (including those living within their home in the community), the second round of UX evaluation was completed 3 years after the first study in a laboratory context with participants living with moderate to severe TBI. Despite their cognitive impairments, this step was possible as COOK was previously demonstrated as helpful for 3 individuals with TBI (step 4) by allowing them to prepare 3 meals per week independently and safely [15], and the prototype had since been improved (steps 3 and 5). Moreover, contrary to UX evaluations completed within a real-world context (which involves implementation and training with COOK), UX evaluations in a laboratory could be completed with a larger sample, thus allowing more variability in terms of needs. This study was approved by the ethical review board of the Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (CRIR-1173-0616). All participants provided their informed consent.

Participants

A total of 10 adults living with moderate to severe TBI and interested in meal preparation were recruited to participate in this study. Recruitment was completed in collaboration with rehabilitation centers in and around Montreal and a regional TBI association. Before the first session, each participant was asked questions about his or her TBI (ie, TBI severity and time post injury). They also had to complete the same Likert scale as the one used in the first study to measure their habits (ie, use of an electronic tablet and number of meals prepared during a week) and describe their difficulties.

Task and Procedure

Overview

UX evaluation was completed in a laboratory setting over two sessions: the first session focused on the SSS, and the second focused on the cognitive support module (including functionalities from versions 2.1 and 2.2). Similar to the first study, each session included three steps: (1) a general presentation of COOK by the evaluator, (2) various guided scenarios simulating the use of the technology during an activity of meal preparation or meal planning, and (3) administration of a French version of the SUS and the AttrakDiff scale. This method was inspired by the *cognitive walkthrough with users* approach, which involves documenting UX and usability outcomes through task performance in specific scenarios using *think-aloud* strategies to document the thoughts and opinions of end users [33]. A complementary semistructured interview of approximately 10 minutes was also conducted at the end of each session to explore their opinions on COOK and facilitators and barriers they perceived regarding the potential use of the technology within their home environment (see Textbox 1 for the questions). The UX evaluation was completed between January 2019 and July 2019 with an evaluator and a research assistant who videotaped the sessions.

Textbox 1. Interview guide for study 2 with participants living with moderate to severe traumatic brain injury.

First session

- How did you find your experience with the COOK (Cognitive Orthosis for Cooking)?
  - Elements that you liked
  - Elements that you disliked
  - Ease of use
  - Ease of learning
- How do you think COOK could be improved?

Second session

- How do you think COOK could help you with meal preparation?
  - How often would you use COOK?
  - Confidence in your abilities to use COOK?
- How do you think COOK could interfere with your meal preparation?
- In your opinion, what would be the elements that could make it more difficult to use COOK in your home?
- In your opinion, what would be the elements that could facilitate the use of COOK in your home?

Following an exploration of the cooking assistant, participants were invited to trial various scenarios simulating the use of COOK during a meal preparation task and think aloud about the process (eg, ease of use, potential usability issues, and how they could use the technology within their own living context). Owing to cognitive impairments associated with moderate to severe TBI, all participants were guided by an evaluator (ie, occupational therapist) to ensure progression and help them stay motivated and engaged in the testing when confronted with difficulties with the technology. However, as participants were not expected to learn to use COOK following the UX evaluation, flexibility was provided to allow participants to make mistakes and to allow them to try to correct them by themselves. The scenarios used in this study were similar to those described in the *Task and Procedure* section of Study 1.

First Session (SSS)

A total of 7 scenarios were completed to test the safety rules when using the stove, including going out of the apartment.

Second Session (Cognitive Support Module)

A total of 3 scenarios were completed to simulate 2 activities of meal preparation (ie, with and without a recipe) and meal planning and explore all the functionalities included in the cooking assistant to help the person complete these tasks.

All sessions were videotaped and transcribed to document observable behaviors (gestures, facial expressions, and automatic reactions) and participant comments. Then, qualitative data (ie, comments and interviews) were analyzed in 2 steps. First, as in study 1, comments specific to COOK's functionalities were regrouped and translated into requests for the ATC development team to improve COOK. Then, an inductive thematic analysis as described by Miles et al [34] was completed and validated by 2 authors (MGR and RBL) to highlight potential factors that could influence the implementation of COOK within the home of individuals with TBI.

Results

Study 1: Experts' Perspective on UX

Overview

Of the 8 participants, 2 (25%) women and 6 (75%) men with expertise in HCI or clinical experience with clients with cognitive impairments, including an expert with 10 years of experience with clients with visual impairments, participated in the UX evaluation. Participants' characteristics and the UX tests in which they were involved are presented in Table 1. Each UX test lasted between 64 and 113 minutes, with an average of 80.9 minutes per session.

Table 1. Participant characteristics and involvement in user experience (UX) tests.

Characteristics	Age (years)	Level of expertise (years)		Electronic tablet use (score)[a]	Cooking habits (score)[a]	UX tests		
		HCI[b]	Cognitive impairments[c]			2.1	2.2	SSS[d]
Gender								
Male	35	10	0.25	7	3	✓[e]	✓	✓
Female	36	0	3	5	7	✓		
Male	27	3	1	7	4	✓	✓	✓
Male	28	2	2	7	3	✓		✓
Male	27	17	1	7	5	✓		✓
Male	25	3	1	7	3		✓	✓
Male	25	8	0	1	5		✓	
Female	25	3	0.25	1	4		✓	
Values, mean (SD)	28.5 (4.5)	5.75 (5.6)	1.3 (1)	5.25 (2.7)	4.25 (1.4)	N/A[f]	N/A	N/A

[a]A higher score is associated with more frequent use of an electronic tablet and number of meals prepared per week at their entry into the study.

[b]HCI: human-computer interaction.

[c]Cognitive impairments: With a clientele with cognitive impairments.

[d]SSS: self-monitoring security system.

[e]✓: Indicates which UX tests were completed by participants.

[f]N/A: not applicable.

In total, 320 comments were documented and regrouped over the 3 UX tests of the first round, with 155 (48.4%) comments for version 2.1, 53 (16.7%) comments for version 2.2, and 112 (35%) comments for SSS. In response, 108 requests (n=53, 49.1%, n=34, 31.5%, and n=21, 19.4% issues) were translated and transmitted to the development team, of which many were considered and integrated into the next prototype of the cooking assistant. The documented comments encompassed UX and, in particular, usability issues such as navigation inconsistencies (eg, size and location of logos, optimizing navigation between the cooking assistant functionalities, and having access to a search mode to browse through the recipe book), technical bugs, and difficulties of use (eg, with the on-screen keyboard, when writing notes for later use, and with voice command). The need for more feedback (eg, when sending an email) and information (eg, in the recipes, following shut down by the SSS for both the user and the caregiver) was also identified.

Questionnaires

Overall, the usability of the preliminary version of COOK was adequate, with scores on the SUS ranging from 79.5 (ie, good usability) to 82.5 (ie, excellent usability) out of 100. The scores are presented in Table 2.

Table 2. Scores on the System Usability Scale (SUS) and AttrakDiff for each user experience test.

Questionnaire	Version 2.1, mean (SD)	Version 2.2, mean (SD)	SSS[a], mean (SD)
SUS[b] (out of 100)	82 (9.91)	82.5 (2.50)	79.5 (9.10)
AttrakDiff (between -3 and 3)			
PQ[c]	1 (0.40)	1.46 (0.44)	1.49 (0.50)
HQ-S[d]	1.63 (0.42)	1.2 (0.67)	1.31 (0.63)
HQ-I[e]	1.34 (0.90)	1.4 (0.60)	1.51 (0.55)
ATT[f]	2.09 (0.55)	2.03 (0.56)	1.97 (0.62)

[a]SSS: self-monitoring security system.

[b]SUS: System Usability Scale.

[c]PQ: pragmatic quality.

[d]HQ-S: hedonic-stimulation quality.

[e]HQ-I: hedonic-identity quality.

[f]ATT: global attraction.

In terms of UX, all dimensions were identified as positive, as shown in Figure 5. Global attraction was the most positive dimension for all versions of the cooking assistant, whereas the pragmatic quality for version 2.1 received the lowest score. When focusing on the portfolio of the AttrakDiff (see Figure 6 for an example and Multimedia Appendix 1), COOK was overall placed as desired, although version 2.1 also emerged as self-oriented.

Figure 5. Mean values of the 4 scales of the AttrakDiff for each version that was tested. ATT: global attraction; HQ-I: hedonic-identity quality; HQ-S: hedonic-stimulation quality; PQ: pragmatic quality; SSS: self-monitoring security system.

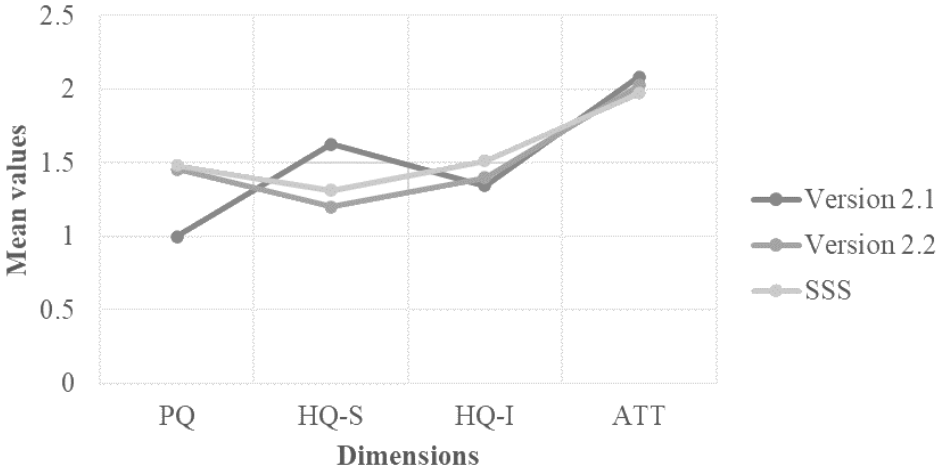
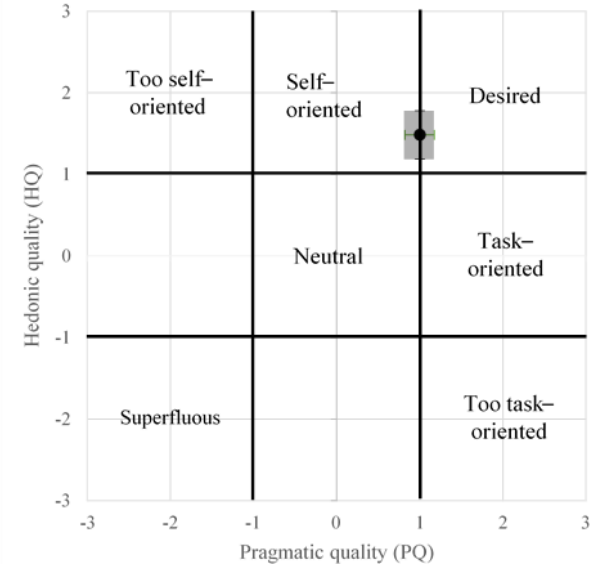


Figure 6. Portfolio of the AttrakDiff–version 2.1.



Study 2: People With TBI's Perspective on UX

Overview

A total of 10 participants—3 (30%) women and 7 (70%) men—living with a moderate to severe TBI participated in this study. At the time of the study, all participants had completed or were completing their outpatient rehabilitation. Participants were living in the community within their homes (with or without a family member), except for a participant who was living in a residence. Their age varied between 23 and 61 years (mean 39, SD 11.4 years), and their mean level of education was 12.7 (SD 2.7) years. Of the 10 participants, 2 (20%) had sustained a moderate TBI, and 8 (80%) had a severe TBI, mainly caused by motor vehicle accidents. The mean time post injury was 11.0 (SD 11.8) years (range 1.7-38 years). None of them had returned to work at the time of the study. When questioned about their difficulties when preparing meals and using technologies, the main identified difficulties included visual deficits (eg, sensitivity to blue light), physical impairments (eg, tremors and coordination deficits), cognitive difficulties (eg, fatigue, difficulty with multitasking, and forgetting things), and lack of knowledge and ideas about meals. The participants' characteristics are presented in Table 3.

Table 3. Characteristics of participants living with traumatic brain injury (TBI).

Identifiers and values	Gender	Age (years)	TBI severity		Time post injury (years)	Electronic tablet use (score)[a]	Cooking habits (score)[a]
			Moderate	Severe			
Participant identifier							
1	Male	34		✓	10.7	7	4
2	Male	23		✓	2.3	6	1
3	Male	52	✓[b]		38	7	4
4	Female	30		✓	12.1	5	2
5	Male	39		✓	2.1	1	2
6	Female	48		✓	24	1	2
7	Female	35		✓	2.5	6	2
8	Male	34		✓	5	1	5
9	Male	34		✓	1.7	6	6
10	Male	61	✓		11.2	7	7
Values, mean (SD)	N/A[c]	39 (11.4)	N/A	N/A	11 (11.8)	4.7 (2.6)	3.5 (2)

[a]Higher score is associated with more frequent use of an electronic tablet and number of meals prepared per week (maximum score is 7).

[b]✓: Indicates the TBI severity for each participant.

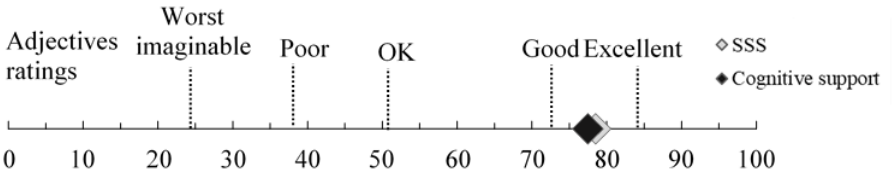
[c]N/A: not applicable.

226 different comments and observable behaviors were documented over the 2 sessions by participants with TBI (n=48, 21.2% comments for the SSS and n=178, 78.8% comments for the cognitive support module). Many of these comments highlighted potential improvements to COOK (eg, indicating that a burner is empty, listing the tools required for a recipe, and optimizing the functionality to add a recipe), including further improvements to the modifications previously identified in the first study (eg, feedback when sending an email and optimizing the on-screen keyboard). Technical problems also emerged during the UX evaluation, mainly with the SSS (eg, automatic return to the home page and inability to turn on the stove). Moreover, although some participants were able to instinctively use the functionalities of COOK, most participants required assistance and guidance to explore the functionalities during the scenarios (following the general presentation of the technology). Assistance was provided according to the person's level of ease with the technology, ranging from questions (eg, "What could you use to explore the recipe book?") and cues (eg, *Explore the left part of the screen*) to physical guidance (eg, pointing to the functionalities). In fact, of the 10 participants, all participants required assistance at least once during the 2 sessions, and 4 (40%) of them were provided continuous assistance throughout the exploration of COOK. Each UX test lasted between 56 and 130 minutes (total duration ranged from 85 to 240 minutes for the 2 sessions), with an average duration of 84 minutes per session (or 151.2 minutes per participant, as 2/10, 20% of them explored all the functionalities in 1 session). The duration varied widely among participants depending on their need for assistance and guidance.

Questionnaires

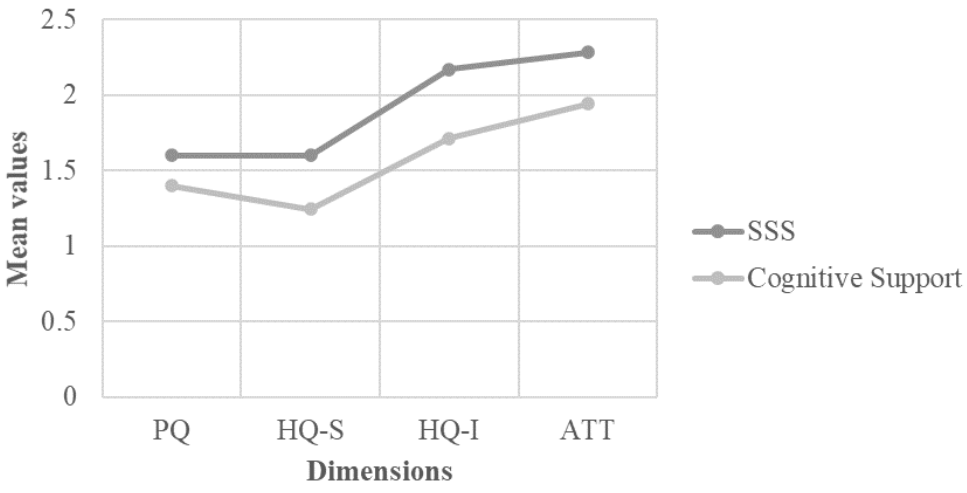
Regarding usability, the SUS score for the SSS was 78.5 (range 62.5-95) out of 100, and the SUS score for the cognitive support system was 77.5 out of 100. Both scores rated COOK's usability between good and excellent (Figure 7).

Figure 7. System Usability Scale diagram for the self-monitoring security system and the cognitive support module. SSS: self-monitoring security system.



All the dimensions of UX were identified as positive, as shown in Figure 8. Global attraction and the hedonic quality of identity were the most positive dimensions for both systems. Moreover, the SSS system surpassed the cognitive support module for all dimensions of UX, which was coherent with the qualitative feedback that the participants provided during the evaluation sessions. The AttrakDiff also rated COOK as desired in terms of UX (Multimedia Appendix 2).

Figure 8. Mean values of the 4 scales of the AttrakDiff for the self-monitoring security system and the cognitive support module. ATT: global attraction; HQ-I: hedonic-identity quality; HQ-S: hedonic-stimulation quality; PQ: pragmatic quality; SSS: self-monitoring security system.



Interviews

Overall, the participants with TBI appreciated both the SSS and the cognitive support system of COOK, describing them as well-made, accessible, and easy to use. In fact, some participants explained that for them, the learning phase could be really short:

> *I think it's really obvious. So I don't think [learning to use COOK] would be problematic, long or arduous.* [Participant 9]

COOK was also described by participants as helpful for them and others (eg, people with memory deficits and older adults), including for reducing potentially at-risk situations (eg, forgetting the oven or leaving a burner on), helping them return to the task when distracted, and managing meals over the week. For example, a participant explained that she was not cooking without the presence of her spouse because of previously experienced unsafe situations (eg, forgetting something on the stove and burning her meal). Thus, using COOK could allow

her to resume meal preparation independently while reducing her spouse's burden. On the other hand, 20% (2/10) of participants expressed that they would use COOK to help them manage their schedule and find new meal ideas (as they tended to do the same meals over and over again). As a result, 90% (9/10) of the participants mentioned that they would like to have COOK support them at home with meal preparation.

Nonetheless, when discussing the potential use of COOK within their homes, the participants also identified obstacles. First, the participants highlighted that their cooking environment might not be adapted to use COOK. For example, some participants mentioned that they lacked the space to install and use a screen close to the stove:

> *I am too restricted where I am living, it's too narrow. [COOK] would be too cumbersome.* [Participant 3]

The presence of pets was also identified as potentially problematic, as some participants perceived that the sensors could detect their pets in the cooking environment (thus biasing the detection of unsafe behaviors), and the pets could damage electronic equipment (eg, gnaw on the wires). Finally, a participant explained that because of her physical deficits (tremors and having to move around in a wheelchair), her cooking environment was not adapted for her to cook independently using COOK (eg, stove placed too high and lack of support when mixing or stirring her meal). On the other hand, factors related to the participants' abilities and deficits were also highlighted. Participants mentioned that having difficulties in using everyday technologies (eg, smartphones and computers) could interfere with using COOK and make the learning phase more difficult. For example, a participant explained this as follows:

> *it's going to take a long time for me to understand the system, how it works, because it's technology, it's something I have trouble with in general.* [Participant 4]

Visual deficits (eg, difficulty recognizing tools and items in the kitchen, reduced visual acuity, and difficulty finding items in the left space of the screen) were also identified as problematic.

Finally, needs in terms of support for learning were discussed. Many participants highlighted the need for practice, accompanied or not, before being able to use COOK independently within their home environment. Technical support in person or via phone was also mentioned as a requirement following the learning process. Nonetheless, most participants perceived that they could use COOK by themselves with little or no support.

Discussion

Principal Findings

The purpose of this paper was to present the results of a UX evaluation completed at various moments throughout the development process of an ATC named COOK. Using similar methodologies, both studies showed that COOK had positive usability outcomes, with SUS scores ranging from good to excellent usability and great UX as assessed using the AttrakDiff scale. Furthermore, both rounds of the study highlighted the potential modifications to COOK. The exploration of COOK in a laboratory setting with participants living with moderate to severe TBI and having various needs and living contexts (eg, living at home with or without a family member or living in a residence) also allowed the identification of factors to consider before using COOK in the community, including space availability in the kitchen, presence of pets, presence of visual deficits, and the person's level of comfort with everyday technology. Interestingly, although the intention to develop COOK was initially pragmatic (ie, allowing people with TBI to complete a meal preparation task independently and safely and potentially optimizing long-term independence in this task), hedonic qualities emerged as strong in both the studies, which is a positive aspect for future use and implementation of the technology. In fact, awareness of deficits is frequently reduced following a TBI [35,36], and as a result, these individuals often do not perceive the need for cognitive assistance. Consequently, developing a technology that is pleasant, usable, and well-designed, which could ultimately promote acceptability with end users (ie, people with TBI), strongly supported the qualities of COOK for its eventual use.

For this project, the UX evaluation was based on a triangulation of data collection, including standardized questionnaires and the use of scenarios with a *think-aloud* strategy. Although standardized questionnaires allowed comparisons between the versions of COOK and potential users [26,28], using scenarios combined with an explanatory interview emerged as of paramount importance in the process of designing the cooking ATC. First, contrary to the AttrakDiff and SUS, the use of scenarios and analyses of participants' observable behaviors when following them allowed us to target specific improvements to make to the technology. Second, although most participants with TBI perceived COOK as easy to use and learn (which is coherent with the SUS scores), using a more objective method such as analyzing observable behaviors and assistance provided throughout the scenarios brought to light the extent to which the participants would require a learning phase and support before being able to use COOK independently at home. UX tests were, in fact, conducted by a certified occupational therapist, thus bringing expertise to comprehensively assess a person's ability to use assistive technology to complete complex activities. Using this expertise, the evaluator was able to provide assistance according to the person's needs in an informative manner. This is also coherent with prior studies, which suggest that the use of standardized questionnaires or other subjective methods (eg, interviews) as a stand-alone method is not as effective for evaluating UX and its usability outcomes [37,38]. Moreover, very few standardized questionnaires have been developed and validated to evaluate UX of people living with cognitive impairments, such as people with TBI [39]. Thus, the use of both methods was a strength of this project.

Limitations

Using a triangulation of qualitative methods (eg, scenarios, interviews, and questionnaires), this project demonstrated that COOK has great usability and UX outcomes. Nonetheless, both studies also had some limitations. First, although 5 participants were involved in each UX testing in the first study, only 8

different participants were recruited. As a result, there may have been some learning effect over time, thus influencing the participants' appreciation of COOK. Nonetheless, new features were tested each time, which likely reduced the learning effect on our results. In addition, although there is a lack of consensus in the literature about the number of participants that should be involved in usability studies, some authors suggest that 5 participants are not enough to identify most usability issues (with identification of only 55% of potential problems in some samples) [40,41]. Nonetheless, we considered that this sample was appropriate for the first study, considering that it was early in the development process and that it included only experts. However, the sample size was larger in the second study as it included participants with cognitive impairments and various needs and living contexts.

By evaluating UX at various times throughout the development process of COOK, our research team was able to obtain a technology that is usable, pleasant, and well-designed while considering the various needs, living contexts, and characteristics of end users (ie, people with TBI). Although other technologies to support meal preparation have been previously developed and tested with people with TBI [11-13], few were formally evaluated in terms of usability and UX. Moreover, in accordance with user-centered design, our research team strongly considered the end users' needs by including usability evaluation with experts and end users in a laboratory context (study 1 and 2), real-world implementation of the technology [15], and qualitative interviews with stakeholders [42-45], thus contrasting from technologies developed and tested only in a laboratory setting. However, it should be noted that all included participants were adults aged <65 years. Other studies that include older adults are required to explore the UX with COOK in this population as they may experience other obstacles when using technologies [42].

Conclusions

This paper aimed to present how the UX of different participants when using an ATC for cooking, named COOK, was evaluated in a laboratory context at various times during its development process. Using results from both studies, COOK was improved to facilitate its use by people living with TBI within the community. Factors influencing this process, such as environmental and personal aspects, were identified. Considering the positive appreciation by participants for COOK, further steps should focus on assessing UX when COOK is used within a real-world environment (ie, homes of people with TBI living in the community) and improve its accessibility.

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Authors' Contributions

SP, CB, FLM, CL, HP, SG, and NB were involved in the development, data collection, and data analysis for the first study. MGR, CB, RBL, AY, and NB were involved in the second study. SP and CL wrote the first draft of the first study. MGR wrote the first draft, including both studies. All authors reviewed and approved the present version of the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Portfolio of the AttrakDiff for study 1–Version 2.2 and self-monitoring security system.
[DOCX File , 24 KB - rehab_v9i1e28701_app1.docx]

Multimedia Appendix 2
Portfolio of the AttrakDiff for study 2–Cognitive support module and self-monitoring security system.
[DOCX File , 49 KB - rehab_v9i1e28701_app2.docx]

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Abbreviations

ATC: assistive technology for cognition
COOK: Cognitive Orthosis for Cooking
FRQS: Fonds de la recherche du Québec–Santé
HCI: human-computer interaction
SSS: self-monitoring security system
SUS: System Usability Scale
TBI: traumatic brain injury
UX: user experience

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Original Paper

The Association Between Actigraphy-Derived Behavioral Clusters and Self-Reported Fatigue in Persons With Multiple Sclerosis: Cross-sectional Study

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Abstract

Background: Persons with multiple sclerosis frequently report increased levels of fatigue and fatigability. However, behavioral surrogates that are strongly associated with self-reports are lacking, which limits research and treatment.

Objective: The aim of this study was to derive distinct behavioral syndromes that are reflected by self-reports concerning fatigue and fatigability.

Methods: We collected actigraphic data of 30 persons with multiple sclerosis over a period of 1 week during an inpatient stay at a neurorehabilitation facility. Further, participants completed the German fatigue severity scale. A principal component analysis of actigraphic parameters was performed to extract the latent component levels of behaviors that reflect fatigue (quantity of activity) and fatigability (fragmentation of activity). The resulting components were used in a cluster analysis.

Results: Analyses suggested 3 clusters, one with high activity (d=0.65-1.57) and low clinical disability levels (d=0.91-1.39), one with high levels of sedentary behavior (d=1.06-1.58), and one with strong activity fragmentation (d=1.39-1.94). The cluster with high levels of sedentary behavior further revealed strong differences from the other clusters concerning participants' reported levels of fatigue (d=0.99-1.28).

Conclusions: Cluster analysis data proved to be feasible to meaningfully differentiate between different behavioral syndromes. Self-reports reflected the different behavioral syndromes strongly. Testing of additional domains (eg, volition or processing speed) and assessments during everyday life seem warranted to better understand the origins of reported fatigue symptomatology.

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KEYWORDS

multiple sclerosis; actigraphy; cluster analysis; fatigue; physical activity; neurology; neurorehabilitation; rehabilitation; digital health; health technology; digital tools

Introduction

Persons with multiple sclerosis (MS) frequently show low levels of physical activity and increased levels of sedentary behavior [1,2] and report high levels of fatigue and fatigability [3-6]. Although fatigue is often used as an umbrella term for being exhausted in a resting state (fatigue) and easily entering a state of exhaustion (fatigability), fatigue and fatigability represent 2 different dimensions [7]. This is important since they therefore need to be assessed as 2 distinct dimensions to evaluate the progression of the disease or the effects of interventions (eg, medication or physical therapy). It has been shown that reported levels of fatigue are associated with reduced quality of life [4].

However, studies have revealed very little to no meaningful association between objectively assessed function (capacity) or behavior and self-reported dimensions like quality of life, fatigue, or depression [4,8]. Such a missing association could indicate either insufficient validity of self-reports or objective assessments or, alternatively, low sensitivity of self-reports or current approaches to objectively assess such psychological constructs. Especially when considering fatigue and fatigability (since they are commonly assessed or recognized by their consequence, which is a lack of activity), actigraphy could be a feasible measure to continuously gather objective data [9] and circumvent "assessing a snapshot of the person's feelings and current interpretation of subjective experience" [4]. When anticipating a certain intraindividual and interindividual variance of self-reports, as there can be a plethora of biases [10-12], cluster analyses of actigraphic data would have the potential to identify behavioral patterns and validate self-reports by treating a cluster of persons as one type of person. Such an approach could allow us to extract general rules and acknowledge that humans are not very skilled in estimating global aspects of their life [11] or their current sensorimotor performance capacity [13] (ie, that humans tend to show strong interpersonal and intrapersonal variance in self-reports). However, such an exploratory cluster analysis could also result in a single cluster, for instance, if the assessed behavior is a single continuum with only one attractor. The added value of this approach would be the possibility of objectively classifying persons and further avoiding restrictions of self-reports (independent of the number of clusters) and further allowing sensitive longitudinal data collection, for instance, to test responsiveness to medication or to allow precision therapies.

Actigraphy is already a frequently used method to assess behavior in MS [14-17]. In actigraphic studies, persons with MS commonly show less activity and higher levels of sedentary behavior than healthy controls [14,16]. Further, persons with MS who have higher grades of disability, especially more strongly impaired ambulatory function, show a shift in activity intensity (eg, less moderate but more light activity) [15,16]. This approach generally reveals good psychometric properties when assessing the behavior of persons with MS [17].

In this study, we collected actigraphic and self-reported data of persons with MS to examine if behavioral patterns can help us better understand self-reports. We hypothesized that cluster analyses would reveal behavioral clusters that also show psychometric and clinical differences.

Methods

Participants

A convenience sample of 30 persons with MS was used for this study (Table 1). All participants were recruited during an inpatient rehabilitation stay at a specialist clinic for neurology, the Center for Clinical Neuroplasticity, Medical Park Loipl, in Germany. The following exclusion criteria were used: the inability to walk, strong depressive symptomatology (ie, Beck Depression Inventory-II scores of ≥20), other diagnosed psychiatric disorders, an age of <18 years, and the inability to give written informed consent. Regarding the clinical severity of MS, the sample showed a mean Expanded Disability Status Scale (EDSS) score of 3.5 and concerning the sensorimotor performance, a mean Watzmann Severity Scale (WSS) score of 3.5. The EDSS score was determined by trained neurologists from the specialist clinic and the WSS was assessed on first contact with the participants. Overall, the neurological status of the patients' MS was mild to moderate. Of the 30 participants, 22 (73%) presented with relapsing-remitting MS and 8 (27%) presented with a progressive form of MS [18]. This was based on each participant's medical records and an interview (by a trained neurologist on rehabilitation entry) on the course of MS for confirmation. The mean disease duration, taken as the time since the patient's first diagnosis, was between 0 and 24 years, with a mean of 7.5 years (Table 1). Demographic and clinical characteristics were not only taken into account for comparability, but also considered due to mixed reports on their association with self-reported fatigue [19,20].

Table 1. Demographic and clinical characteristics of the participants (N=30).

Characteristic	Value
Age in years, mean (SD), range	43.7 (11.5), 21-65
Sex, n (%)	
Female	19 (63)
Male	11 (37)
BMI in kg/m², mean (SD), range	26.2 (4.7), 18.2-35.1
Expanded Disability Status Scale score, mean (SD), range	3.5 (1.4), 1.0-6.5
Watzmann Severity Scale score, mean (SD), range	3.5 (1.1), 1.7-5.8
Type of multiple sclerosis, n (%)	
Relapsing-remitting	22 (73)
Progressive	8 (27)
Time since first diagnosis (DISDUR) in years, mean (SD), range	7.5 (6.6), 0-24

Ethics Approval

Ethical approval was granted by the ethics committee of the medical faculty of the Technical University of Munich on July 14, 2020 (approval identifier: 478/19 S-SR). All participants provided written informed consent.

Study Parameters

Each participant was asked to wear a wrist-worn actigraph (ActiGraph wGT3X-BT, ActiGraph LLC; the 100 Hz measurement frequency was downsampled to 1 Hz, ie, 1-second epochs) on the dominant or better functioning side (concerning the upper limb) of their body for 1 full week. The triaxial acceleration signal was collected and stored as compressed raw data on the device. After that period, participants completed the German fatigue severity scale (FATIGUE parameter) [21] to assess their experienced level of fatigue. The parameters that were extracted from the actigraphic data were the average number of daily steps (STEPS), the body mass–adjusted metabolic equivalent (MET), the estimated ratio of sedentary behavior (SEDENTARY), and the ratio of the number of activity bouts lasting ≥5 minutes and ≥10 minutes (RATIO) [22]. STEPS aimed to assess kinematic physical activity, MET assessed dynamometric physical activity, SEDENTARY was a coarse estimate of fatigue, and RATIO assessed fatigability. The metabolic equivalent and time in sedentary behavior were estimated by the actigraph (using ActiLife software, version 6.13.4; ActiGraph LLC); the ActiLife software was based on the Freedson adult algorithm [23]. The threshold used for sedentary behavior was 99 activity counts per minute.

A 2-component confirmatory principal component analysis with a varimax rotation for the actigraphic data was calculated (1 component as fatigue and 1 as fatigability). Thresholds for the Kaiser-Meyer-Olkin test of sample adequacy were set to ≥0.50, and minimum communalities were set to ≥0.50. Based on the component scores, a cluster analysis using k-means clustering (Hartigan-Wong) was performed. The number of clusters was determined from a scree plot. Cluster differences in terms of behavioral, psychometric, and demographic or clinical properties were tested by analyses of variance; for sex and type of MS, chi-square tests were used. Effect-sizes were derived post hoc using the Cohen *d*. α was set to .05. All statistical tests were run using R (version 1.4.1106; R Foundation for Statistical Computing).

Results

The actigraphic and psychometric outcomes for the sample are reported in Table 2. There were no missing data; the actigraphs were tolerated during nighttime and were waterproof, so participants had 7 complete 24-hour data sets. The overall measure of sample adequacy was middling, with 0.75, and none of the 4 parameters scored below 0.50 (Table 2). The principal component analyses had a proportion of explained variance of 0.88 and communalities of 0.80 for MET, 0.86 for STEPS, 0.88 for SEDENTARY, and 0.98 for RATIO. The component loadings are displayed in Figure 1. Component 1 (Figure 1, x-axis) correlated with FATIGUE (r=–0.54; P=.002), but not component 2 (Figure 1, y-axis; r=–0.13; P=.49).

The cluster analysis resulted in 3 clusters; cluster 1 had 11 persons, cluster 2 had 13 persons, and cluster 3 had 6 persons. Table 3 reports the statistical differences between the resulting clusters. Cluster 1 had higher STEPS and MET and lower RATIO, SEDENTARY, EDSS, and WSS than the other 2 clusters. Cluster 2 showed the highest SEDENTARY and FATIGUE values and cluster 3 had the highest RATIO values. Clusters 2 and 3 were similar in terms of STEPS, MET, EDSS, and WSS. All clusters were comparable concerning the following variables: age, sex distribution, BMI, DISDUR (time since diagnosis), and type of MS (Table 3). As with component 1 (Fatigue component), MET, STEPS, and SEDENTARY were significantly associated with FATIGUE, while RATIO showed no significant correlation with FATIGUE (Table 4). Figure 2 illustrates the individual scores of persons in the different clusters for key parameters like the WSS score.

Table 2. Actigraphic and psychometric outcomes among participants.

Parameter	Mean (SD)	Range	Measure of sample adequacy
STEPS[a]	13,400 (3800)	8100-22,400	0.71
MET[b]	1.43 (0.11)	1.26-1.76	0.85
RATIO[c]	6.0 (3.4)	2.4-15	0.74
SEDENTARY[d]	0.74 (0.04)	0.67-0.82	0.71
FATIGUE[e]	41.7 (14.6)	13-69	0.74

[a]STEPS: number of steps per day.

[b]MET: body mass–adjusted metabolic equivalent.

[c]RATIO: ratio of the number of activity bouts lasting ≥5 minutes and ≥10 minutes.

[d]SEDENTARY: estimated ratio of sedentary behavior.

[e]FATIGUE: German fatigue severity scale score.

Figure 1. Component loadings of the 4 different actigraphic parameters. MET: body mass–adjusted metabolic equivalent. SEDENTARY: estimated ratio of sedentary behavior. STEPS: number of steps per day. RATIO: ratio of the number of activity bouts lasting ≥5 minutes and ≥10 minutes.

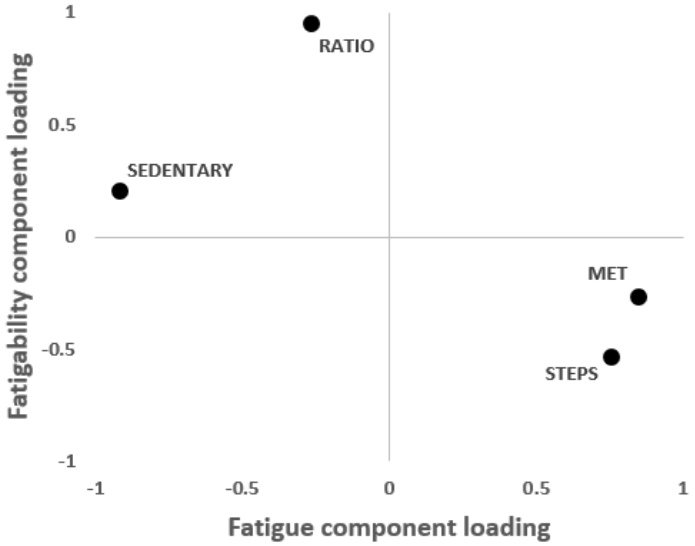


Table 3. Cluster comparisons including means, SDs, and ranges.

Parameter	Cluster 1	Cluster 2	Cluster 3	*P* value[a]	Post hoc comparisons
STEPS[b], mean (SD), range	16,700 (3000), 12,900-22,400	10,500 (1900), 8100-14,000	11,400 (1400), 9300-13,100	<.001	Cluster 1-2: *P*<.001; *d*=0.99 Cluster 1 and 3: *P*<.001; *d*=0.65
MET[c], mean (SD), range	1.53 (0.09), 1.44-1.76	1.34 (0.05), 1.26-1.41	1.40 (0.07), 1.28-1.47	<.001	Cluster 1-2: *P*<.001; *d*=1.57 Cluster 1-3: *P*=.007; *d*=1.22
RATIO[d], mean (SD), range	3.4 (0.9), 2.4-5.8	6.6 (2.3), 4.3-9.6	10.9 (2.4), 7.7-15.0	<.001	Cluster 1-2: *P*<.001; *d*=–1.39 Cluster 1 and 3: *P*<.001; *d*=–1.94 Cluster 2-3: *P*<.001; *d*=–1.41
SEDENTARY[e], mean (SD), range	0.71 (0.02), 0.67-0.74	0.78 (0.02), 0.72-0.82	0.74 (0.03), 0.70-.077	<.001	Cluster 1-2: *P*<.001; *d*=–1.58 Cluster 1-3: *P*=.05; *d*=–1.06 Cluster 2-3: *P*=.03; *d*=1.13
FATIGUE[f], mean (SD), range	37.3 (14.4), 13-59	51.5 (10.2), 32-69	33.3 (13.6), 15-49	.01	Cluster 1-2: *P*=.01; *d*=–0.99 Cluster 2-3: *P*=.02; *d*=1.28
Age in years, mean (SD), range	41.3 (11.2), 25-58	42.5 (11.9), 21-55	51.3 (9.8), 36-65	.19	N/A[i]
Sex, n (%)					
Female	8 (77)	8 (64)	2 (33)	.19	N/A
Male	3 (23)	5 (36)	4 (67)	.19	N/A
BMI in kg/m², mean (SD), range	25.8 (4.0), 20.9-32.2	27.0 (4.8), 18.2-33.8	25.6 (6.4), 18.7-35.1	.80	N/A
Expanded Disability Status Scale score, mean (SD), range	2.7 (1.1), 1.0-5.0	3.9 (1.4), 2.0-6.5	4.7 (1.1), 3.5-6.5	.005	Cluster 1-2: *P*=.03; *d*=–0.91 Cluster 1-3: *P*=.005; *d*=–1.39
Watzmann Severity Scale score, mean (SD), range	2.8 (0.9), 1.7-4.9	4.0 (1.0), 2.3-5.8	3.9 (0.9), 2.8-5.5	.008	Cluster 1-2: *P*=.005; *d*=–1.10 Cluster 1-3: *P*=.04; *d*=–1.08
DISDUR[g] in years, mean (SD), range	6.2 (6.2), 0-16	7.2 (7.5), 0-24	11.0 (5.2), 3-17	.33	N/A
TYPE[h], n (%)					
Relapsing-remitting	8 (77)	9 (73)	4 (67)	.89	N/A
Progressive	3 (23)	4 (27)	2 (33)	.89	N/A

[a]The *P* values for all parameters, except sex and TYPE, were derived using ANOVA. The *P* values for sex and TYPE were derived using the chi-square test.

[b]STEPS: number of steps per day.

[c]MET: body mass–adjusted metabolic equivalent.

[d]RATIO: ratio of the number of activity bouts lasting ≥5 minutes and ≥10 minutes.

[e]SEDENTARY: estimated ratio of sedentary behavior.

[f]FATIGUE: German fatigue severity scale score.

[g]DISDUR: time since initial diagnosis.

[h]TYPE: type of multiple sclerosis.

[i]N/A: not applicable.

Table 4. The correlation between FATIGUE and demographic, clinical, and actigraphic parameters.

Variable	Age	BMI	EDSS[b]	WSS[c]	DISDUR[d]	MET[e]	STEPS[f]	SEDENTARY[g]	RATIO[h]
FATIGUE[a]									
r	–0.03	0.22	0.23	0.04	–0.0003592	–0.43	–0.41	0.43	0.04
P value	.87	.25	.22	.83	.99	.02	.03	.02	.98

[a]FATIGUE: German fatigue severity scale score.

[b]EDSS: Expanded Disability Status Scale score.

[c]WSS: Watzmann Severity Scale score.

[d]DISDUR: time since initial diagnosis.

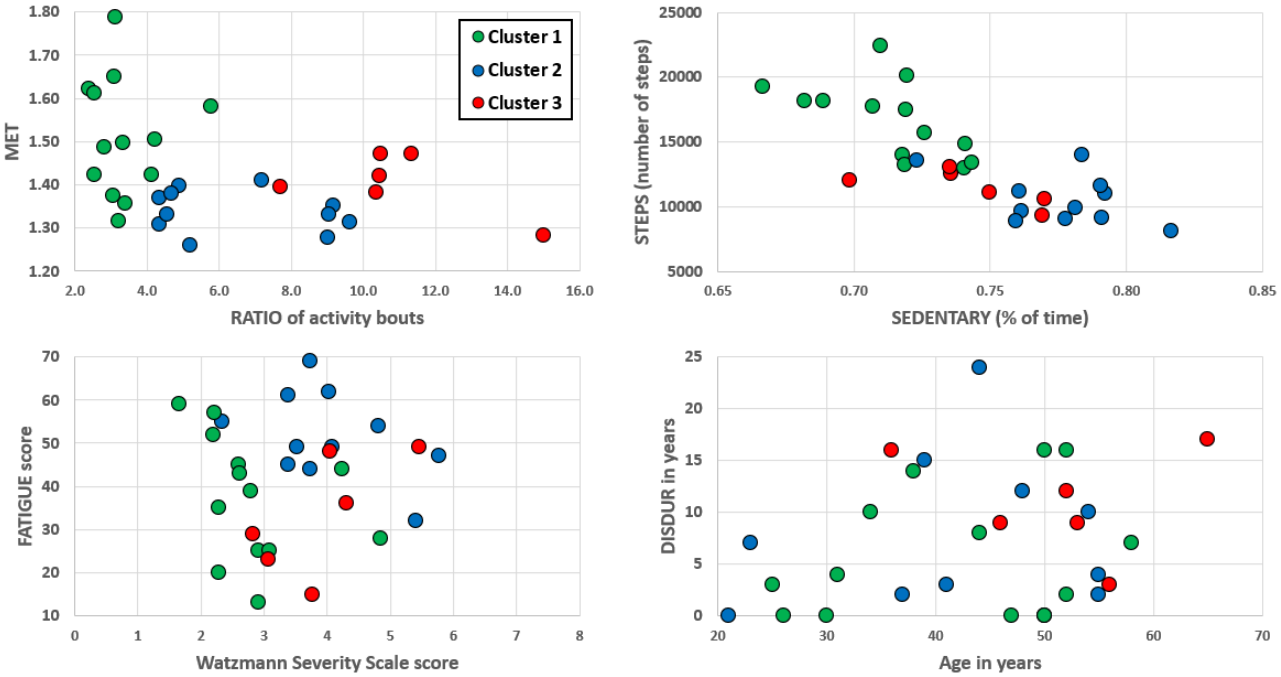
[e]MET: body mass–adjusted metabolic equivalent.

[f]STEPS: number of steps per day.

[g]SEDENTARY: estimated ratio of sedentary behavior.

[h]RATIO: ratio between short and longer activity bouts.

Figure 2. Illustration of cluster distributions in different parameter pairs. MET: body mass–adjusted metabolic equivalent. RATIO: ratio of the number of activity bouts lasting ≥5 minutes and ≥10 minutes. STEPS: number of steps per day. SEDENTARY: estimated ratio of sedentary behavior. FATIGUE: German fatigue severity scale score. DISDUR: time since initial diagnosis.



Discussion

Principal Findings

In this study, we assessed data on physical activity and reported levels of fatigue and depression from 30 persons with MS during an inpatient stay at a rehabilitation facility. Although not being in the home environment, behavioral characteristics could be similar [24]. Statistical modelling confirmed our initial differentiation of parameters surrogating fatigue (SEDENTARY) and fatigability (RATIO) and suggested 3 clusters, which revealed very strong differences in actigraphic parameters, reported levels of fatigue, and the severity of MS (clinical and sensorimotor). Cluster 1 was the most active group with more daily steps (STEPS), higher body mass–adjusted metabolic equivalents (MET), smaller ratios between short and longer activity bouts (RATIO), less sedentary behavior (SEDENTARY), and lower EDSS and WSS scores than the other 2 clusters. Cluster 2 showed the highest ratios of sedentary behavior (SEDENTARY) and reported the highest levels of fatigue (FATIGUE). Cluster 3 had the highest ratios between short and longer activity bouts (RATIO). Overall, there was 1 active cluster with the lowest disability (cluster 1), 1 cluster with the highest signs of and reported fatigue (cluster 2), and 1 cluster with the highest fatigability (cluster 3). Clusters 2 and 3 had comparable MET and STEPS as well as clinical and sensorimotor disease severity, and clusters 1 and 3 had comparable levels of reported fatigue. This is in line with other studies that showed reported fatigue to be quite independent of performance [25] since our fatigue cluster revealed intermediate ratios of short and longer activity bouts (RATIO). The cluster with higher fatigability, on the contrary, reported average levels of fatigue (FATIGUE). Interestingly, the differentiation between the various behavioral clusters had strong effect-sizes, while correlations were quite weak, which supports our initial thoughts

that led to the clustering approach (ie, low reliability of persons assessing their own condition, which can be circumvented by objective sensor-supported assessments). This would also allow for the monitoring of the psychological and behavioral course of persons with MS (or, for instance, frail elderly individuals, stroke survivors, etc.) in a reliable and valid way. Such information, of course, needs to be understood as a complementary, not alternative, data source. However, it is important to note that all clusters had individuals reporting very high levels of fatigue, which is important concerning the validity of the used questionnaire, as this has been questioned for a set of fatigue questionnaires in general [26]. Interestingly, there were no significant differences between the clusters concerning most of the demographic and clinical characteristics such as TYPE (type of MS), DISDUR (time since initial diagnosis), BMI, age, or sex; however, there was a significant difference between the clinical and sensorimotor severity of the condition. This suggests that the assessed dimensions were not strongly influenced by conceivable confounders like BMI, age, or biological sex and that fatigue and fatigability could be seen as valid psychological constructs. Further, none of the nonactigraphic parameters were associated with the reported levels of fatigue. As shown in other publications on the topic [19,20], the outcomes concerning the associations of self-reported fatigue and demographic and clinical characteristics can strongly depend on the statistical approach used, underscoring the need to employ objective assessments like, in our case, actigraphy to overcome the limited reliability of self-reports [4,13].

Limitations

It is crucial to note that the interpretation of our findings is based on the assumption that fatigability leads to more fragmented activity, but not necessarily less volume of activity. Concerning the potentially limited validity of the questionnaire used, the following factor may have been involved: a bias towards extremes within the questionnaire (none of the single items were normally distributed, but the sum score of the questionnaire was) due to humans being quite inaccurate in estimating their own conditions and differentiating between state and trait [11]. Further, low item difficulties can prevent the identification of persons with extremely high levels of fatigue [27].

Conclusions

To conclude, clustering of behavioral data proved to be a strong approach in examining self-reports. Our analyses, suggesting 3 different clusters, deliver behavioral correlates of the fatigue and fatigability constructs and warrant future studies on actigraphy in the home environment of persons with MS. A further examination of the feeling of fatigue by objective psychometric means (eg, tests of problem-solving, motivational priming, processing speed measured by reaction time) would be recommended to better understand if the umbrella term of fatigue dominantly arises from bodily, cognitive, or emotional domains [28].

Conflicts of Interest

None declared.

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Abbreviations

EDSS: Expanded Disability Status Scale
MS: multiple sclerosis
WSS: Watzmann Severity Scale

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Original Paper

A Novel Body Weight–Supported Postural Perturbation Module for Gait and Balance Rehabilitation After Stroke: Preliminary Evaluation Study

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Abstract

Background: Impaired balance regulation after stroke puts patients and therapists at risk of injury during rehabilitation. Body weight support systems (BWSSs) minimize this risk and allow patients to safely practice balance activities during therapy. Treadmill-based balance perturbation systems with BWSSs are known to improve balance in patients with age- or disease-related impairments. However, these stationary systems are unable to accommodate complex exercises that require more freedom of movement.

Objective: This study aims to evaluate the effect of a new balance perturbation module, which is directly integrated into a track-mounted BWSS, on balance impairments secondary to acute stroke.

Methods: This unblinded quasi-randomized controlled preliminary study was conducted in a rehabilitation-focused long-term acute care hospital. Participants were recruited from stroke rehabilitation inpatients with an admission Berg Balance Scale (BBS) score of 21 (out of 56) or greater. Over a 2-week period, consented participants completed 8 BWSS or BWSS with perturbation (BWSS-P) treatment sessions; study activities were incorporated into regular treatment to avoid disruption of their normal care. Although both groups conducted the same balance and gait activities during their treatment sessions, the BWSS-P sessions included lateral, anterior, and posterior balance perturbations. Pre- and postintervention BBS and Activities-Specific Balance Confidence (ABC) assessments were the primary outcome measures collected. Institutional BBS data from the year before installation of the track-mounted BWSS were retrospectively included as a post hoc historical standard of care comparison.

Results: The improved postintervention BBS and ABC assessment scores showed that all participants benefited from therapy (P<.001 for all pre- and postintervention comparisons). The average BBS percent change for the BWSS-P sample (n=14) was 66.95% (SD 43.78%) and that for the BWSS control sample (n=15) was 53.29% (SD 24.13%). These values were greater than those for the standard of care group (n=30; mean 28.31%, SD 17.25%; P=.02 and P=.005 respectively), with no difference among the BWSS groups (P=.67). ABC score changes were also similar among the preintervention and postintervention BWSS groups (P=.94 and P=.92, respectively).

Conclusions: Both BWSS groups demonstrated similar BBS and ABC score improvements, indicating that balance perturbations were not detrimental to postacute stroke rehabilitation and were safe to use. These data provide strong rationale and baseline data for conducting a larger follow-up study to further assess if this new perturbation system provides additional benefit to the rehabilitation of gait and balance impairments following stroke.

Trial Registration: ClinicalTrials.gov NCT04919161; https://clinicaltrials.gov/ct2/show/NCT04919161

(JMIR Rehabil Assist Technol 2022;9(1):e31504) doi:10.2196/31504

KEYWORDS

stroke rehabilitation; postural balance; gait and ambulation; balance perturbation; postural perturbation; body weight support system; occupational therapy; physical therapy; long-term acute care hospital, Berg Balance Scale; Activities-Specific Balance Confidence Scale

Introduction

Background

Each year, more than 795,000 people experience a stroke [1]. Stroke, or cerebral vascular accident, is a neurological event that can lead to devastating physical and cognitive deficits, such as the inability to ambulate, impaired balance regulation, loss of coordination, and impaired communication [2]. Because of the physical and cognitive deficits experienced following a stroke, many patients require admission to an inpatient rehabilitation facility with the goal of maximizing their independence before returning to the home setting [3]. Gait dysfunction is a common secondary impairment of stroke that usually requires specific rehabilitative actions [4].

Following a stroke, patients are often observed via motion analysis to navigate obstacles more conservatively and with abnormal gait patterns [5]. This is likely associated with the loss of muscle strength secondary to stroke, which could increase the risk of falling [5]. Within 6 months of discharge, falls occur in up to 70% of patients following a stroke, highlighting the importance of focusing on improving patients' balance and gait during the early rehabilitation phase [6].

It is estimated that over 90% of stroke survivors would report that the fear of falling would negatively impact their performance in daily living activities [7]. Fear of falling has been shown to influence balance and gait control in older adults, supporting the theory that balance and gait should be considered during rehabilitative methods [7]. These psychological factors are also strong predictors of falling compared with physical factors or the presence of pathology. Patient self-assessments can be important indicators of fall risk, as patients may better understand their capabilities and limitations than what the physical tests demonstrate [8].

The ability to walk, stand, climb stairs, and other mobility-related functional tasks are critical components in achieving functional independence. However, following a stroke, it is often difficult for patients with balance impairments to safely practice balance and gait training without putting both therapists and patients at risk for injury. Incorporating robotic technologies for neurological rehabilitation can play a critical role in delivering safe and effective gait and balance therapy [9].

The integration of body weight support systems (BWSSs) following a stroke, spinal cord injury, or other neurological disorders has continued to expand over the last 2 decades [10]. The range of tools available to therapists to treat patients with these impairments continues to grow [10]. Using BWSSs to unload paretic lower limbs, patients with gait impairments can practice a higher repetition of steps in a safe and controlled manner. As the patient performs gait training, these systems support the patient's body weight. This permits those with excessive weakness and poor coordination to minimize the risk of injurious falls and to ambulate and perform more intensive therapy sessions sooner in their recovery.

In addition to BWSSs, balance perturbation systems improve gait and balance control after stroke, or in response to other age- and disease-related balance impairments. This is accomplished by purposefully unbalancing patients so that they can rehabilitate their postural control [11-16].

Objectives

In this study, we evaluate the efficacy of a recently developed, not yet reported, balance perturbation module for the ZeroG BWSS. This new balance perturbation training module is directly integrated into the BWSS and allows therapists to induce safe lateral, anterior, and posterior perturbations via a Wi-Fi–enabled handheld device. During both stationary and ambulatory activities, this system was used to unbalance participants to train their reactive balance control and balance reactions, including ankle, hip, and stepping strategies [17]. The purpose of this preliminary study was three-fold: (1) evaluate the safety and feasibility of using this technology in the clinical setting, (2) develop a practical protocol for clinical use, and (3) determine whether there is any evidence to suggest that this newly developed BWSS balance perturbation system provides additional benefits to patient gait and balance rehabilitation after stroke over the standard BWSS protocol without perturbations, which would support further investigation of the technology.

Methods

Research Design

This was an unblinded quasi-randomized parallel active comparator–controlled preliminary study conducted at Gaylord Specialty Health Care (Wallingford, Connecticut, United States), a long-term acute care hospital (LTACH). As a result of an oversight in the requirements for clinical trial registration and the definition of an applicable clinical trial [18], the authors humbly admit there was a delay in clinical trial registration for this study. However, we are pleased to report that the educational and procedural issues leading to this oversight have been rectified and that the study has been retrospectively registered as follows: ClinicalTrials.gov NCT04919161 [19].

Ethical Considerations

Before participant recruitment, the study was reviewed and approved by the hospital's Institutional Review Board to ensure the study complied with the ethical standards set by the Declaration of Helsinki and CONSORT (Consolidated Standards of Reporting Trials) 2010 (Multimedia Appendix 1) [20]. All patients provided informed consent.

Participants

All participants were admitted to the LTACH under the inpatient stroke rehabilitation program after receiving a stroke diagnosis at a regional acute care hospital. Participant recruitment occurred over 12 months (October 2019 to September 2020). Patients admitted to the inpatient stroke rehabilitation program were evaluated by physical and occupational therapy within the first 72 hours of admission, at which point an initial Berg Balance Scale (BBS) score was obtained as appropriate. To be considered, patients had to score ≥21 on the BBS during their initial physical therapy evaluation. As defined by Berg [21], with a BBS score of ≥21, patients were considered to have a *fair global balance* rating and could walk with assistance. In this context, a fair balance rating was interpreted to be equivalent to a moderate fall risk [21]. Patients who did not meet these inclusion criteria during their initial evaluation were able to screen-in later, pending BBS reassessment. If the reassessment showed sufficient functional improvement (ie, BBS ≥21) and the patient's planned discharge date was at least two weeks after the reassessment, the patient was approached for study recruitment.

In addition to meeting the BBS score criteria, participants needed to be ≥18 years of age, be able to understand and respond to simple verbal instructions in any language, and be able to tolerate and actively participate in at least three, 30-minute, weekly sessions in the BWSS. Patients were ineligible to participate if they did not meet any one of these criteria or presented with 1 or more of the exclusion criteria shown in Textbox 1.

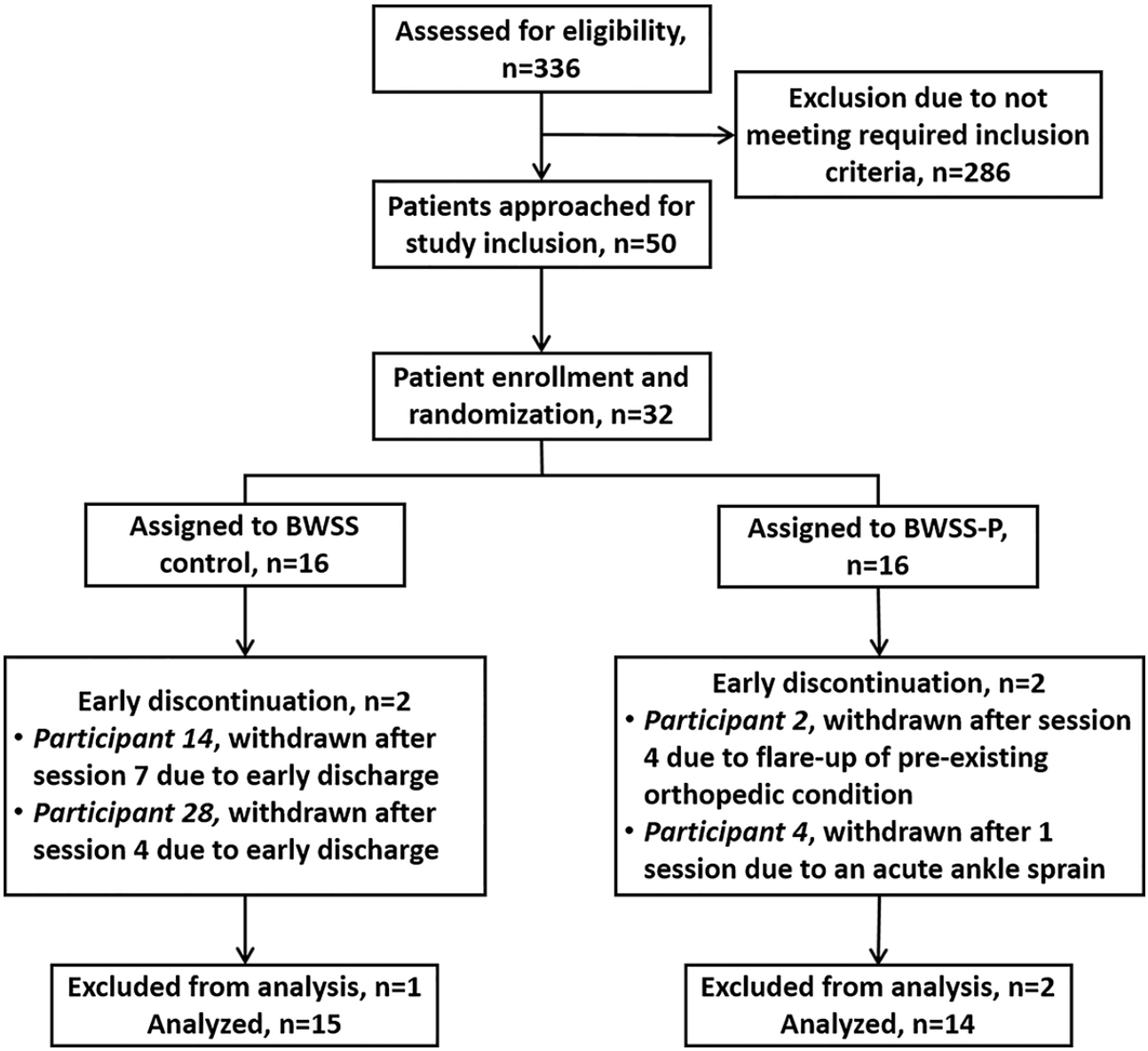
Textbox 1. Exclusion criteria for study participation.

Exclusion criteria

- Cognitive deficits that would disrupt the ability to provide informed consent
- Berg Balance Scale score <21
- Active seizure
- Spinal stabilization requiring use of Halo device
- Uncontrolled hypertension
- Uncontrolled hypotension
- Unstable skin structures (ie, skin grafts and chest tubes)
- Unstable rib or lower extremity fractures
- Osteoporosis
- Active enteric infection control precautions
- New limb amputations
- Need for >50% high flow oxygen
- Bodyweight of more than 450 pounds (204 kg), that is, the structural limitation of the body weight support system

After providing informed consent, participants were assigned in an alternating fashion by the investigators to either the BWSS control or BWSS with perturbation (BWSS-P) group. To our knowledge, this is the first instance of this technology being studied. As such, we targeted a convenience sample of at least 30 participants for preliminary evaluation. Of the 50 patients approached for inclusion, 32 (64%) were enrolled, and 29 (58%) completed the study (Figure 1).

Figure 1. Participant flowchart. Of the 336 patients admitted for stroke rehabilitation that were assessed for study eligibility, 14.9% (50/336) were approached for study inclusion. Ultimately, 64% (32/50) of participants were enrolled in the study and assigned to either the body weight support system (BWSS) control or body weight support system with perturbation (BWSS-P) groups. During the study, 13% (4/32) of participants withdrew from the study early; 50% (2/4) because of early discharge, 25% (1/4) because of a flare-up of a pre-existing orthopedic condition, and 25% (1/4) because of an acute ankle sprain. Data from 9% (3/32) of participants was excluded from the final analysis.



Patients admitted for acute stroke rehabilitation typically received 2-5 hours of skilled rehabilitative services 5-6 days per week, including physical, occupational, and speech therapies and therapeutic recreation. All participants enrolled in this study were deemed appropriate to receive this level of care.

Outcome Instruments

The BBS and the Activities-Specific Balance Confidence (ABC) scale were the primary study end points. Both assessments have been validated for use in the inpatient stroke population and have high interrater reliability [22-25]. The BBS is a standardized balance assessment that uses various balance tasks to objectively measure a person's balance and determine if a participant is at low, moderate, or high fall risk. The ABC scale is a 16-item patient-reported outcome measure that subjectively measures one's self-perceived balance confidence. The ABC scale achieves this by asking the user to consider various hypothetical situations and tasks and if they could perform them without losing balance or experiencing a sense of unsteadiness; it is based on a rating scale from 0% (no confidence) to 100% (completely confident) [8,23].

To identify eligible candidates for the study, chart reviews were regularly conducted to collect the admission BBS scores of patients with stroke, who were recently admitted. The progression of patients who were disqualified from the study because of their admission BBS scores were tracked through periodic chart reviews to determine if they had sufficiently improved to be approached for study recruitment.

During regular treatment, a 10-point modified functional independence measure (mFIM) was used to assess each participant's assistance needs when ambulating and undergoing toilet transfers. On the basis of the original 7-point functional independence measure (FIM) [26], the mFIM was developed

by our LTACH institution to better describe the progress of our patient population. The mFIM is similar to the traditional FIM in that it ranges from dependent to independent and is used to score patients in various functional domains, including ambulation and transfers. The mFIM differs by subdividing the original FIM category of *minimal assistance (category 4)* into *minimal assistance (category 4)* and *contact guard assistance (category 5)*. The original FIM category of *supervision (category 5)* is also subdivided into *close supervision (category 6)*, *supervision (category 7)*, and *distant supervision (category 8)*. The criteria used to grade each of the 10 points can be found in Table S1 in Multimedia Appendix 1.

A final chart review was conducted at the end of the study to collect the participants' BBS and mFIM scores from their physical therapy discharge documentation. The ABC scale was administered by site investigators at the time of consent and immediately after the last intervention session.

Additionally, BBS scores of patients admitted to the same stroke rehabilitation program between October 2017 and August 2018 were retrospectively collected for post hoc analysis as a historical standard of care (SOC) comparison. These retrospectively collected scores were filtered to remove initial BBS scores <21 and those collected after the launch of the BWSS at our institution in September 2018. This resulted in the inclusion of retrospective BBS data from 30 patients who were not treated with BWSS. Similar historical data were not available for ABC assessment or mFIM scores.

BWSS Equipment

For this study, the BWSS used was the Food and Drug Administration listed ZeroG Gait and Balance System (Aretech, LLC) [27]. Unlike some BWSSs, this device is mounted on an overhead track that follows patients as they ambulate, maintaining a vertical direction of unloading via the tether [27,28]. Like other BWSSs, this system is designed to unload patients of up to 200 pounds (91 kg) of body weight, while simultaneously protecting them from falling. Unlike some other systems, this device maintains the preset amount of body weight support even if there is a change in vertical displacement by the patient, that is, when navigating stairs or sitting down. For this study, only 10 pounds (4.5 kg) of participants' body weight—the minimum weight required to engage the BWSS—was continuously unloaded for participants in both the control and intervention groups. The rationale for using only 10 pounds (4.5 kg) was to minimize unloading effects and balance support provided by the straps during balance perturbation. However, if a participant were to fall, the system would still detect the change, decelerate the fall, and stop the descent after a set distance. The fall distance was set between 8 and 12 inches for this study.

Unlike other BWSSs, a newly developed balance perturbation module, known as the training response in postural rehabilitation (TRiP), is directly integrated into the ZeroG BWSS. This perturbation module is different from other systems as the balance perturbations are elicited directly through the BWSS and do not require a treadmill [11-14], tilt-table, shaking platform [14,15], or manual exertion by a therapist [16]. Further, they can be induced during normal gait and balance exercises during therapy.

BWSS and BWSS-P Exercises and Interventions

The BWSS control group interventions consisted of various balance activities, including marching, side-stepping, retro-ambulation, step-taps, and step-ups. The BWSS control group also practiced various gait tasks, including ambulation over the ground, going up and down stairs, and performing sit-to-stand transitions. The BWSS-P intervention group performed the same balance and gait activities as the control group with the addition of left and right lateral, anterior, and posterior perturbations.

Assistive devices and equipment were used during intervention sessions as recommended by the participant's primary therapist to facilitate ambulation, including canes, rolling walkers, hemi-walkers, ankle-foot-orthoses, ankle support braces, and upper extremity slings. The goal of using assistive devices was to only facilitate ambulation and *real-life* function and not necessarily protect against balance perturbations in the BWSS-P group. We believe that delivering balance perturbations while using assistive devices are transferable and appropriate challenges of real-life functions and are an important component of rehabilitation and recovery. Of note, although assistive devices were used during the study sessions, they were not used during the BBS assessments.

In the absence of balance perturbations, the BWSS motor remained positioned vertically above the participants as they moved along the track, ambulating, or performing other exercises with the investigator. As participants moved in line with the track, therapists used a Wi-Fi–enabled handheld device linked to the BWSS to elicit anterior or posterior balance perturbations during ambulation. These were induced by causing the BWSS motor to either rapidly accelerate ahead of or decelerate and reverse behind the participant. The resulting force of this acceleration or deceleration caused balance perturbation. Left and right lateral perturbations were similarly induced while the participant was in a static stance positioned under and perpendicular to the track. As demonstrated in video examples provided by the manufacturer, the rapid movement of the overhead component allowed little time for participants to prepare for the oncoming perturbation [29]. Participants in the BWSS-P group experienced 8 total perturbations in each session, 2 in each of the 4 directions described above.

All BWSS-P participants started at perturbation level *one* and progressed up to a maximum perturbation level of *ten* through the course of the study. The amount of force exerted at each perturbation level was preset by the manufacturer. The perturbation level (ie, intensity or force) used in each session was based on the participants' progress and observational analysis made by the therapist from the participants' responses to the perturbation level. If a participant was able to tolerate the initial perturbation level without exhibiting an appropriate balance reaction (including absent or aberrant ankle, hip, or stepping strategies), the perturbation level was incrementally increased until an appropriate balance reaction was exhibited [17]. If a participant was unable to recover and elicited a fall response in the system, the perturbation level was decreased by

1 level to ensure patient safety and the exercise was repeated to reinforce the exercise mechanics and participant confidence. The highest perturbation level was recorded after each session.

Participants in both study groups received 8 treatment sessions over 2 weeks. As necessary, participants received up to 2 sessions in 1 day to ensure they completed the required 8 sessions before discharge. To be pragmatic and not disrupt participant care, study sessions were incorporated into the participants' regular care. At our institution, treatment sessions were broken into 30-minute blocks. This time included patient transportation, equipment setup, and for this study, donning the BWSS harness. In general, participants received 20 minutes of active time in the BWSS for each 30-minute treatment block. All sessions were analyzed equally, despite possible variations in the length of time the participants were in the BWSS.

Data Analysis

Data were analyzed using GraphPad Prism (version 9.0.0; GraphPad Software). To compare the observed proportion of male and female in the BWSS groups, Fisher exact test was used. Additionally, the odds ratios (ORs) for the proportions and the respective 95% CIs (Baptiste Pike testing) were calculated. Participant age was also compared between groups using the nonparametric Mann–Whitney *U* test was used.

When data from multiple time points and 2 or more groups were present, we used a 2-way mixed effects model analysis of variance (ANOVA). This was to evaluate for the presence or absence of time effects independent of treatment modality, treatment modality effects independent of time, and the effect of time and treatment modality combined. Šídák multiple comparison test was then used to calculate all the in-group and between-group comparisons. The BBS, ABC, toileting transfer mFIM, and ambulation mFIM before and after intervention scores were included in this analysis.

To account for baseline BBS score differences among the BWSS, BWSS-P, and SOC groups, the degree of change for each participant was also calculated using *percent change* as follows: ([Postintervention – Preintervention] / Preintervention) × 100.

Whereas calculating the straight score change would lose information about the preintervention scores, this normalization strategy minimizes the amount of information lost by returning the degree or amount of change made by each individual relative to their preintervention score. Although BBS percent change was normally distributed for each group (Shapiro–Wilk test; SOC, *P*=.12; BWSS, *P*=.39; BWSS-P, *P*=.37), the SDs significantly differed (Brown–Forsythe test for variance; *P*<.001). As such, a 1-way Brown–Forsythe ANOVA and Dunnett T-3 multiple comparisons test for BBS percent change group comparisons was used.

To evaluate changes in the perturbation level progression, an ordinary 2-way ANOVA with Šídák multiple comparisons test was used for the entire data set. Subsets (low, moderate, and high responders) were analyzed using paired Kruskal–Wallis ANOVA with Dunn multiple comparison test.

For data represented as a box plot, each box represents the median and the 25% and 75% quartiles, respectively. The whiskers extend 1.5 and −1.5 of the IQR, respectively, triangle symbols reflect data points beyond the 1.5 IQRs, and the + symbol represents the arithmetic mean.

Results

Participant Characteristics

Of the 29 participants who completed the treatment course, 15 (52%) were alternately assigned to the BWSS control group and 14 (48%) were alternately assigned to the BWSS-P group. In the BWSS group, 87% (13/15) were men and 13% (2/15) were women **(**Table 1**)**. In the BWSS-P group, 71% (10/14) were men and 29% (4/14) were women **(**Table 1**)**. A participant in the BWSS control group did not complete the eighth and final session because of an early discharge; however, the data from their 7 completed sessions were included in the analysis. Compared with the control group, the BWSS-P group was similarly aged (*P*=.92; Table 1). Using Fisher exact test, we also observed similar proportions of men and women (*P*=.39). This was also reflected in the OR testing of the proportions (OR 2.6, 95% CI 0.47 to 15.30).

Table 1. Participant characteristics.

	BWSS[a] control (n=15)		BWSS-P[b] (n=14)		Group difference (95% CI)[c]	*P* value
	Participant, n (%)	Age (years), mean (SD; range)	Participant, n (%)	Age (years), mean (SD; range)		
Cohort (N=29)	15 (52)	57.8 (12.98; 46 to 78)	14 (48)	57.5 (14.24; 28 to 78)	−1.0 (−12 to 12)	.92
Male	13 (87)	57.5 (12.53; 42 to 73)	10 (71)	57.4 (11.31; 41 to 78)	−1.0 (−13 to 11)	.76
Female	2 (13)	60.5 (20.51; 46 to 75)	4 (29)	57.8 (22.25; 28 to 78)	−0.5 (−47 to 32)	.99

[a]BWSS: body weight support system.

[b]BWSS-P: body weight support system with perturbation.

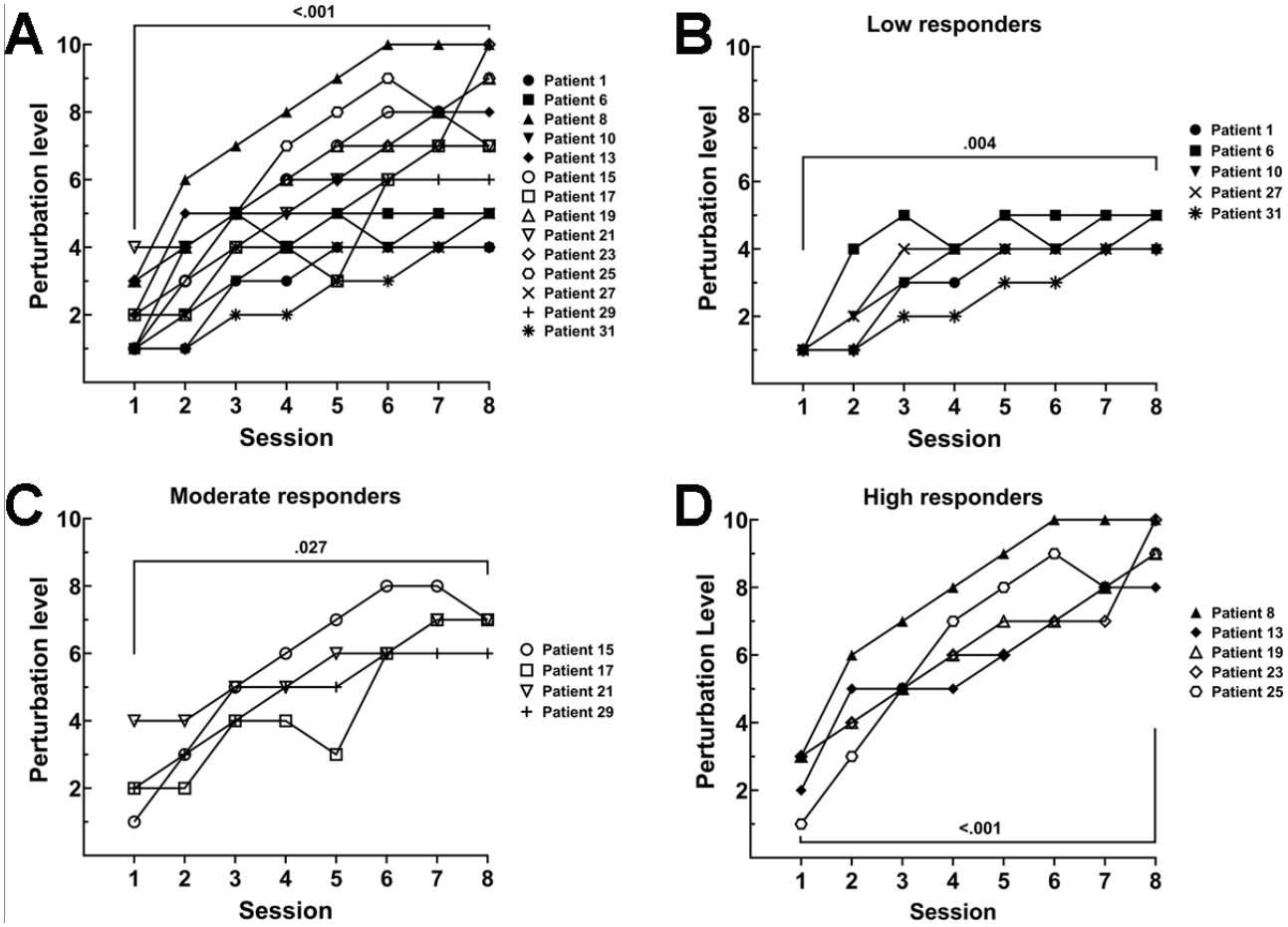
[c]Nonparametric Mann–Whitney *U* test was used; group differences and reported 95% CI are based in differences of the medians.

Throughout the study, most participants tolerated the BWSS induced perturbations well. However, 2 (6%) of the 32 original participants enrolled in the BWSS-P group did not complete all 8 therapy sessions because of injury. A participant experienced an unexpected flare-up of a pre-existing chronic orthopedic condition unrelated to the BWSS perturbation module after session 4. A second participant had an acute ankle sprain during ambulation in the BWSS during session 1. The nature of this injury was deemed likely because of a combination of the BWSS perturbation module and ankle instability secondary to the participant's stroke. A third participant also withdrew early from the study because of an early discharge after session 4. The data from these 3 individuals was excluded from analysis (Figure 1).

BWSS Perturbation Level Progression

From the BWSS perturbation module, the highest perturbation level achieved for each patient in each session was recorded. Although the final perturbation level achieved by the final session varied, all participants showed increases in perturbation level by the end of the study (P<.001; Figure 2A).

Figure 2. Perturbation level progression. From the body weight support system, the highest perturbation level achieved was recorded for each participant, after each therapy session. Each participant who completed the study successfully increased their perturbation level between the first and last study-related therapy session (A). The perturbation level progression for the participants that completed the study could be broken down into three categories: low responders (B), moderate responders (C), and high responders (D). *P* values shown are for the comparison of session 1 and session 8 perturbation levels.



Interestingly, no statistical difference in perturbation level was observed between sessions 6, 7, and 8 (Table S2 in Multimedia Appendix 1). Further, these data can be divided into 3 categories. First, the *low responders* showed early perturbation level progression but plateaued early, peaking at perturbation levels 4-5 (Figure 2B). The *moderate responders* showed steady progress throughout the study, peaking between perturbation levels 6-8 (Figure 2C). The *high responders* rapidly progressed through the BWSS-P levels, peaking between BWSS-P levels 9-10 (Figure 2D).

Evaluation of Participant BBS Scores

To evaluate pre- and postintervention BBS data (Table 2), a 3 column × 2 row 2-way mixed effects ANOVA was used. This analysis showed that there was a significant main effect ($F_{DFn, DFd}$) associated with time ($F_{1,56}$=283.5; P<.001) on BBS scores with grouped postintervention scores (mean 48.02) being greater than grouped preintervention scores (mean 33.61). Further, there was a significant main effect of treatment modality ($F_{2,56}$=9.609; P<.001) on BBS scores, with the pooled group mean of the SOC (mean 45.35) being greater than the BWSS-P (mean 39.36) and BWSS (mean 37.73). Finally, there was also a significant interaction effect between time and treatment modality ($F_{2,56}$=7.902; P<.001).

Table 2. Summary of Berg Balance Scale assessments.

Group	Preintervention, mean (SD; range)	Postintervention, mean (SD; range)	Score change[a], mean (SD)	Percent change[b], mean (SD)
SOC[c] (n=30)	40.20 (7.66; 25-52)	50.50 (5.41; 33-56)	10.30 (5.11)	28.31 (17.25)
BWSS[d] (n=15)	30.20 (6.41; 21-41)	45.27 (6.67; 34-54)	15.07 (5.61)	53.29 (24.13)
BWSS-P[e] (n=14)	30.43 (7.97; 21-47)	48.29 (6.94; 35-56)	17.86 (8.57)	66.95 (43.78)

[a]Score change was calculated as (postintervention – preintervention).

[b]Percent change was calculated as (([postintervention – preintervention] / [preintervention]) ×100%).

[c]SOC: standard of care.

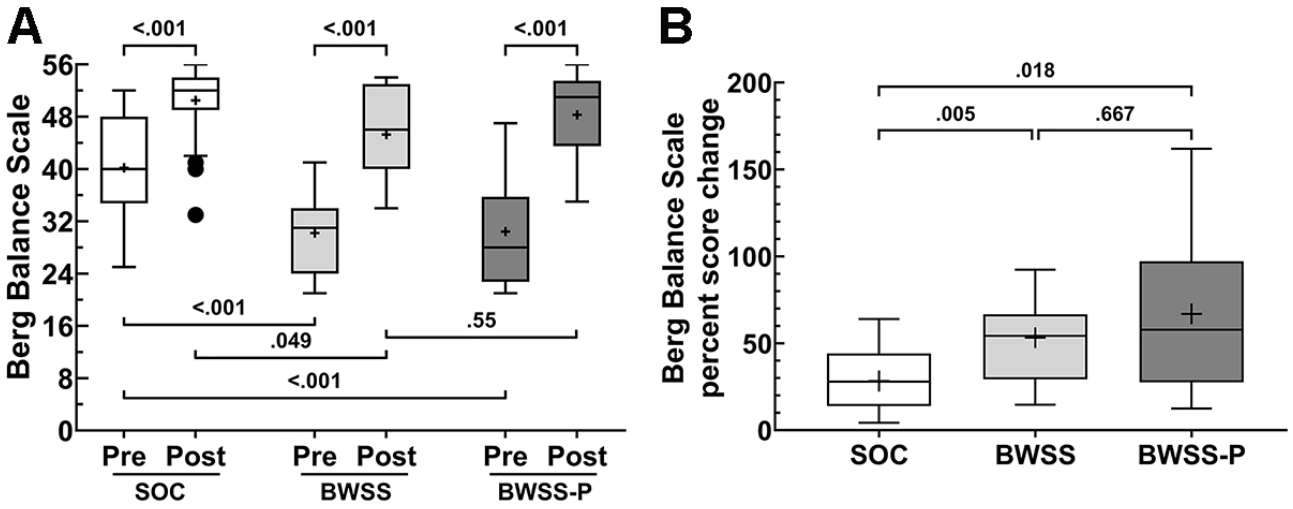
[d]BWSS: body weight support system.

[e]BWSS-P: body weight support system with perturbation.

Šídák multiple comparisons test was used to determine if any in-treatment group comparisons were different. All in-treatment group comparisons were significantly different (P<.001), highlighting the time effect noted in the 2-way mixed effects ANOVA (Figure 3A; Table S3 in Multimedia Appendix 1). Evaluating the between-group comparisons at the 2 different time points, we observed that the mean preintervention BBS score of the SOC group was significantly higher than the mean preintervention BBS score of both the BWSS and BWSS-P groups (P<.001); the BWSS and BWSS-P preintervention BBS scores did not differ (P=.99). In addition, the mean postintervention BBS score of the SOC group was significantly higher than the BWSS mean postintervention BBS score of the BWSS group (P=.049) but not that of the BWSS-P group (P=.68); BWSS and BWSS-P postintervention BBS scores were not different (P=.55; Figure 3A; Table S4 in Multimedia Appendix 1).

We assessed the degree of change for each individual by calculating the percent change (Figure 3B; Table 2) and analyzing group differences using a 1-way Brown–Forsythe ANOVA ($F^*_{DFn,\ DFd}$). This analysis indicated that there were significant between-group interactions ($F^*_{2.00,\ 23.4}$=7.859; P=.003). Although the mean pre- and postintervention BBS scores were similar among groups, multiple comparison testing showed the percent change for the BWSS-P group (n=14; mean 67%, SD 43.8%) was greater than the SOC group (n=30; mean 28.3%, SD 17.3%; P=.02). The percent change in the BWSS control group (n=15; mean 53.3%, SD 24.1%) was also greater than that in the SOC group (P=.005). Although the percent change of the BWSS-P group was marginally greater than that of the BWSS control group, it was not significantly different (P=.67).

Figure 3. Berg Balance Scale assessment (BBS). Participant's pre- and postintervention BBS assessment scores were used to track their improvement and response to the therapy. In addition to the body weight support system (BWSS) control and body weight support system with perturbation (BWSS-P) protocols, data from 2018, before the implementation of the BWSS, served as a historical standard of care (SOC) comparison group. Raw scores were first examined in aggregate (A). BBS percent change was calculated for each participant to show the magnitude of change between pre- and postintervention scores (B). In panel A, P values are shown only for comparisons that are significantly different or of clinical interest. Box plots represent the median and the 25% and 75% quartiles, respectively. The whiskers extend 1.5 and −1.5 of the IQR, respectively; circle symbols reflect data points beyond the 1.5 interquartile ranges; + symbols represent the mean; SOC: n=30, BWSS control: n=14 to 15, BWSS-P: n=13 to 14.



Assessing Participant Functional Independence With Ambulation and Transfers

Using the institution's mFIM scoring (Table S1 in Multimedia Appendix 1), participants' functional independence during ambulation and toilet transfers at admission and discharge was assessed using a 2 column × 2 row 2-way mixed effects ANOVA.

For ambulation mFIM scores, where the mean ambulation assistance score increased in both the BWSS control (4.36, SD 1.03, to 7.80, SD 1.20) and BWSS-P treatment (4.75, SD 0.83, to 8.64, SD 0.93) groups, this analysis showed a significant time effect ($F_{DFn,\ DFd}$) associated with mFIM ambulation scores ($F_{1,27}$=257.9; P<.001), with grouped postintervention scores (mean 8.22) being greater than grouped preintervention scores (mean 4.54). Further, a significant treatment modality effect ($F_{1,27}$=4.26; P=.049) associated with mFIM ambulation scores was observed, with the BWSS-P group mean (mean 6.70) being modestly greater than that for the BWSS group (mean 6.07). Finally, no significant interaction effects were observed between time and treatment modality ($F_{1,27}$=0.99; P=.33) for ambulation mFIM scores.

Using Šídák multiple comparisons test, we observed that in-group preintervention versus postintervention comparisons were significantly different (P<.001). Both between-group preintervention ambulation mFIM scores (P=.47) and postintervention scores (P=.06) did not differ (Figure S1A in Multimedia Appendix 1; Tables S5 and S6 in Multimedia Appendix 1).

Similarly, the mean toilet transfer mFIM scores increased in both the BWSS control (4.30, SD 0.59 to 7.70, SD 1.16) and BWSS-P treatment (4.89, SD 0.79, to 8.39, SD 1.04) groups. The 2-way mixed effects ANOVA analysis showed a significant time effect ($F_{DFn,\ DFd}$) on mFIM toilet transfer scores ($F_{1,27}$=257.9; P<.001), with grouped postintervention scores (mean 8.05) being greater than grouped preintervention scores (mean 4.60). Further, there was a significant main effect of treatment modality ($F_{1,27}$=5.79; P=.02) on mFIM toilet transfer scores, with BWSS-P group mean (mean 6.64) again being marginally greater than the BWSS group (mean 6.00). Finally, there was no significant interaction effect observed between time and treatment modality ($F_{1,27}$= 0.05; P=.82).

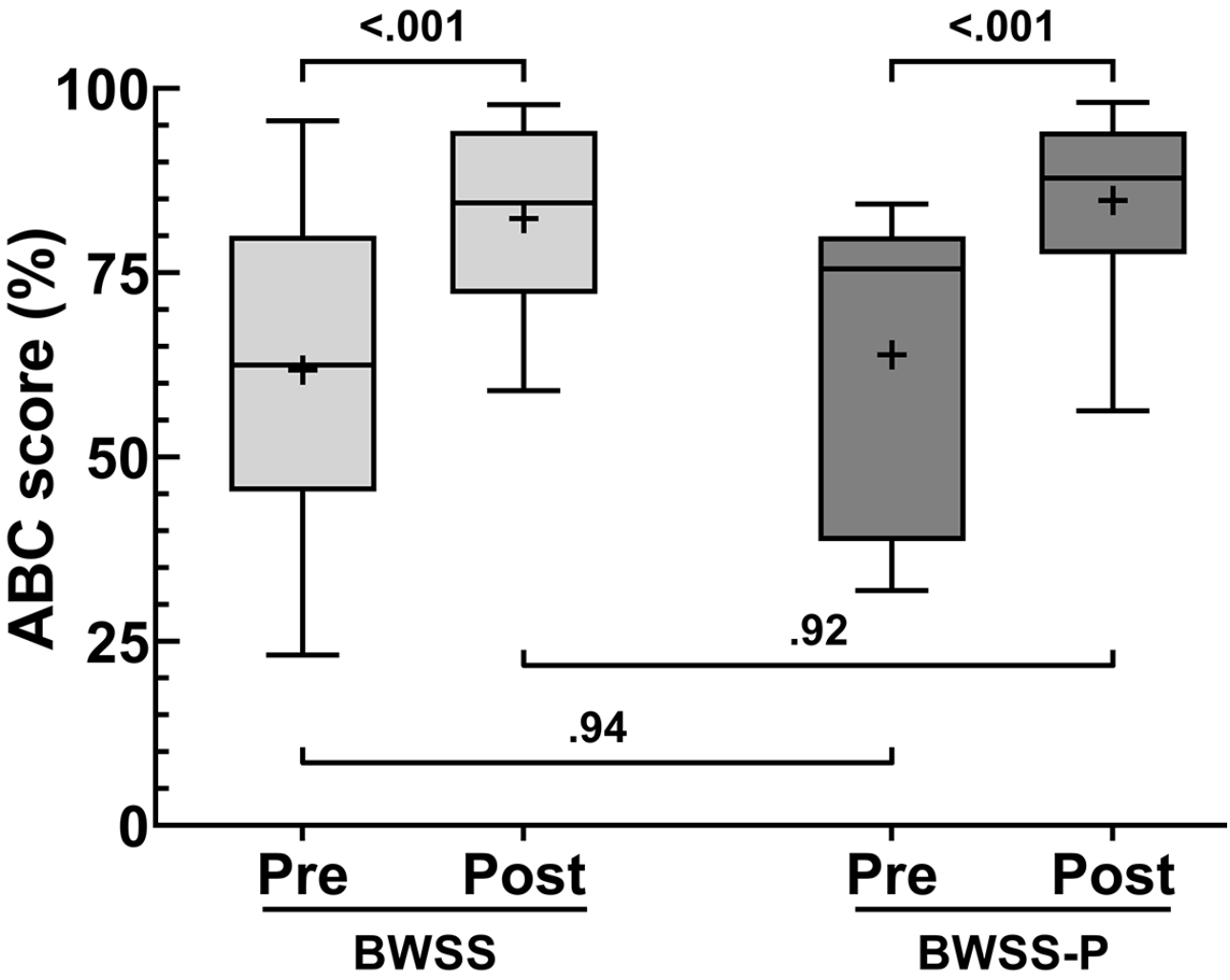
Using Šídák multiple comparisons test, we observed that the in-treatment group preintervention versus postintervention comparisons were significantly different (P<.001). Both between-group preintervention scores (P=.17) and postintervention mFIM toilet transfer scores (P=.09) were not different (Tables S7 and S8 and Figure S1B in Multimedia Appendix 1).

Measuring Participant Self-reported Balance Confidence

Participants' self-confidence in performing daily tasks was also evaluated using the ABC scale. The mean ABC scores (%) increased in both the BWSS control (61.81, SD 22.55, to 82.38, SD 13.43) and BWSS-P treatment (63.88, SD 20.34, to 84.81, SD 11.52) groups. A 2-way mixed effects ANOVA identified a significant time effect ($F_{DFn,\ DFd}$) on ABC scores ($F_{1,26}$=34.26; P<.001), with grouped postintervention scores (mean 83.59) being greater than grouped preintervention scores (mean 62.85). Unlike the BBS and mFIM scores described up to this point, a significant treatment modality effect ($F_{1,26}$=0.16; P=.69) was not observed, with the BWSS-P group mean (mean 74.35) being only marginally greater than the BWSS group (mean 72.09). Further, an interaction effect between time and treatment modality ($F_{1,26}$=0.05; P=.82) was not observed (Table S6 in Multimedia Appendix 1) for the ABC scale score.

Using Šídák multiple comparisons test, we observed that in-group preintervention versus postintervention comparisons were significantly different for ABC scores (BWSS: P<.001; BWSS-P: P<.001). Between-group preintervention scores (P=.94) and postintervention scores (P=.92) were not significantly different (Figure 4; Tables S9 and S10 in Multimedia Appendix 1).

Figure 4. Activities-Specific Balance Confidence (ABC) scale assessment. The ABC scale was given to participants before and after the intervention to gauge their confidence in performing daily tasks. The box plot represents the median and the 25% and 75% quartiles, respectively. The whiskers extend 1.5 and −1.5 of the IQR, respectively; + symbols represent the mean; body weight support system (BWSS) control: n=14 to 15, body weight support system with perturbation (BWSS-P): n=13 to 14.



Discussion

Principal Findings

We conducted this preliminary study to evaluate the effectiveness of a new BWSS-integrated balance perturbation training module. If effective, this tool may be able to further improve patient balance after an acute stroke. This module induced controlled reactive and potentially anticipatory balance perturbations during normal gait and balance exercises without using a treadmill or other equipment. Participants in the BWSS and BWSS-P groups demonstrated similar improvements in BBS, ABC assessment, ambulation mFIM scores, and toileting transfer mFIM scores. This indicates that the BWSS-P protocol is not detrimental and may benefit postacute stroke rehabilitation. With retrospectively collected BBS data from 2018 serving as a retrospective post hoc SOC comparison group, both BWSS groups displayed greater BBS percent score changes than the SOC group. These data support the overall conclusion that this new BWSS balance perturbation module may help improve patient balance after acute stroke when following a prescribed treatment and rehabilitation plan. However, additional research is required to definitively determine the full benefits of this technology in rehabilitation.

Conventional balance perturbation training, including modified treadmills [11-14], tilt-tables [14,15], or external force provided by the therapist directly [16], may pose an injury risk to the therapist and the patient. In addition, if a patient experiences an injurious fall during treatment, it may further contribute to a fear of falling after stroke. Although the incorporation of BWSSs over treadmills decreases the injury risk, this is not representative of functional ambulation in patients' homes or community environments [30,31]. Further, these strategies are stationary and limit the types of activities and exercises that can be performed during balance perturbation (eg, navigating a turn). Systems such as these may also limit the participation of some patients who would otherwise benefit from reactive balance perturbation training, such as those uncomfortable or unable to ambulate on a treadmill.

Therapists also have the option of inducing balance perturbations by manually exerting an external force (ie, pulling or pushing the patient) while a patient is in a BWSS. Although more accessible than using specialized equipment, both the application of force by the therapist and the amount of perturbation

experienced by the patient are subjective and could be difficult to control and replicate consistently. Integration of the balance perturbation module in the BWSS described here resolves many of these issues, including allowing for freedom of movement to perform most gait and balance exercises in a dynamic environment, increasing the accessibility for eligible patients, and performing perturbations in a consistent, repeatable, and quantitative manner, while optimizing therapist and patient safety.

The ABC scale was used to determine how the BWSS-P would affect participants' self-perceived balance confidence when asked to consider hypothetical scenarios that would challenge their balance. Interestingly, our analysis found that although a significant time effect was observed, an effect associated with treatment modality was not present. This suggests that BWSS and BWSS-P are equally effective in improving participants' balance confidence. However, we were unable to determine whether these scores were better than those in the SOC group.

Limitations, Caveats, and Considerations for Future Studies

As this was the first study to evaluate this novel technology, we can identify several limitations and caveats that need to be considered when interpreting the data and planning future studies.

In this study, we retrospectively included BBS data from the year leading up to the implementation of the BWSS. The rationale for this was to include these data as a post hoc historical SOC comparison group, representative of therapy with no BWSS. Although including a prospective *No BWSS* group would have led to cleaner comparisons, our stance is this would have been unethical, as it would have meant withholding care known to benefit patient outcomes. It is well documented that rehabilitative gait and balance training in BWSSs largely benefit patient rehabilitation. Therefore, we were unable to collect data for all outcomes of the SOC group, as they were not regularly collected during normal care (ie, ABC score) or were not readily available (ie, mFIM scores).

Further, the admission BBS scores of the SOC group were approximately 10 points higher than those of the BWSS groups because the preintervention scores started at a higher baseline; it was not unexpected that the postintervention BBS scores were higher. To account for this, we could have curated the SOC data set to be case-matched to the BWSS control group, so the range and mean of the preintervention scores were similar. However, to avoid any selection bias that might have been introduced, we normalized the data by calculating the percent change.

An important caveat to note is that the study activities were only a small part of the participants' overall treatment strategy. Several factors, including physical therapy outside the study and natural progression, were likely to have contributed to improvements in patient status and function. As we were unable to control for what physical therapy (ie, gait and balance training) activities occurred outside of the study sessions, we included the BWSS control and historical SOC comparison groups.

Improvements to the BWSS perturbation module alone were made difficult, as both BWSS groups showed similar BBS score improvements. Although the mean scores were not significantly different, the variability of the initial BBS scores of the BWSS study groups may have limited our ability to accurately determine the impact of the perturbation module. This variability, in part, is reflective of the diverse patient population that was recruited; any qualifying inpatients with stroke and with a BBS of ≥21 were approached. Although calculating the percent change for each participant works to address this, this variability can be improved in one of several ways.

First, the data analysis could be stratified to compare the amount of change or improvement by admission BBS scores. This would allow us to better refine what populations benefit the most from this treatment. Second, an upper BBS score could be incorporated into the inclusion criteria. For example, for patients with an acute stroke, a BBS score of 45 (out of 56) has been used to describe normal functional ability after stroke [24]. Finally, a matched-control method could be implemented to ensure that the same range of initial BBS scores were represented in the BWSS groups. However, as described above, this strategy is not ideal, as it can introduce implicit selection biases. In any case, a larger population will be required in future studies to achieve the appropriate power needed to fully determine the impact of the BWSS perturbation module.

Variability in the timing of the postintervention BBS assessments may have also contributed to the lack of significant differences among the BWSS groups. The postintervention BBS scores were obtained by the participants' primary physical therapist at the time of their discharge. Most participants had discharge dates close to the last session of the study intervention. However, this does not account for any progress the participant might have made after the last session leading up to their discharge date, especially if there were unexpected delays to discharge. To address this in future studies, we propose delivering a separate BBS assessment within 48 hours of the last session, if the participant's discharge assessment was not already collected during that time.

Most participants completed the study-related sessions over a 2-week period; however, this study was partly conducted during the early months of the COVID-19 pandemic (March-August 2020). This environment may have shortened the time that eligible patients were willing to spend in the inpatient setting if they were able to safely navigate the home environment with the assistance of family members. As a result, many patients who met the inclusion criteria for the study did not remain inpatients long enough to receive the required 8 sessions. As a further consequence of expedited discharge dates because of COVID-19, 34% (10/29) of the participants, at least once, needed to receive 2 sessions per day to complete all 8 sessions; in 1 case, the patient was discharged before they were able to complete the last treatment session. It is unclear if the increased intensity positively or negatively contributed to the rate of progress.

To address the possibility of irregular lengths of stay in the future, we propose evaluating and comparing the dose-response relationship of the balance perturbation module over 2-6

sessions, as well as the total time in the system. We feel it is rational to reduce the number of total sessions as there was no significant difference in perturbation level progression following session 6 (Table S2 in Multimedia Appendix 1) and it would open up the recruitment pool to eligible patients with a shorter length of stay and allow us to refine the optimal dosing. Additional studies could also investigate how many sessions per day and per week are most effective at improving balance control, reaction, and confidence.

Despite these limitations, this preliminary study was strengthened by the quasi-randomized controlled design and low participant dropout rate (3/32, 9%). Further, the incorporation of the post hoc historical SOC BBS data strengthened the study as it allowed for comparisons to be made with a population without BWSS treatment. With 52 years of combined physical therapy rehabilitation experience, the study was further reinforced by the advanced specialty and board certifications of the treating investigators.

This preliminary study allowed for the development of a feasible protocol and provided the preliminary data needed to calculate effect size, conduct power analysis, and estimate an appropriate sample size for future studies. With an appropriately powered sample size, we believe the effect of this BWSS-P protocol and technology on patient balance rehabilitation after stroke, compared with BWSS alone, could be better generalized than what we were able to conclude in this preliminary study. Furthermore, such studies could examine how other variables (ie, stroke location and other compounding diagnoses) impact patient progress and response to balance perturbation training. Incorporating additional dynamic gait assessments that more closely resemble functional movement patterns and reactive balance–specific outcome measures, such as the dynamic gait index or functional gait assessment [32,33], may also help us to better understand the full implications of this new balance perturbation module.

Conclusions

This study has multiple implications for clinical practice in inpatient rehabilitation settings. The BWSS-P protocol positively impacted the balance performance of a subset of inpatients with stroke, who scored ≥21 on their BBS assessment. Not only did the BWSS-P improved participants' balance and decreased their fall risk compared with the SOC and BWSS alone it also improved participants' overall confidence and reduced their fear of falling, similar to that observed using the BWSS alone. As the prevalence of BWSS-integrated balance perturbation modules, such as the track-mounted ZeroG TRiP system, continues to grow, there will be a number of opportunities for continued research and development in this area.

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Conflicts of Interest

None declared.

Editorial Notice: This randomized study was retrospectively registered, explained by authors as an administrative oversight in early stages of study planning. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials, because the risk of bias appears low and the study was considered formative, guiding future development of the application. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1
Referenced supplemental materials and the completed CONSORT (Consolidated Standards of Reporting Trials) 2010 checklist.
[PDF File (Adobe PDF File), 699 KB - rehab_v9i1e31504_app1.pdf]

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Abbreviations

ABC: Activities-Specific Balance Confidence
ANOVA: analysis of variation
BBS: Berg Balance Scale
BWSS: body weight support system
BWSS-P: body weight support system with perturbation
CONSORT: Consolidated Standards of Reporting Trials
FIM: Functional Independence Measure
LTACH: long-term acute care hospital
mFIM: modified functional independence measure
OR: odds ratio
SOC: standard of care
TRiP: training response in postural rehabilitation

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Review

Remote Assessments of Hand Function in Neurological Disorders: Systematic Review

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Abstract

Background: Loss of fine motor skills is observed in many neurological diseases, and remote monitoring assessments can aid in early diagnosis and intervention. Hand function can be regularly assessed to monitor loss of fine motor skills in people with central nervous system disorders; however, there are challenges to in-clinic assessments. Remotely assessing hand function could facilitate monitoring and supporting of early diagnosis and intervention when warranted.

Objective: Remote assessments can facilitate the tracking of limitations, aiding in early diagnosis and intervention. This study aims to systematically review existing evidence regarding the remote assessment of hand function in populations with chronic neurological dysfunction.

Methods: PubMed and MEDLINE, CINAHL, Web of Science, and Embase were searched for studies that reported remote assessment of hand function (ie, outside of traditional in-person clinical settings) in adults with chronic central nervous system disorders. We excluded studies that included participants with orthopedic upper limb dysfunction or used tools for intervention and treatment. We extracted data on the evaluated hand function domains, validity and reliability, feasibility, and stage of development.

Results: In total, 74 studies met the inclusion criteria for Parkinson disease (n=57, 77% studies), stroke (n=9, 12%), multiple sclerosis (n=6, 8%), spinal cord injury (n=1, 1%), and amyotrophic lateral sclerosis (n=1, 1%). Three assessment modalities were identified: external device (eg, wrist-worn accelerometer), smartphone or tablet, and telerehabilitation. The feasibility and overall participant acceptability were high. The most common hand function domains assessed included finger tapping speed (fine motor control and rigidity), hand tremor (pharmacological and rehabilitation efficacy), and finger dexterity (manipulation of small objects required for daily tasks) and handwriting (coordination). Although validity and reliability data were heterogeneous across studies, statistically significant correlations with traditional in-clinic metrics were most commonly reported for telerehabilitation and smartphone or tablet apps. The most readily implementable assessments were smartphone or tablet-based.

Conclusions: The findings show that remote assessment of hand function is feasible in neurological disorders. Although varied, the assessments allow clinicians to objectively record performance in multiple hand function domains, improving the reliability of traditional in-clinic assessments. Remote assessments, particularly via telerehabilitation and smartphone- or tablet-based apps that align with in-clinic metrics, facilitate clinic to home transitions, have few barriers to implementation, and prompt remote identification and treatment of hand function impairments.

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KEYWORDS

neurological disease; hand function; remote assessment; assessment; telemedicine; rehabilitation; telerehabilitation; review; neurological; hand; function; diagnosis; intervention; dysfunction; feasibility; mobile phone

Introduction

Background

Normally functioning human hands allow everyday participation in self-care, work, and leisure activities that involve precise grip and object manipulation [1]. Specifically, daily activities and fine motor tasks require finger dexterity, thumb-finger opposition, and hand opening-closing, which adapt to task requirements, including those needed to navigate the *digital world*. [2] Unfortunately, chronic disorders of the central nervous system (CNS) can impair hand function even during the early stages of the disease [3]. Damage to the CNS, including the spinal cord, can result in tremor, spasticity, sensory loss, weakness, and coordination loss in the upper limbs, which can negatively impact the ability to adapt to task requirements, thus limiting independence in activities of daily living (ADL) and quality of life [3]. For example, most individuals with Parkinson disease (PD) develop hand tremors over the course of the disorder, leading to difficulty with precise finger and hand movements [4]. In addition, ischemic strokes occur most commonly in the cortical regions supplied by the middle cerebral artery [5], affecting areas of the motor and sensory cortices responsible for the fine motor activity of the hands [6]. In these disorders and others, evaluating hand function at regular intervals can detect changes signaling neurological decline, or monitor response to disease-modifying therapies, symptomatic therapies, or rehabilitation.

Although assessments of hand function are routinely performed in clinics, clinicians have an increasing interest in deploying tools to measure hand function remotely. In-home remote monitoring of function, in general, provides benefits to patients by increasing convenience, reducing travel, and providing the ability to capture data more frequently. Over the past decade, many studies have examined remote monitoring devices in neurological and nonneurological populations [7,8]. For example, in multiple sclerosis (MS), studies have shown that continuous remote monitoring of ambulatory step count can capture—and even predict—changes in MS-related disability and can serve as a longitudinal outcome measure for targeted interventions [9,10]. To date, reviews have mainly focused on lower extremity function or overall physical activity [11]; in fact, the methodological discrepancies in remote device use and reporting regarding hand function have yielded conflicting results in terms of validity, reliability, and ease of clinical use.

Objectives

In this systematic review, we evaluate the existing evidence regarding remote assessment devices for hand function in populations with chronic CNS disorders. We specifically examine evidence of validity, reliability, and feasibility for each domain of hand function and the stage of development of the assessments. Our findings are expected to facilitate ready implementation of remote assessment of hand function in prevalent neurological disorders.

Methods

Eligibility Criteria

This review was structured using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [12] framework. Studies were included based on the following criteria: (1) participants had chronic neurological pathologies of the CNS, (2) participants were aged ≥18 years, (3) the studies were peer reviewed and original, (4) the studies were designed to objectively assess hand function, and (5) the assessments were deployable remotely (ie, outside of traditional in-person clinical settings). Studies were excluded if they were (1) conducted in participants with orthopedic impairments of the wrist or hand, (2) conducted in nonhuman primates, (3) designed as an intervention to improve an aspect of hand function (as the intent was to focus on assessment tools rather than a change of function), or (4) not published in English.

Search Procedures

A literature search was performed using the following databases: PubMed and MEDLINE, CINAHL, Web of Science, and Embase. The search was conducted using both Medical Subject Heading terms and the following keywords independently and in combination: *remote*, *assessment*, *outcome*, *test*, *measurement*, *hand*, *upper extremity*, *arm*, and *function*. Independently, 2 researchers (AG and WYH) assessed articles for relevance and adherence to the eligibility criteria. Studies were recursively searched to identify cited and cited-by articles.

Data Extraction and Categorization

To evaluate the methodological quality of the included studies, we used the National Institutes of Health quality assessment for observational cohort and cross-sectional studies [13]. Each study was evaluated according to 8 criteria. The overall study quality was assessed as *good* (>5 criteria met), *fair* (4-5 criteria met), or *poor* (<5 criteria met).

The data were extracted (AG) and checked (WYH); discrepancies were resolved through discussion with the senior author (RB). The variables of interest included participant demographics, study design and duration, device type and modality, disease-specific severity levels, comparison assessments, and stage of development and implementation (to understand whether assessments were currently available for use). Participant satisfaction with the study protocol and assessment and time taken to complete the novel assessment were extracted when available. Extracted statistical data included concurrent validity (defined as the comparison between a new test and a well-established one [14]) and reliability (defined as a measure of stability or consistency [15]).

The selected studies evaluated many variables relating to hand function. To compare the most salient domains across studies, we classified assessments into the following hand function domains based on the Functional Repertoire of the Hand established by the American Journal of Occupational Therapy

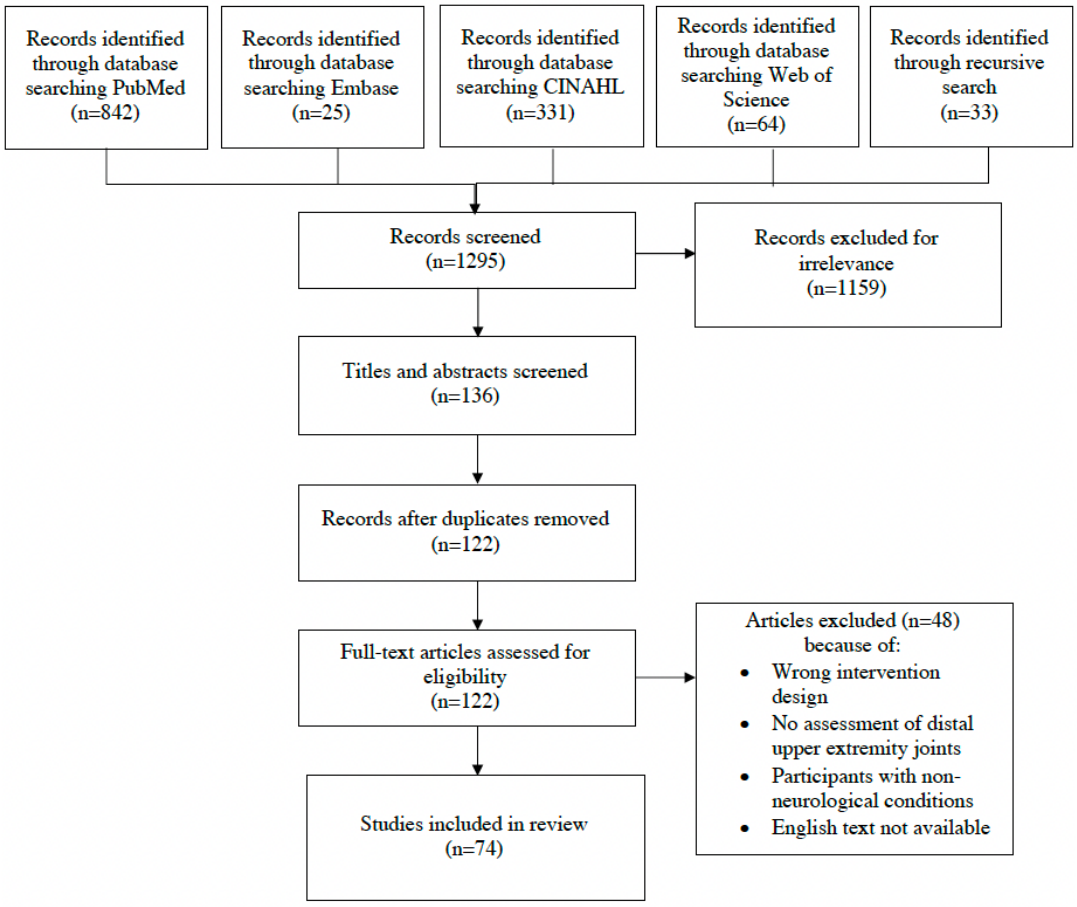
[16]: (1) finger tapping, which is the speed and accuracy of finger taps onto a prespecified target; (2) whole hand grasp, which is the range of motion and coordination of full hand movement; (3) pincer grasp, which is the range of motion and coordination of thumb to index finger movement; (4) hand tremor, which is the quantification of tremor distal to the wrist at rest; (5) reaction time, which is the time taken to respond to a predetermined stimulus using only fingers; (6) pinch and grip strength, which is the quantification of the maximum pinching and gripping strength; (7) finger dexterity, which is the in-hand manipulation of an object; (8) handwriting, which is the clarity and accuracy in drawing or writing; (9) ADL, encompassing tasks required for self-care independence [17]; and (10) instrumental ADL (IADL), encompassing tasks required for household or community-level independence [18].

Results

Search Strategy

A search of databases in June 2021 identified 1295 studies, and 33 additional studies were identified through recursive searches. After title and abstract screening and removal of duplicates, 9.42% (122/1295) of studies remained, and the full texts were assessed for eligibility based on the inclusion and exclusion criteria. Approximately 41% (50/122) of full-text studies were excluded for not meeting the inclusion criteria. The final 74 studies were confirmed by a second reviewer (WYH) to have met all eligibility criteria. The PRISMA diagram of the search process is outlined in Figure 1, and individual studies are summarized in Multimedia Appendix 1 [19-90]. Of the 74 studies reviewed, 49 (66%) were rated *good* in terms of overall methodological quality, 14 (19%) were rated *fair*, and 9 (12%) were rated *poor*. Study quality is summarized in Multimedia Appendix 2 [19-90].

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



Modalities of Hand Function Assessment

Across the included studies, 3 different modalities of assessment devices were used, summarized in Multimedia Appendix 1. The most frequently used assessment was an external device specific to hand assessment, with the most common types being wrist-worn accelerometers [19-37] and specialized keyboards [38-47]. These designated external devices allowed the collection of information on reaction time, finger tapping speed, and finger dexterity. Although many study authors noted that their external devices were able to capture granular, specific data, many devices were developed under proprietary agreements and are not currently commercially available. The second most common type of assessment was generic smartphone- or tablet-based electronic devices adapted for hand assessment [48-59] or suites of assessments [60-66]. These assessments included an app designed to test finger tapping speed and the accuracy of drawing and tracing various shapes. Such apps facilitated the gathering of data on specific hand

function domains at a relatively low cost for people who already had these electronic devices. Finally, 4% (3/74) of studies used telerehabilitation platforms to validate remote administration of well-established in-clinic assessments [67-69]. For example, Amano et al [69] validated the administration of the Fugl-Meyer Assessment and Action Research Arm Test (ARAT) via telehealth platforms, allowing clinical researchers to gather standardized outcome data through secure telehealth tools.

Most of the included studies (51/74, 69%) performed same-day, cross-sectional validation experiments where participants completed novel and comparative assessments at the same time point. However, 28% (21/74) of studies [23,25,36,37,42,46,47,61,63,64,66,70-80] remotely monitored participants' hand function longitudinally. The duration of the remote monitoring period was 3 days [37] to 3 years [77]. Participant retention and adherence were reported by 5% (4/74) studies [61,66,75,76], all of which had >90% participant retention.

Target Population

The included studies targeted 5 populations of patients with neurological conditions. Most studies (57/74, 77%) included individuals with PD [37,45,65,67,68,70,73,81]. Other populations evaluated were those with stroke (9/74, 12%) [71,72,82] and MS (6/74, 8%) [59,66,91]. Neurological conditions designated as spinal cord injury [83] and amyotrophic lateral sclerosis [47] were described in 1% (1/74) of studies each.

Most included studies evaluated individuals with mild to moderate disease severity on average, as graded by established disease-specific metrics (eg, the Movement Disorder Society–Unified Parkinson's Disease Rating Scale [MDS-UPDRS] and the Expanded Disability Status Scale for people with MS) [37,45,59,65,67,69,70,73,82]. Only 8% (6/74) of studies specified the inclusion criteria to limit recruitment to participants with mild to moderate disease severity [37,41,53,58,63,71].

The sample sizes of studies varied between 1 (case study) [26] and 495 participants [66] in the experimental groups. Most studies (41/74, 55%) included control groups of healthy individuals or those with nonneurological conditions in determining the discriminant validity of the assessments (Multimedia Appendix 1).

Validity and Reliability

Validity data were reported by 73% (54/74) of heterogeneous studies for comparison with well-established in-clinic assessments (Table 1). Approximately 12% (9/74) of studies examining external devices reported high, statistically significant correlations with well-established assessments [19,20,47,50,52,72,73,83,91]. In addition, 8% (6/74) of studies using smartphone assessments [28,49,52,66,79,84] and 1% (1/74) of studies using telerehabilitation [69] found moderate to high, statistically significant correlations with well-established assessments.

Table 1. Validity and reliability.

Study	Comparison assessment	Validity	Reliability
Adams [46]	—[a]	• Hand tremor (AUC[b]=0.76)	—
Aghanavesi et al [48]	MDS-UPDRS[c]	• Finger tapping (r=0.23) • Handwriting (r=0.46)	Interrater reliability: • Finger tapping (r=0.61) • Handwriting (r=0.65)
Akram et al [38]	MDS-UPDRS	• Finger tapping (r=−0.49; *P*<.001)	—
Albani et al [73]	MDS-UPDRS	• Finger tapping (ICC[d]=0.73)	—
Amano et al [69]	In-clinic assessment	• Finger dexterity (r=0.99) • Whole hand grasp (r=0.99) • Pincer grasp (r=0.99)	Interrater reliability: • Finger dexterity (r=0.99)
Arora et al [70]	MDS-UPDRS	• Finger tapping (mean error of 1.26 UPDRS[e] points)	—
Arroyo-Gallego et al [49]	MDS-UPDRS	• Finger tapping (AUC=0.85; *P*<.001)	—
Bazgir et al [50]	MDS-UPDRS	• Hand tremor (97% accuracy)	—
Bochniewicz et al [82]	ARAT[f]	• IADL[g] (r=−0.14; *P*=.70)	—
Boroojerdi et al [37]	MDS-UPDRS	• Finger tapping (r=0.291) • Hand tremor (r=0.746)	—
Burdea et al [71]	—	—	—
Cabrera-Martos et al [67]	In-clinic assessment	—	Interrater reliability: • Finger dexterity (r=0.89) • Finger tapping (r=1.0) • Hand tremor (r=0.99)
Cai et al [19]	MDS-UPDRS	• Hand tremor (r^2=0.95)	—
Channa et al [20]	MDS-UPDRS	• Hand tremor (91.7% accuracy)	—
Cole et al [21]	MDS-UPDRS	—	—
Creagh et al [59]	9HPT[h]	• Handwriting: dominant hand (r^2=0.39) and nondominant hand (r^2=0.41)	—
Cunningham et al [74]	—	—	—
Dai et al [22]	MDS-UPDRS	• Finger tapping (r=−0.970; *P*<.01) • Hand tremor (r=0.93; *P*<.001)	Interrater agreement (Kendall *W*): • Finger tapping (0.86) • Hand tremor (0.84)
Dubuisson et al [91]	9HPT	• Finger dexterity (r=0.9; *P*<.001)	—
Ferreira et al [23]	MDS-UPDRS	—	—
Giancardo et al [39]	MDS-UPDRS	• Finger tapping (AUC=0.75)	—
Giuffrida et al [24]	MDS-UPDRS	• Hand tremor (r=0.89)	—
Goetz et al [75]	MDS-UPDRS	—	—
Halloran et al [25]	CAHAI[i]	• ADL[j] (r= 0.63; *P*<.001)	—

Study	Comparison assessment	Validity	Reliability
Heijmans et al [26]	ESM[k] app (tremor questionnaire)	• Hand tremor (r=0.43)	—
Hoffman et al [68]	In-clinic assessment	• Hand tremor (83.3% agreement) • Handwriting (41.6% agreement)	Interrater reliability: • Finger dexterity (r=0.99)
Hssayeni et al [27]	MDS-UPDRS	• Hand tremor (r=0.84)	—
Iakovakis et al [52]	MDS-UPDRS	• Finger tapping (AUC=0.92)	—
Iakovakis et al [51]	MDS-UPDRS	• Finger tapping (r=0.66)	—
Jeon et al [28]	MDS-UPDRS	• Hand tremor (85.5% agreement)	—
Jha et al [60]	MDS-UPDRS	• Hand tremor (κ=0.68; *P*<.001, substantial) • Finger tapping (κ=0.54; *P*<.001, moderate)	Interrater agreement: • Hand tremor (96%) • Finger tapping (50%)
Kim et al [29]	MDS-UPDRS	• Hand tremor (85% accuracy)	Interrater reliability: • Hand tremor (r=0.78)
Kleinholdermann et al [85]	MDS-UPDRS	• Finger tapping (r=0.445)	—
Kostikis et al [81]	MDS-UPDRS	• Hand tremor,: right hand (r=0.75; *P*<.001) and left hand (r=0.85; *P*<.001)	—
Lam et al [41]	9HPT	• Finger dexterity (r=−0.553)	Test–retest reliability: • Finger dexterity (ICC 0.601)
Lee et al [53]	MDS-UPDRS	• Finger tapping (AUC=0.92, 95% CI 0.88-0.96)	—
Lee et al [84]	FMA[l]	• Whole hand grasp (92% accuracy)	—
Lee et al [54]	MDS-UPDRS	—	—
Lin et al [88]	—	—	—
Lipsmeier et al [61]	MDS-UPDRS	• Finger tapping (*t*=2.18; *P*=.03) • Hand tremor (*t*=2.17; *P*=.03)	Test–retest reliability: • Finger tapping (ICC=0.64) • Hand tremor (ICC=0.90)
Londral et al [47]	—	—	Test–retest reliability: • r=0.96; *P*=.09
Lopez-Blanco et al [76]	MDS-UPDRS	• Hand tremor (r=0.81; *P*<.001)	Interrater reliability: • Hand tremor (ICC=0.89)
Mahadevan et al [30]	MDS-UPDRS	• Hand tremor (r=0.67; *P*<.001)	Interrater reliability: • Hand tremor (ICC=0.75)
Matarazzo et al [42]	UPDRS-3	—	—
Memedi et al [77]	Visual assessment	• Handwriting (85% accuracy)	Test–retest reliability: • Handwriting (ICC=0.69)
Mera et al [31]	—	—	—
Mitsi et al [65]	MDS-UPDRS	—	—
Noyce et al [43]	MDS-UPDRS	• Finger tapping (r=0.53)	—
Orozco-Arroyave et al [62]	UPDRS-3	—	—

Study	Comparison assessment	Validity	Reliability
Pan et al [63]	MDS-UPDRS	• Hand tremor (r=0.81)	—
Papadopoulos et al [40,55]	MDS-UPDRS	—	—
Powers et al [78]	MDS-UPDRS	• Hand tremor (r=0.72)	—
Pratap et al [66]	Longitudinal Neuro-QoL^{m} scores	• Finger tapping (β=.40; *P*<.001)	—
Prochazka and Kowalczewski [83]	ARAT and FMA	• Finger dexterity (r^2=0.49) • Whole hand grasp, (r^2=0.88) • Pincer grasp (r^2=0.88)	Test–retest reliability: • 0.67% (SD 3.6)
Rigas et al [32]	MDS-UPDRS	• Hand tremor (87% accuracy)	—
Salarian et al [87]	MDS-UPDRS	• Hand tremor (r=0.87; *P*<.001)	—
San-Segundo et al [33]	—	—	—
Sanchez-Perez et al [34]	MDS-UPDRS	—	—
Schallert et al [56]	—	—	—
Shribman et al [44]	9HPT	• Finger tapping (r=0.926)	—
Sigcha et al [79]	MDS-UPDRS	• Hand tremor (r=0.969)	—
Simonet et al [57]	MDS-UPDRS	• Finger tapping (r=−0.49)	—
Stamatakis et al [35]	MDS-UPDRS	• Finger tapping (Goodman–Kruskal index=0.961)	—
Tavares et al [86]	MDS-UPDRS	• Finger tapping (r=0.67; *P*<.001)	—
Trager et al [45]	MDS-UPDRS	• Finger dexterity (r=0.14; *P*=.43) • Finger tapping (r=0.58; *P*<.001)	—
Westin et al [80]	MDS-UPDRS	• Handwriting (r=0.41)	Test–retest reliability: • Handwriting (r=0.71)
Wissel et al [58]	MDS-UPDRS	• Finger tapping (r=0.55)	Test–retest reliability: • Finger tapping (r>0.75)
Wu et al [89]	MDS-UPDRS	• Hand tremor (r=−0.798)	—
Yu et al [72]	FMA	• Finger dexterity (r^2=0.70) • Pinch strength (r^2=0.72)	—
Zambrana et al [90]	—	—	—

Study	Comparison assessment	Validity	Reliability
Zhan et al [64]	MDS-UPDRS	• Finger tapping (mean 71%, SD 0.4%)	—
Zhang et al [36]	MDS-UPDRS	• Hand tremor (85.9% accuracy)	—

[a]Data unavailable.
[b]AUC: area under the curve.
[c]MDS-UPDRS: Movement Disorder Society–Unified Parkinson's Disease Rating Scale.
[d]ICC: interclass coefficient.
[e]UPDRS: Unified Parkinson's Disease Rating Scale.
[f]ARAT: Action Research Arm Test.
[g]IADL: instrumental activities of daily living.
[h]9HPT: 9-hole peg test.
[i]CAHAI: Chedoke Arm and Hand Inventory.
[j]ADL: activities of daily living.
[k]ESM: experience sampling method.
[l]FMA: Fugl-Meyer Assessment.
[m]QoL: quality of life.

Of the 74 studies, 15 (20%) heterogeneous studies reported reliability statistics; 2 (3%) telerehabilitation assessments [68,69] revealed a high, statistically significant interrater reliability; and 1 (1%) external device assessment [76] revealed a high, although statistically insignificant reliability.

Hand Function Domain, Based on the Functional Repertoire of the Hand

Finger Tapping Speed

The most common hand function domain assessed was finger tapping speed [22,31,35,37-39,42-45,48,49,51-54,57,58,60-62,64-67,70,73,75,80,85,86,92]. Finger tapping can provide clinicians with an understanding of fine motor control and stiffness, especially in individuals with spasticity. Of the included studies that examined finger tapping, Albani et al [73] reported the highest correlation with MDS-UPDRS scores in participants with PD. In their study, the authors used an external device, a gesture-based tracking system involving a specialized depth camera and gloves with colored markers, to track and quantify fine hand movements. The MDS-UPDRS item on finger tapping relies on visual assessments of finger tapping (eg, interruptions in the tapping rhythm), and specialized equipment such as an external device aid in quantifying finger tapping capability [73].

Hand Tremor

The second most commonly assessed domain was hand tremor, a prevalent impairment in many neurological disorders. Quantifying tremors can help determine the efficacy of pharmacological and rehabilitative therapies. The studies that examined this domain were conducted in participants with PD [19-21,23,24,26-30,32-34,36,37,46,50,55,60,61,63,64,67,68,74-76,78,79,81,87]. Hoffman et al [68] found a 100% agreement of their visual examination of hand tremor at rest in their evaluation of telerehabilitation administration of the MDS-UPDRS assessment in comparison with in-clinic evaluation. Sigcha et al [79] developed a novel smartphone app using an internal gyroscope and accelerometer to measure resting hand tremors. This method had a strong correlation (r=0.97) with in-clinic MDS-UPDRS resting hand tremor scores.

Finger Dexterity

The third most commonly assessed domain was finger dexterity [41,45,47,67,68,72,83,88,91]. Finger dexterity assessment tasks included manipulation of small objects (eg, the 9-hole peg test [9HPT] and the coin rotation test), which are useful metrics of fine motor control required for ADL, such as buttoning clothing. Finger dexterity was examined in all 5 of the neurological conditions examined in this review. Of the included studies examining participants with PD, Cabrera-Martos et al [67] found a mean difference of 0.3 (SD 1.2) in scores between telerehabilitation and in-clinic administration of the coin rotation task [93] in the affected limb. Similarly, using telerehabilitation to examine the pinch domain of participants with stroke, Amano et al [69] reported a Spearman ρ of 0.99 between telerehabilitation and in-clinic administered items. In participants with MS, Dubuisson et al [91] validated an external device, a cardboard 9HPT with a correlation of 0.96 between this novel assessment tool and a standard, plastic 9HPT.

Handwriting

Approximately 8% (6/74) of studies [48,56,59,68,77,80] examined handwriting accuracy, a specific and sensitive measure of fine motor coordination. The greatest accuracy in comparison with in-clinic assessments was reported by Hoffman et al [68], who found a high percentage of agreement (85%) between in-clinic measures and an external telemetry device of the MDS-UPDRS item for handwriting.

Specific Functions

Specific functional domains were evaluated by 11% (8/74) of studies. Grip and pinch strength were examined in 4% (3/74) of studies [68,72,83] using remote deployment of these standard in-clinic metrics. Prochazka et al [83] evaluated the validity of a novel external device to collect force data from grip and pinch tasks and found a coefficient of determination (R^2) of 0.88 between the remote device and in-clinic administered ARAT.

Only 4% (3/74) of studies [25,68,82] specifically examined ADL and IADL. Hoffman et al [68] compared in-clinic and telerehabilitation-administered functional independence measures and found 100% agreement in scores for eating and 91.7% agreement for dressing. Bochniewicz et al [82] developed a wrist-worn accelerometer to capture and quantify disability in individuals after stroke. The protocol simulated IADL such as doing laundry and shopping in a grocery store, and the authors reported 88.4% accuracy compared with ARAT scores of upper extremity functional use.

Participant Acceptability

In populations with PD, 9% (7/74) of studies reported participant acceptability and usability of assessments. Albani et al [73] found that participants rated the hand gesture–based tracking system 5.9/7 on a poststudy usability questionnaire, indicating ease of use, high interface quality, and usefulness. In 4% (3/74) of studies [24,30,37], participants using wearable sensors to monitor hand tremors and finger tapping found the devices comfortable and easy to use. Both Goetz et al [75] and Ferreira et al [23] reported >80% of participant satisfaction with external devices to examine hand tremors. Mitsi et al [65] found that 76% of participants using a tablet-based assessment for finger tapping [65] and reaction time found it easy to use, with an additional 63% reporting willingness to use it long-term to monitor disease activity.

In populations with stroke, Burdea et al [71] asked both participants and caregivers to provide feedback on their video game–like assessment and intervention using a 5-point study-specific Likert scale (higher scores indicating statement agreement). Participants reported that the device was moderately easy to use (mean score 3.1/5.0), that they would encourage others to use it (mean score 4.3/5.0), and that they liked the system overall (mean score 4.2/5.0). However, participants encountered some technical difficulties during use (mean score 2.2/5.0). Caregivers also found the device setup appropriate for the home environment and easy to use (mean score 3.5/5.0).

In people with MS, Dubuisson et al [91] reported that 66.7% of participants preferred the portable in-home 9HPT in comparison with the standard in-clinic version.

Safety

Only 3% (2/74) of studies reported safety data [37,68]. Hoffman et al [68] reported that participants who received assessment via telerehabilitation were accompanied by a researcher to ensure safety. Boroojerdi et al [37] used a wearable patch and reported no adverse skin reactions at the application site or device malfunction. Adverse events were not reported in any of the included studies.

Stage of Development and Implementation

As the assessments in this review were novel, the availability for clinical implementation varied. Most studies (44/74, 59%) evaluated assessments requiring specialized equipment for implementation. These devices included specialized cameras, wearable devices, electromyography, and specialized keyboards. Although not an application, the cardboard 9HPT developed by Dubuisson et al [91] was designed specifically to be environmentally friendly, cost-effective, and used by patients at home. The remaining external devices evaluated in this review were designated as developmental, with a need for subsequent safety and prospective studies on usability before clinical use.

Approximately 3% (2/74) of studies using telerehabilitation methods required videoconferencing devices and a stable internet connection for both providers and patients for implementation. However, although Hoffman et al [68] similarly used telerehabilitation methods, their protocol required participants to use clinical equipment during in-home assessments (eg, a hand dynamometer and the 9HPT), potentially limiting widespread implementation.

A smartphone or tablet-based application was used in 27% (20/74) of studies to administer assessments. The FLOODLIGHT application studied by Creagh et al [59] is currently available for download for iOS and Android devices. The remaining applications were study-specific developments but, given compatible devices and secure broadband internet connection availability, have limited barriers to implementation.

Discussion

Principal Findings

The purpose of this review was to systematically gather available literature on remote assessments for monitoring hand function in people with central, chronic, and neurological diseases. The search yielded 74 studies that met the inclusion criteria, and 71 unique assessments were examined for validity, reliability, and clinical implementation. A wide variety of metrics were collected on a number of hand function domains, including the amplitude of finger tapping, finger dexterity, hand tremor, and ADL independence. Altogether, the studies provide a number of insights; however, to date, no single tool, or combination of tools, validly and reliably captures hand function across these major neurological conditions.

Many of the studies were of good quality, and several study characteristics were found to enhance their quality. Including controls with nonneurological conditions as a comparison, when available, helped demonstrate the discriminant validity of the novel assessments examined. Most studies included participants with lower disability status, which likely allowed for more dynamic testing of hand function domains. Unfortunately, most of the included studies reported statistically insignificant associations with standard in-clinic metrics. As prior literature suggests that traditional in-clinic assessments have limited granularity for upper limb function in populations with neurological conditions, differences between the novel assessments and these traditional in-clinic tests could indicate that the new tools capture additional aspects of function (eg, quantifying pincer grasp) relative to the traditional in-clinic assessments or vice versa. In addition, few studies reported reliability, especially interrater reliability, suggesting the need for more research and that the included tools remain primarily in the development phase.

The most commonly assessed hand function domain was finger tapping speed, with moderate to high agreement across comparison assessments. The finger tapping test is a valid and

reliable measure of bradykinesia in PD [94] and a predictor of ADL independence in acute stroke [95]. It is relatively simple to quantify finger tapping in-clinic or via a smartphone or tablet app by counting the number of finger taps within a specific time frame. Although overall construct validity and participant satisfaction were high, further work in other hand function domains will help determine the most salient predictors of ADL independence and response to treatment and intervention.

This review highlights important aspects of the feasibility of remote evaluations. Participant and caregiver satisfaction, when reported, were moderate to high for these technologically innovative assessments. This suggests that participants found the novel assessments easy to use and effective in evaluating their hand function despite being nontraditional. Further, 28% (21/74) of the included studies demonstrated the feasibility of remotely monitoring hand function over multiple days. This is a key finding, as long-term monitoring of hand function in a patient's natural environment has the potential to identify changes in real time, allowing for timely intervention modifications.

Regarding patient safety, although the included assessments were noninvasive and posed a relatively low safety risk, ensuring the secure transfer of data, especially with internet-based communication (eg, telerehabilitation and smartphone or tablet-based apps) between patient and clinician, is critical to confidentiality and Health Insurance Portability Accountability Act compliance. Future studies should report on data storage and encryption methodologies.

The assessments evaluated were in varying stages of development and implementation. The most readily implementable types of assessment were those using telerehabilitation or smartphone- or tablet-based apps. According to 2019 data, 85% of Americans own a smartphone, and 93% use the internet regularly, of whom 75% use a home high-speed broadband network [96]. Given these statistics, telerehabilitation and application-based assessments, if interoperable across devices, might be relatively accessible for most patients. Lower costs could make clinical implementation less of a challenge. Furthermore, with no specialized devices to purchase or distribute to patients, clinics could similarly benefit from these cost-effective measures.

Limitations

A major limitation of this review is the heterogeneity of hand function domains evaluated, which, when compounded with the methodological variability (in comparison assessments, inclusion criteria, and statistical approaches), made it difficult to compare the various tools. Future studies that include more homogeneous patient populations and standardized reporting of correlation coefficients with comparison assessments will facilitate analysis across domains and assessment types. A second limitation was the paucity of studies conducting repeated trials of the assessments, limiting the identification of any practice effects with use of a new device. In repeated trials of smartphone-based assessments, performance improved in the first 10 trials because of a practice effect, followed by a narrowing of variance as the practice effect waned and familiarity with the assessment increased [97]. Follow-up studies should include repeated trials, preferably over multiple days, to capture these effects and fluctuations in disease progression. Third, the effect of confounding variables (eg, disease-modifying therapies, age, and disease duration) was infrequently described in validity statistics; the generalizability of this review should proceed with caution. Fourth, all tools included require active participant engagement as opposed to passive monitoring (eg, collecting data on dexterity as a participant types to complete a survey). Passive monitoring may be able to capture similar metrics with a reduced participant time burden. Finally, we may have missed relevant studies published in non-English languages.

Conclusions

This review suggests that remote assessments can be valid and reliable tools for measuring hand function impairments in chronic neurological diseases and that doing so is clinically feasible and acceptable to patients. In the past decade, personal smartphone and computer ownership have become commonplace; with it, patients and health care providers are able to communicate in real time, opening new avenues for care delivery and disease monitoring. We highlight the current potential to implement remote assessments via telerehabilitation and smartphone- or tablet-based apps. As interventions for ambulation and lower extremity function become increasingly robust, these methods will allow clinicians to reliably assess multiple domains of hand function to monitor disease progression and response to interventions.

Conflicts of Interest

WYH is supported by the National Multiple Sclerosis Society (FG-1908-34831). RB receives research support to University of California, San Francisco from Biogen and Roche Genentech, as well as personal fees for consulting from Alexion, Biogen, EMD Serono, Genzyme Sanofi, Novartis, and Roche Genentech.

Multimedia Appendix 1
Summary of studies.
[DOCX File , 41 KB - rehab_v9i1e33157_app1.docx]

Multimedia Appendix 2
Quality assessment of studies.
[DOCX File , 31 KB - rehab_v9i1e33157_app2.docx]

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Abbreviations

9HPT: 9-hole peg test
ADL: activities of daily living
ARAT: Action Research Arm Test
CNS: central nervous system
IADL: instrumental activities of daily living
MDS-UPDRS: Movement Disorder Society–Unified Parkinson's Disease Rating Scale
MS: multiple sclerosis
PD: Parkinson disease
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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Review

An Investigation Into the Use of mHealth in Musculoskeletal Physiotherapy: Scoping Review

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Abstract

Background: Musculoskeletal physiotherapy provides conservative management for a range of conditions. Currently, there is a lack of engagement with exercise programs because of the lack of supervision and low self-efficacy. The use of mobile health (mHealth) interventions could be a possible solution to this problem, helping promote self-management at home. However, there is little evidence for musculoskeletal physiotherapy on the most effective forms of mHealth.

Objective: The aim of this review is to investigate the literature focusing on the use of mHealth in musculoskeletal physiotherapy and summarize the evidence.

Methods: A scoping review of 6 peer-reviewed databases was conducted in March 2021. No date limits were applied, and only articles written in the English language were selected. A reviewer screened all the articles, followed by 2 additional researchers screening a random sample before data extraction.

Results: Of the 1393 studies, 28 (2.01%) were identified. Intervention characteristics comprised stretching and strengthening exercises, primarily for degenerative joint pain and spinal conditions (5/28, 18%). The most reported use of mHealth included telephone and videoconferencing calls to provide a home exercise program or being used as an adjunct to physiotherapy musculoskeletal assessment (14/28, 50%). Although patient satisfaction with mHealth was reported to be high, reasons for disengagement included a lack of high-quality information and poor internet speeds. Barriers to clinical uptake included insufficient training with the intervention and a lack of time to become familiar.

Conclusions: mHealth has some benefits regarding treatment adherence and can potentially be as effective as normal physiotherapy care while being more cost-effective. The current use of mHealth is most effective when ongoing feedback from a health care professional is available.

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KEYWORDS

physiotherapy; musculoskeletal; mHealth; rehabilitation; scoping review; mobile phone

Introduction

Background

Musculoskeletal conditions can have a major impact on people's quality of life, leading them to seek medical care in the form of nonsteroidal anti-inflammatory drugs or surgery (eg, joint replacements), with people aged 55 to 65 years being the most common age group experiencing these conditions [1]. Musculoskeletal physiotherapy can provide cost-effective management for multiple conditions via modalities, including strengthening and flexibility exercises, postural and ergonomic advice, manual therapy (eg, joint mobilizations and soft tissue massage), and education for self-management of pain [2]. Effective physiotherapy helps improve short-term pain and disability, which facilitates earlier discharge from care [3], lowering the burden on the health care system by reducing waiting lists and financial costs [4]. Chronic conditions can result in pain and sickness-related absence from work and in patients seeking additional care up to 10 years after first receiving treatment, primarily for conditions with the highest recurrence rates such as low back and neck pain [5]. A possible contribution to the lack of success with treatment for chronic musculoskeletal issues is the lack of adherence to home exercise programs, low self-efficacy, failure to recall coping strategies, or lack of education provided by the therapist [6]. Furthermore, ongoing engagement with self-management is an important predictor of successful rehabilitation [7], and a series of focus groups of musculoskeletal physiotherapists have reinforced this regarding the management of patients with subacromial impingement syndrome [8]. A person-centered approach to treatment should be taken to encourage prolonged engagement with exercise [9]. Studies have concluded that patients prefer individualized, supervised exercise programs with clinician input [10,11]. An increasingly popular tool in a range of health care settings is the development of exercise programs delivered through mobile devices. An ideal app would enable web-based input from the clinician to support the patient to participate in rehabilitation from the comfort of their home [12]. There is evidence suggesting that the use of mobile apps with input from clinicians, particularly with the ability to set and monitor the quality of completion of the exercise, leads to higher adherence rates than traditional paper handouts [13].

eHealth is an umbrella term that refers to the use of modern information and communication technology to deliver health care [14]. A branch of eHealth showing growth in development is mobile health (mHealth) [15] as a result of the increasing use of mobile devices, partnered with improvements in technology development (eg, smartphones), with predictions that device availability will increase over the next decade [16]. According to the 2019 Ofcom report, the UK telecom sector generated £33.8 billion (US $45.03 billion), with mobile devices accounting for 51% of the total revenue. The average individual broadband data use increased from 30 GB per month in 2013 to 240 GB per month in 2018, whereas mobile data use increased by 37% from 2018, indicating increased access to internet-powered devices. This report also states that smartphones account for 60% to 90% of all telecommunications use for people aged 16 to 64 years, with those aged 16 to 34 years accounting for the largest proportion within this range. There is some evidence that younger patients may be more likely to engage in rehabilitation through the use of smartphones [17], although this does not mean that the older population is disadvantaged, as there is evidence showing that mHealth adherence is high throughout all age groups [18]. Other smart devices, including tablets and laptops, are mainly used by people aged 45 to 54 years, accounting for approximately 60% of smart device use, not including smartphones [19].

This innovative branch of health care has increased accessibility and affordability for patients [20], providing health care to patients with low income or those in rural locations where face-to-face health care is not practical [21]. There is already evidence of mHealth being implemented successfully to improve medication adherence [22]. Within health care settings, mental health and diabetes appear to have higher numbers of mHealth interventions with positive health outcomes [23-25]. Success in the management of mental health is because of the strict governance put in place by popular app sites such as Google Play and the App Store, alongside a larger research base behind these conditions [26]. The Developer Program Policies, along with the Developer Distribution Agreement [27], provide clear guidelines to developers. This ensures that any app being made widely available must be transparent with how it manages the user's data, combined with ensuring that it contains appropriate content.

Another factor contributing to the rapid development of mHealth apps is the COVID-19 pandemic [28]. Owing to the need for whole populations to isolate, face-to-face appointments are being considered high risk, resulting in many patients still being in urgent need of treatment [29]. It has become vital to implement strategies that promote access to remote health care. The most viable and safe option has been to increase the number of mHealth apps being made available [30].

With the rise in smartphone availability, there has been a concomitant increase in research involving mobile device apps (mHealth) for the management of chronic pain [31]. The mHealth apps can be generalized into three main categories—(1) education, (2) pain measurement, and (3) pain therapy—with some apps falling into ≥1 category [32]. The third category potentially represents an intervention with the possibility of increasing the quality of life and function. Some mHealth apps require input from clinicians, whereas others do not. The latter presents fewer barriers, such as the user not needing to rely on an assessment from a clinician before use; however, a lack of clinician input may lead to disengagement and potentially risk an incorrect selection of exercises because of the lack of a working diagnosis [33]. This potentially represents a fourth category for mHealth, namely self-management. This, if applied effectively, gives the patient ownership of their own treatment—an important predictor of successful rehabilitation [34]. Despite this increase in research, there is still a need for specific research relating to musculoskeletal physiotherapy.

Rationale

Little evidence underpins which aspects of mHealth are most effective and allow for the greatest level of engagement regarding musculoskeletal conditions [35]. A recent randomized

controlled trial (n=68 participants) [2] compared an internet-based app supported by FitBit (Google LLC) with telephone-based health coaching sessions and an information booklet, with the advice to stay active by using the information booklet. Participants receiving the mHealth intervention had a 38% reduced rate of care seeking; however, statistical differences between groups were not reached regarding primary or secondary outcomes. Therefore, the authors could only state a possible advantage of using mHealth, with a more adequately powered trial needed. This trial relates to the current findings of research on mHealth in musculoskeletal physiotherapy, with a consensus on more rigorous research being needed, as the effectiveness of these interventions is not conclusive [36,37]. Research on mHealth within general physiotherapy has focused on treatment for respiratory conditions such as chronic obstructive pulmonary disease [38] or the views of therapists' use of the interventions [39]. Previous systematic reviews conducted in this area of physiotherapy focused on multiple chronic diseases such as asthma, diabetes, and cancer [40,41]. Other systematic reviews that focused on physiotherapy mHealth interventions reported on diabetes mellitus and Duchenne muscular dystrophy, focusing on the features of the mHealth intervention compared with the clinical use of the intervention [42,43]. There is a gap in the research regarding the use of mHealth in musculoskeletal physiotherapy; therefore, there is scope for this review to be undertaken.

The aim of this review is to explore and chart the evidence on the use of mHealth within musculoskeletal physiotherapy, with a view to identifying relevant gaps in the literature by conducting a structured, systematic scoping review and developing relevant themes of the topic in question to address the feasibility of mHealth interventions.

Methods

Overview

This scoping review was conducted in accordance with a standardized framework [44]. This review was structured according to the five stages of this framework: (1) identifying the research question; (2) identifying relevant studies; (3) study selection; (4) charting the data; and (5) collecting, summarizing, and reporting the results. This scoping review was also guided by the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) [45].

Stage 1: Identifying the Research Question

Objectives

The primary objective was to analyze the use of mHealth and the outcomes it had produced in musculoskeletal physiotherapy (eg, pain reduction and reported increase in self-efficacy). The secondary objectives were to determine the following: how mHealth has previously been applied, the types of conditions mHealth has been used for, interventions that have been proposed and implemented using mHealth, the reasons for barriers to and facilitators of mHealth, and the barriers to clinical uptake.

Eligibility Criteria

Studies were assessed against the inclusion and exclusion criteria described in Textbox 1.

Textbox 1. Inclusion and exclusion criteria for the studies.

Inclusion criteria

- English language articles
- Peer-reviewed articles published in journals where full text was available
- Focus on the use and application of mobile health in musculoskeletal physiotherapy, including in patients and therapists
- Application of mobile health could be in an outpatient or home-based setting
- Studies in which mobile health was used as a whole or partial aspect of treatment combined with or without other modalities

Exclusion criteria

- Studies focusing on mobile health in other areas of health care (eg, as mental health and diabetes)

Stage 2: Identifying Relevant Studies

Peer-reviewed articles were identified using key databases, including MEDLINE, Embase, ProQuest Health and Medical Complete, CINAHL Plus, AMED, and IEEE Xplore. These databases were chosen as they include a large collection of literature related to physiotherapy research alongside literature on health technology. Gray literature was also searched to allow for the inclusion of further relevant studies that were not identified through database searches. The search was conducted in March 2021.

The search strategy (Multimedia Appendix 1) used the terms *mHealth*, *eHealth*, or *Telemedicine* to identify articles related to the application of mHealth within physiotherapy. The reference lists of the appropriate articles were also snowball searched to identify any further literature.

The database searches were undertaken by three researchers (JMRA, DK, and CH) to identify all relevant literature, with no date limitations being applied to capture as much relevant literature as possible.

Stage 3: Study Selection

All relevant references were imported into RefWorks (ProQuest), and duplicates were removed. One of the researchers (JMRA) applied the eligibility criteria for both the title and abstract review and full-text review stages. To allow for

consensus on the eligibility criteria, 10% of the selected studies were reviewed by two additional researchers (DK and CH). This was followed by an assessment of the full texts of the included articles for the final inclusion stage by three researchers (JMRA, DK, and CH).

Stage 4: Charting the Data

A data-charting form was developed to steer the collection of data from the included studies. This form included general data such as author and publication year, as well as more specific information relevant to this review. The data-charting form was piloted using a random selection from the database search results. This informed us of any changes needed before charting the data from the remaining studies. One of the researchers (JMRA) subsequently charted the data from all remaining studies, with 3 additional researchers reviewing a selection of these studies to ensure extra rigor.

Stage 5: Collating, Summarizing, and Reporting the Results

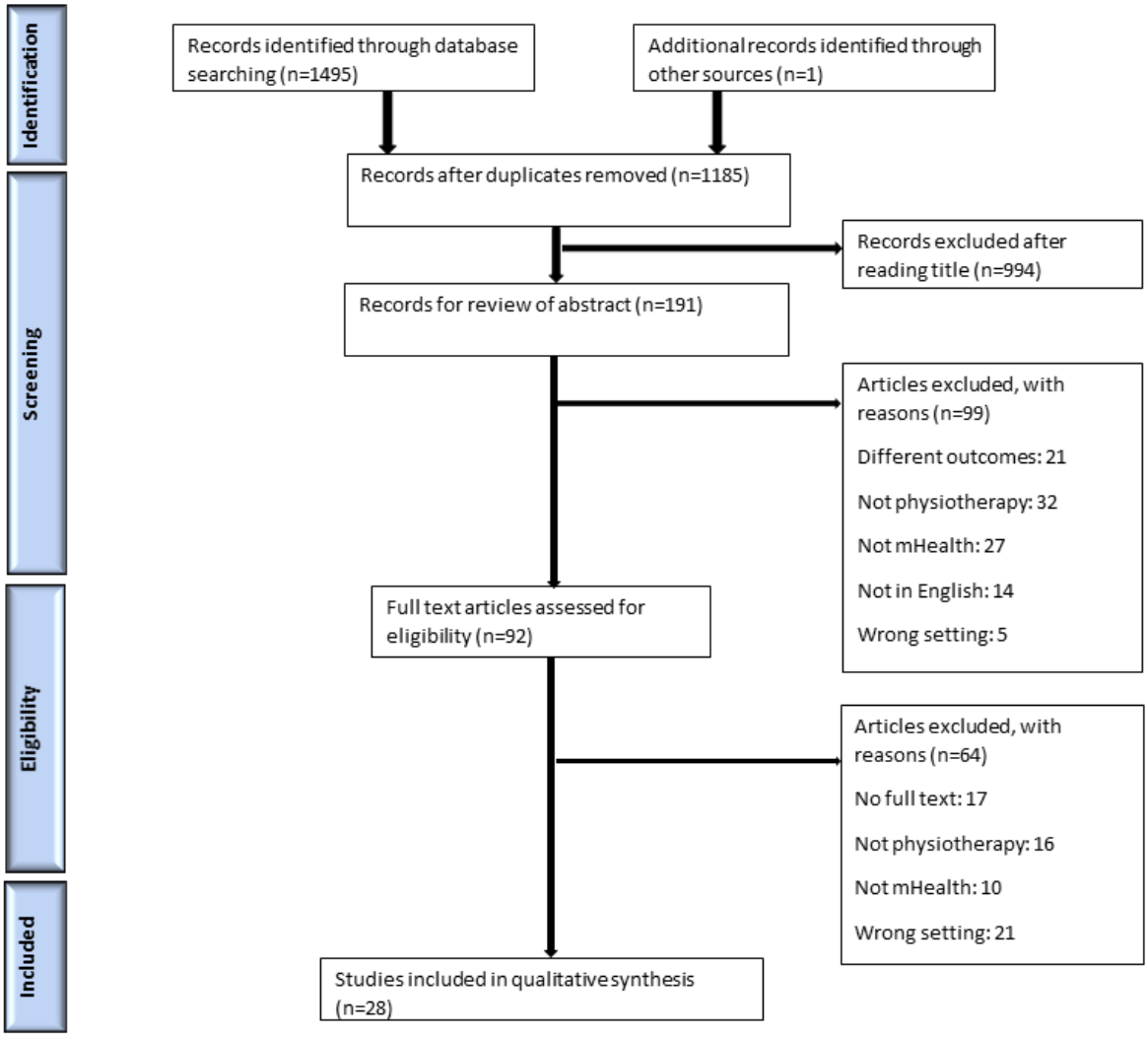
A quantitative overview of the included studies was summarized in a series of tables and diagrams to aid in the synthesis of the literature related to the use of mHealth in physiotherapy. This included aspects such as which countries were applying mHealth, the nature of the intervention, and the common conditions for which mHealth was used. The final extracted data were also presented in a narrative account in the literature. The research team developed themes and categories that emerged with aid from both the research question and data produced using an iterative process.

Results

Study Selection

The initial database search (Multimedia Appendix 1) of the mHealth literature identified 1495 titles. Of these 1495 titles, 311 (20.8%) were duplicates. An additional 66.42% (993/1495) of studies were removed following title review as they did not meet the eligibility criteria. Of the 1495 titles, after an abstract review of 191 (12.78%) titles, 99 (51.8%) articles were removed; 21 (21%) articles were removed because of incorrect outcomes, 32 (32%) were removed because they did not focus on physiotherapy, 27 (27%) were removed because mHealth was not included, 14 (14%) were removed because they were non-English articles, and 5 (5%) were removed because they were studies conducted in settings not included in this review (ie, an inpatient hospital setting where mHealth may not be relevant as remote access would not be warranted). Of the 191 papers, the final full-text review of the remaining 92 (48.2%) papers provided 28 (14.7%) articles, with the reasons for exclusion involving no full-text availability in 17 (18%) papers, no focus on physiotherapy in 16 (17%) papers, mHealth not included in 10 (11%) papers, and 21 (23%) studies conducted in the incorrect setting as stated above. The search process is summarized in the flowchart (Figure 1).

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



Study Characteristics

The study characteristics and findings are outlined in Tables 1-3. A total of 1393 participants were included in the final 28 included articles. The trial sample sizes ranged from 3 to 368 participants.

Table 1. Study characteristics.

Study	Study type	Location	Participants, N	Setting
Adamse et al [46]	Systematic review	The Netherlands	Not stated	• Participants: aged >18 years • Condition: chronic pain in any physical location • Health care setting: —[a]
Adhikari et al [47]	Retrospective pre–post design	Nepal	15	• Health care setting: rural home
Azma et al [48]	Randomized clinical trial	Iran	54	• Participants aged 50 to 60 years • Health care setting: home based or office based
Bini and Mahajan [49]	Randomized control study	United States	51	• Health care setting: home based or face to face
Chen et al [50]	Pilot study to assess feasibility	Taiwan	15	• Health care setting: home based
Correia et al [51]	Prospective parallel-group feasibility study	Portugal	69	• Health care setting: home based
Dunphy et al [52]	Semistructured interviews	United Kingdom	24	• Health care setting: outpatients
Eriksson et al [53]	Qualitative interviews	Sweden	10	• Health care setting: home based
Eriksson et al [54]	Controlled study	Sweden	22	• Health care setting: home based
Gialanella et al [55]	Prospective randomized controlled study	Italy	100	• Health care setting: home based
Irvine et al [56]	Randomized controlled trial	United States	368	• Health care setting: home based
Jay et al [57]	Randomized controlled trial	Denmark	38	• Health care setting: office based
Lade et al [58]	Unclear	Australia	10	• Health care setting: outpatients
Lawford et al [59]	Semistructured interviews	Australia	20	• Health care setting: —[a]
Lovo et al [60]	Semistructured interviews analyzed using a mixed methods design	Canada	64	• Health care setting: urban or home based
Mani et al [61]	Systematic review	Malaysia	—[a]	—[a]
Mecklenburg et al [62]	Randomized controlled trial	United States	162	• Health care setting: home based
Meijer et al [63]	Systematic review	The Netherlands	—[a]	—[a]
Nelson et al [64]	Randomized controlled noninferiority trial	Australia	70	• Health care setting: home based
Pastora-Bernal et al [65]	Single-blind prospective randomized clinical trial	Spain	18	• Health care setting: home based
Peterson [66]	Case series	United States	3	• Health care setting: home based
Piqueras et al [67]	Randomized controlled trial	Spain	142	• Health care setting: outpatients or home based
Richardson et al [68]	Repeated measures design	Australia	18	• Health care setting: outpatients
Rothgangel et al [69]	Prospective single-group clinical study	The Netherlands	15	• Health care setting: private practice outpatients
Russell et al [70]	Repeated measures design	Australia	15	• Health care setting: outpatients
Shukla et al [71]	Systematic review and meta-analysis	India	—[a]	—[a]

Study	Study type	Location	Participants, N	Setting
Tousignant et al [72]	Randomized controlled trial	Canada	48	• Health care setting: home based
Wijnen et al [73]	Nonrandomized controlled trial combining a single-arm intervention cohort with historical controls	Netherlands	42	• Health care setting: home based

[a]Not available.

Table 2. Study interventions and conditions.

Study	Condition	Intervention
Adamse et al [46]	Chronic pain to include chronic low back pain, osteoarthritis of the knee or hip, and rheumatoid arthritis	• Telemedicine: internet-based technology used to communicate with patients to provide remote rehabilitation
Adhikari et al [47]	Prolapsed intervertebral disk, tennis elbow, rheumatoid arthritis, mechanical low back pain, traumatic ankle pain, and neck pain	• Exercise pamphlets provided • Via calls (4 times in 4 weeks); physiotherapist aided in the rehabilitation
Azma et al [48]	Knee osteoarthritis	• Pamphlets provided (strengthening, endurance, flexibility, and ROM[a] exercises) • Continue exercises 3 times per week for 6 weeks • Patients remotely contacted weekly regarding exercise progression
Bini and Mahajan [49]	Total knee replacement	• CaptureProof app provided 23 exercise videos • Videos narrated by a therapist with on-screen instructions • Patient responds with a recording of their exercise completion • Therapist reviews and adjusts treatment as appropriate
Chen et al [50]	Shoulder adhesive capsulitis	• MSD[b] measures ROM • Patient app used by patient and physician app used by a health care professional • Effectiveness of rehab measured using patient and physician app
Correia et al [51]	Total knee arthroplasty	• Physiotherapist trained patient or caregiver in the use of the platform • Sessions performed 5 times per week for a minimum of 30 minutes
Dunphy et al [52]	ACL[c] reconstruction	• Interviews with physiotherapists and patients
Eriksson et al [53]	Shoulder joint replacement	• Patients supervised by a physiotherapist • Physiotherapist contacted patient via videoconferencing
Eriksson et al [54]	Shoulder joint replacement	• Patients supervised by a physiotherapist • Physiotherapist contacted patient via videoconferencing
Gialanella et al [55]	Chronic neck pain	• HBT[d] group comprising fortnightly calls • Unscheduled calls in the event of uncontrolled pain • Advice on exercise, disease status, pain, and disability provided
Irvine et al [56]	Sedentary behavior in older adults	• Active after 55 to 12 sessions, 10 to 15 minutes each • More challenging exercises progressively introduced • SMS text messages and video messages to assist with goal setting
Jay et al [57]	Upper limb musculoskeletal pain	• Video-based exercises showing correct performing of exercises • Audio instructions provided for each exercise • Web-based instructional material also made accessible
Lade et al [58]	Musculoskeletal elbow disorders	• Participants were interviewed and examined face to face and remotely via a telerehabilitation system
Lawford et al [59]	Knee osteoarthritis	• Participants received 5 to 10 telephone calls over 6 months • Initial calls lasted approximately 40 minutes, with follow-up calls lasting 20 minutes • Action plan involving home strengthening exercise program and physical activity plan were devised • Program and goals adjusted as necessary
Lovo et al [60]	Chronic back disorder management	• Urban PT[e] joined with NP[f] via telehealth to undergo a full neuromusculoskeletal lumbar spine assessment • Patients provided with a summary of findings and answers to questions
Mani et al [61]	Musculoskeletal disorders assessments	• Validity and inter- and intrarater reliabilities of telerehabilitation-based physiotherapy examined • Two independent reviewers used QAREL[g] and QUADAS[h] to assess the methodological quality

Study	Condition	Intervention
Mecklenburg et al [62]	Chronic knee pain	• Hinge health delivered remotely for 12 weeks • Information provided for exercise therapy, education, CBT[i], weight loss, and psychosocial support
Meijer et al [63]	Traumatic bone and soft tissue injuries	• A total of 12 articles were included • No studies on wearable-controlled games or rehabilitation games included • All studies were low to moderate quality
Nelson et al [64]	Total hip replacement	• Remotely delivered telerehabilitation into the home • Technology-based HEP[j] provided using iPad app
Pastora-Bernal et al [65]	Subacromial decompression	• Customized exercises through a web application • Participants received 12-week (5 days per week) video exercises alongside a telerehabilitation patient manual
Peterson [66]	Chronic low back pain	• Participants tracked daily pain levels and HEP adherence using a mobile phone app for 12 months following discharge
Piqueras et al [67]	Total knee arthroplasty	• IVT[k] comprising 1-hour sessions for 10 days (5 performed under supervision and 5 performed at home)
Richardson et al [68]	Musculoskeletal disorders of the knee	• Patient interview and face-to-face and web-based assessment via telerehabilitation system • Telerehabilitation assessments involved facilitated self-palpation, self-applied modified orthopedic tests, and active movements and functional tasks
Rothgangel et al [69]	ACL reconstruction	• A total of 7 Dutch private practices participated in this study • Data collected regarding physiotherapists' most used components, acceptability, and suggested improvements
Russell et al [70]	Musculoskeletal ankle disorders	• Patient interviews conducted face to face and on the web via telerehabilitation • Web-based assessment recorded via eHAB system to allow for interrater and intrarater reliability components to be performed
Shukla et al [71]	Total knee arthroplasty	• Six publications included • Patients experienced high levels of satisfaction with telerehabilitation alone • No changes to outcomes of active knee extension and flexion
Tousignant et al [72]	Total knee arthroplasty	• 16 telerehabilitation sessions over 2 months • Conducted via videoconferencing delivered to patients' home
Wijnen et al [73]	Total hip arthroplasty	• 12-week home-based telerehabilitation program with instructions provided via a web-based app • Strengthening and walking exercises of the affected hip included • Remote coaching provided via weekly telephone calls • Recommendations were given regarding exercise progression

[a]ROM: range of motion.

[b]MSD: motion sensor device.

[c]ACL: anterior cruciate ligament.

[d]HBT: home-based telemedicine.

[e]PT: physical therapist.

[f]NP: nurse practitioner.

[g]QAREL: Quality Appraisal tool for studies of diagnostic reliability.

[h]QUADAS: Quality Assessment of Diagnostic Accuracy Studies.

[i]CBT: cognitive behavioral therapy.

[j]HEP: home exercise program.

[k]IVT: interactive virtual telerehabilitation.

Table 3. Outcome measures and findings.

Study	Outcome measures	Findings
Adamse et al [46]	• Outcome measure not stated	• Telemedicine vs no intervention showed lower scores for pain (MD[a] –0.57, 95% CI –0.81 to –0.34) • Nonsignificant effects shown for function (MD 19.93, 95% CI –5.20 to 45.06 minutes per week)
Adhikari et al [47]	• Pain: NPRS[b]	• NPRS demonstrated significantly decreased pain: at rest: F=3.5, P<.04; when worst: F=26.4, P<.001; during activity: F=16.6, P<.001; during occupation: F=15.6, P<.001
Azma et al [48]	• Pain: KOOS[c] • Function: WOMAC[d]	• In both groups, KOOS scores increased from baseline to 6 months (50.6 to 83.1 and 49.8 to 81.8) • No significant difference in either group in any of the studied scales
Bini and Mahajan [49]	• PRO[e]: VAS[f], VR-12[g], and KOOS-PS[h]	• No statistically significant difference between groups on any outcome • Overall use of hospital resources 60% less than traditional group
Chen et al [50]	• Pain: VAS • Function: qDASH[i] • Exercise completion rate: self-reported and motion sensor data	• MSD[j] exhibited good to excellent reliability for shoulder ROM[k] (intraclass correlation coefficient range 0.771-0.979) • MSD rehab assisted group displayed better shoulder mobility and function
Correia et al [51]	• Primary outcomes: TUG[l] score • Secondary outcomes: KOOS and knee ROM in degrees	• For primary outcome at 6 months, the median difference between groups was 4.87 (95% CI 1.85 to 7.47) seconds in favor of the intervention group
Dunphy et al [52]	• Interviews analyzed using pragmatic thematic analysis	• Patients' six themes: experience of TRAK[m], reasons for engagement, strengths, weaknesses, future use, and attitudes to digital health care • Physiotherapists' three themes: potential benefits, availability of resources, and service organization to support TRAK
Eriksson et al [53]	• Qualitative content analysis	• Six categories were identified: a different reinforced communication, pain-free exercising as an effective routine, from a dependent patient to a strengthened person at home, closeness at a distance, facilitated daily living, and continuous physiotherapy chain
Eriksson et al [54]	• Pain: VAS • Function: Constant-Murley • ROM: Goniometer • Shoulder condition: SRQ-S[n]	• Statistically significant improvements in all outcomes for both groups, with the telemedicine group improving more (P<.001 for all)
Gialanella et al [55]	• Pain: VAS • Function: Neck Disability Index	• At 6 months, neck pain and disability decreased in both groups (P<.001), with the decline being more marked in HBT[o] group (P=.001) • 87.2% of patients undergoing HBT and 65.9% of control participants were performing home exercises (2-7 sessions per week)
Irvine et al [56]	• Self-reported 14-point questionnaire measuring physical activity status to behavioral intentions to change	• At posttest, intervention participation showed significant improvement on 13 of 14 outcome measures compared with control participants • At 6 months, intervention participants maintained large improvements on all 14 outcomes compared with control participants
Jay et al [57]	• Descriptive statistics: training frequency, use of written and video material, training adherence, and pre- to post-training self-perceived pain of the neck, shoulder, arm, and wrist	• Unilateral shoulder external rotation had a higher normalized error score in the V group of 22.19 (SD 9.30) to 12.64 (SD 6.94) in the *P* group (P=.002)
Lade et al [58]	• Unclear	• There was substantial agreement for validity in systems diagnosis (73%; P=.01) • Almost perfect intrarater reliability (90%; P=.001) • Interrater reliability had a weaker agreement (64%; P=.11)

Study	Outcome measures	Findings
Lawford et al [59]	• Thematic analysis	• Participants described positive experiences with received therapy via telephone, valuing convenience and accessibility • Some desired visual contact with the physiotherapist • Participants valued undivided attention from the physiotherapist and were able to communicate effectively over the phone • Participants felt confident performing their exercise program without supervision
Lovo et al [60]	• Interviews analyzed qualitatively and quantitatively	• Patients were very satisfied (62.1%) or satisfied (31.6%) with the overall experience • Patients were very (63.1%) or somewhat (36.9%) confident with the assessment
Mani et al [61]	• Methodological quality: QAREL[p] and QUADAS[q]	• 11 articles were reviewed • Studies were moderate to good in quality • Physiotherapy assessments of pain, swelling, ROM, muscle strength, balance, gait, and functional assessment demonstrated good validity • Low to moderate validity for lumbar spine posture, special orthopedic tests, neurodynamic tests, and scar assessments
Mecklenburg et al [62]	• Pain: KOOS • Function: KOOS-PS	• Digital care program demonstrated a statistically significantly higher reduction in pain (7.7, 95% CI 3.0 to 12.3; P=.002) • A statistically significantly greater improvement in function (7.2, 95% CI 3.0 to 11.5; P=.001)
Meijer et al [63]	• Outcome measures not stated	• 12 studies were included • Studies were low to moderate quality • 2 studies found beneficial effects of serious games compared with conventional therapy • 1 of 3 studies found beneficial effects of serious games • 1 of 5 trials found a statistically significant advantage in the serious game group regarding treatment adherence
Nelson et al [64]	• Function: SF-12[r] • QoL[s]: HOOS[t] subscale	• No between-group difference detected in the HOOS subscale (P=.97) • Strength, balance, and self-reported function showed no between-group difference
Pastora-Bernal et al [65]	• Function: Constant-Murley	• Telerehabilitation group was shown to have improved functional outcome: mean of 43.5 (SD 3.21) points and 68.5 (SD 0.86) points after 12 weeks
Peterson [66]	• Function: Oswestry Disability Index	• All patients met their individual goals • Excellent home exercise program adherence was displayed • Temporary increase in pain was noted; however, patients managed via telerehabilitation booster sessions and no other resources
Piqueras et al [67]	• Function: WOMAC • Muscle strength, walk speed, and pain data collected	• All participants improved after the 2-week intervention on all outcomes (P<.05) • Telerehabilitation group achieved similar functional improvements to the control group
Richardson et al [68]	• Reference given to assessment findings measured via Likert and binary scales	• System of pathology in agreement in 17 (94%) out of 18 cases • Comparisons of objective findings demonstrated substantial agreement (Cohen κ=0.635) for categorical and binary data (χ^2=400.4; P<.001) • High intrarater (89%) and moderate interrater (67%) reliability was evident for telerehabilitation assessments
Rothgangel et al [69]	• Data regarding platform use and acceptance measured using 7- and 11-point numerical scales	• Platform use was generally limited, with the number of log-ins ranging from 3 to 73 • Overall, therapists' acceptance was low to moderate • Average scores ranged from 2.5 (SD 1.1) to 4.9 (SD 1.5)
Russell et al [70]	• Clinical observations rated on a series of Likert and binary scales	

Study	Outcome measures	Findings
		• Similar agreement (93.3%) was found in pathoanatomical diagnoses • An 80% agreement (χ^2=4.3; P<.04) in primary systems diagnoses found between face-to-face and web-based assessments • Very strong agreement (κ=.92) for categorical data and significant agreement (93.3% agreement; χ^2=234.4; P<.001) for binary data
Shukla et al [71]	• Pain: VAS • Functional assessment: TUG test • Functional capacity: WOMAC • Knee movement and quadriceps strength	• Six studies included • No statistically significant difference in change in active knee extension or flexion in the home telerehabilitation group compared with the control group (MD −0.52, 95% CI −1.39 to 0.35, P=.24 and MD 1.14, 95% CI −0.61 to 2.89, P=.20)
Tousignant et al [72]	• Function: WOMAC • QoL: SF-36[u] • Disability: 30-second chair stand test	• Clinical outcomes improved significantly in both groups between end points • Some variables showed larger improvements in the usual care group 2 months after discharge
Wijnen et al [73]	• Function: TUG test, HOOS, five times Sit-to-Stand test • QoL: SF-36	• Intervention group performed functional tests significantly faster at 12 weeks and 6 months postoperatively • Large effect sizes were found on functional tests at 12 weeks and 6 months (Cohen d=0.5-1.2)

[a]MD: mean difference.
[b]NPRS: Numerical Pain Rating Scale.
[c]KOOS: Knee Osteoarthritis Outcome Score.
[d]WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.
[e]PRO: patient-reported outcome.
[f]VAS: visual analog scale.
[g]VR-12: Veterans-RAND 12.
[h]KOOS-PS: KOOS short form.
[i]qDASH: Quick Disabilities of the Arm, Shoulder, and Hand.
[j]MSD: motion sensor device.
[k]ROM: range of motion.
[l]TUG: Timed Up and Go test.
[m]TRAK: Taxonomy for RehAbilitation of Knee conditions.
[n]SRQ-S: Shoulder Rating Questionnaire.
[o]HBT: home-based telemedicine.
[p]QAREL: Quality Appraisal tool for studies of diagnostic reliability.
[q]QUADAS: Quality Assessment of Diagnostic Accuracy Studies.
[r]SF-12: 12-Item Short Form Health Survey.
[s]QoL: quality of life.
[t]HOOS: Hip disability and Osteoarthritis Outcome Score.
[u]SF-36: 36-Item Short Form Health Survey.

Study Design

Overall, there were more quantitative studies (23/28, 82%) than qualitative studies (4/28, 14%; Table 2). There were only 4% (1/28) of mixed methods studies. The most common study type was randomized controlled trials (10/28, 36%), followed by systematic reviews (4/28, 14%), one of which included a meta-analysis. The various forms of randomized controlled trials included randomized controlled trials (7/28, 25%), prospective randomized controlled trials (2/28, 7%), and randomized controlled noninferiority trials (1/28, 4%). Other quantitative designs included repeated measures design (2/28, 7%), retrospective pre–post design (1/28, 4%), pilot study to assess feasibility (1/28, 4%), prospective parallel-group feasibility study (1/28, 4%), controlled study (1/28, 4%), prospective single-group clinical study (1/28, 4%), case series (1/28, 4%), and nonrandomized controlled trial combining a single-arm intervention cohort with historical controls (1/28, 4%). Qualitative designs included semistructured interviews (3/28, 11%). Only 4% (1/28) of studies were referred to only as a qualitative interview [53]. Mixed methods designs included 4% (1/28) of studies in which data were analyzed using a mixed methods design [60]. The remaining study design (1/28, 4%) was inadequately described [58].

Study Location

A total of 15 geographical locations were reported in all the studies. These studies covered the continents of North America (6/28, 21%), Europe (12/28, 43%), Asia (5/28, 18%), and Oceania (5/28, 18%). The North American locations were

divided into Canada (2/28, 7%) and the United States (4/28, 14%). The continent of Europe included the largest number of locations, including the Netherlands (4/28, 14%), Sweden (2/28, 7%), Spain (2/28, 7%), Portugal (1/28, 4%), the United Kingdom (1/28, 4%), Italy (1/28, 4%), and Denmark (1/28, 4%). Asia contained the next most locations, comprising Nepal (1/28, 4%), Iran (1/28, 4%), Taiwan (1/28, 4%), Malaysia (1/28, 4%), and India (1/28, 4%). Oceania included only Australia (5/28, 18%).

Intervention Characteristics

Despite all studies stating mHealth as part of the intervention, a significant number of studies failed to adequately describe the input of mHealth to the extent that it would be reproducible. Several studies reported the intervention as being *an exercise program delivered to the patient's home*; however, the exact nature of these protocols was not described in sufficient detail. Those studies that provided enough detail described the elements of strengthening [48,56,57,59,73] and stretching [48,56]. One of the studies described walking exercises [73], whereas another study included education, cognitive behavioral therapy, weight loss, and psychosocial support as part of the intervention [62]. Other studies explored the use of mHealth as an adjunct to physiotherapy assessment [58,60,68,70] to assess the inter- and intrareliability of remote assessments using telerehabilitation technologies.

Findings

How mHealth Has Previously Been Applied

Previous Applications of Rehabilitative mHealth

Of the 28 included studies, 4 (28%) systematic reviews [46,61,63,71] and 1 (4%) other study [58] explored the previous applications of mHealth. Relevant studies within the systematic reviews were included separately in this review. The remaining studies focused on the feasibility and efficacy of current and future applications. Reports of previous applications of mHealth largely included telephone-based interventions using videoconferencing connected via the internet to the patients' homes (4/28, 14%). Another study described the inclusion of an interactive web-based telerehabilitation software alongside videoconferencing, including wireless sensors to record patients' movements, an interactive software to demonstrate the strengthening and range of motion (ROM) exercises undertaken following total knee arthroplasty, and a web portal for clinician input [71]. Other methods described in less detail referred to mHealth delivery via smartphones or the internet [46]. This study [46] also referenced that all interventions conducted in a home-based setting included an individually tailored exercise program alongside the promotion of self-management strategies such as chat sessions and group exercises. Other forms of mHealth applications included the use of rehabilitation games widely available on multiple platforms such as the Wii, PlayStation EyeToy, and Xbox Kinect to aid in rehabilitation following traumatic bone and soft tissue injuries. Many of these games involved balance and mobility exercises using Wii [63].

Previous mHealth Applications for Professional Use

Only 7% (2/28) of the studies [58,61] described the use of mHealth as an aid to the physiotherapy assessment of musculoskeletal disorders. The aim of these studies was to explore the validity of web-based assessment compared with traditional face-to-face methods. The inclusion of mHealth once again involved videoconferencing, in which the patient was required to self-palpate and perform modified self-administered special tests. The results showed that mHealth could be a valid alternative to accurately measuring several objective measures such as pain, ROM, muscle strength, gait, and swelling. However, the evidence was not strong enough to suggest that mHealth is a viable solution for measuring neurodynamic tests and spinal posture.

Types of Musculoskeletal Conditions Where mHealth Has Been Used

Although studies have reported the type of musculoskeletal condition for which mHealth was being used, some studies described a broader term covering a range of conditions within the same area (EG, musculoskeletal ankle disorders, musculoskeletal disorders of the knee, and sedentary behavior in older adults; Table 2). Among the adequately described musculoskeletal conditions, total knee replacement or arthroplasty (4/28, 14%) was the most common. Other surgical procedures where mHealth was used also included total hip replacement or arthroplasty (2/28, 7%), anterior cruciate ligament reconstruction (2/28, 7%), shoulder joint replacement (2/28, 7%), and subacromial decompression (1/28, 4%). Several articles explored chronic conditions such as chronic knee pain or knee osteoarthritis (3/28, 11%), chronic hip pain and hip osteoarthritis (1/28, 4%), shoulder adhesive capsulitis (1/28, 4%), chronic or mechanical low back pain (4/28, 14%), chronic neck pain (2/28, 7%), and rheumatoid arthritis (2/28, 7%). Less common conditions included prolapsed intervertebral disk (1/28, 4%) and tennis elbow (1/28, 4%).

Interventions That Have Been Implemented Using mHealth

There appears to be no novel intervention being implemented when compared with how mHealth has previously been applied. The main theme throughout most studies was the aspect of communication between the treating therapist and the patient to allow for a successful course of treatment involving mHealth. This could involve telephone calls (teleconferencing) or videoconferencing (eg, Skype [Microsoft Corporation]). The current articles suggest mHealth is best implemented as an adjunct to *usual care*, which can be defined as face-to-face physiotherapy involving exercise therapy and manual therapy [64]. A number of studies included pamphlets with the addition of weekly teleconferencing calls from participating clinicians [47,59]. For studies that did not include teleconferencing as a part of the intervention, a series of smartphone-based apps [49,66] and web-based applications were implemented [47,51,56,57,62,73]. These interventions included narrated videos of exercises with which the patient would respond by sending back recordings of them completing the exercise. This would allow for appropriate exercise progression via clinician inputs. One of the studies [65] involved the use of a wearable motion sensor device alongside an app for patients (patient app) and an app for clinicians (physician app). The patient app helped participants visualize the correct ROM of the exercises, and the

physician app provided clinicians with a data log of participants' progression, allowing for input via text.

Reasons for Engagement or Disengagement With mHealth

Approximately 64% (18/28) of articles stated the reasons for engagement or disengagement from the intervention. Overall, these reasons were not described in sufficient detail. In general, patient satisfaction was very high as participants valued the interactive features and readily available support as very important. Studies involving preoperative protocols reported that interest in surgery decreased as knowledge of their condition increased because of the constant engagement with their clinician [62]. It was also shown in several articles that mHealth increased long-term (defined as 6 months) adherence to treatment, as the influence of specialist supervision was shown to help maintain motivation and confidence in the process as well as constant goal setting [48,50]. Reasons for disengagement were stated as technological problems such as the speed of the internet connection and the *clunky* design of some of the apps [46,55]. However, it was stated that this could be minimized by implementing a web-based platform on mobile devices that could be used with standard data speeds, as most participants would be in possession of mobile devices capable of doing so [49]. It was reported that video-based interventions gave participants the most effective treatment as the videos informed them of the correct technique and gave them the confidence to perform the exercises correctly [55].

Barriers to mHealth Clinical Uptake

Only 4% (1/28) of the studies specifically explored the experience of clinicians in using mHealth [52]. This study reported the limited use of a novel telemonitoring device with a low to moderate acceptance rate among physiotherapists. A possible explanation for this was the lack of time to become familiar with the telemonitoring platform. The main issue among physiotherapists was the added workload that the intervention imposed, as therapists had to input data into an additional eHealth data log. Suggestions for future use included improvements in user-friendliness, efficiency, and design. Some therapists proposed integrating digital health technology into routine care to more easily become a new habit of clinical practice. A preference for smartphone-based apps over web-based applications was also reported, with no reasons adequately described. The final barrier suggested in this study was the lack of structured training given to current and future health care professionals to promote knowledge of new health care technologies. In the future, novel health care technologies should be more easily integrated into clinicians' routines, and training should be provided alongside this.

Discussion

Principal Findings

This study represents a mapping of the breadth of evidence for the use of mHealth within musculoskeletal physiotherapy and identifies 5 themes of mHealth implementation, including facilitators of and barriers to uptake. The main aim of this scoping review was to analyze the evidence surrounding the use of mHealth in musculoskeletal physiotherapy and the outcomes it produced. The main findings from this review suggest that videoconferencing or phone calls are the most popular among patients as they provide ongoing feedback with a clinician, potentially leading to a higher adherence rate to rehabilitation programs. Another finding has shown a lack of adequate training in mHealth use among clinicians, leading to poor uptake.

This review demonstrates that there is potential in the future for mHealth to be a viable component of musculoskeletal physiotherapy care. Recent studies have proposed that mHealth interventions have the potential to be more effective than usual physiotherapy care, as the increased use of smartphones enables patients to source information and take control of their rehabilitation [69]. However, this review has shown limited evidence to support this claim, as only 11% (3/28) of studies [49,50,66] included the use of smartphones and only 4% (1/28) of studies compared mHealth with physiotherapy, concluding that a comprehensive digital care intervention, combined with ongoing support provided with normal physiotherapy care, significantly improves outcomes for pain and function [62]. The remainder of the studies either claimed that mHealth could potentially be at least as effective as physiotherapy or were inadequately described to make any conclusions.

There is limited evidence suggesting that mHealth can be effectively used for physiotherapy musculoskeletal assessments as an alternative to face-to-face assessments. Of the 28 studies, 2 (7%) studies [58,61] suggested that this form of assessment was both valid and reliable, with 1 (4%) investigating the specific assessment of the elbow [58] and 1 (4%) investigating general musculoskeletal disorders [61]. However, the evidence suggests that this is not an acceptable alternative as special neurodynamic tests were unable to be sufficiently conducted as the patient was unable to apply the tests as a clinician would, leading to unreliable findings. Telephone or videoconferencing calls between the therapist and patient were the most accepted forms of mHealth in musculoskeletal physiotherapy. This could be viewed as a potential pitfall unless further innovation is made in this field, as patients are more likely to respond positively to a readily available app on their smartphone [74]. Most research in other medical fields has concluded that telephone or videoconferencing calls are the most popular intervention, further emphasizing the need for more development [75,76]. It is important that development continues, as reports suggest that patients feel there is a lack of currently available, relevant high-quality mHealth apps providing adequate support [77].

A range of conditions was analyzed in this review, suggesting a lack of research on mHealth use for particular musculoskeletal conditions. Postoperative rehabilitation after total knee replacement was the most researched condition for mHealth use. Only 11% (3/28) of studies investigated mHealth for the treatment of chronic low back pain [46,60,66], and 14% (4/28) of studies were related to shoulder pain [51,53,65,78]. Therefore, there is little evidence to fully support the use of mHealth for a multitude of conditions.

Very few studies described the mHealth intervention in detail in a way that would be reproducible. As this review was

conducted in the context of musculoskeletal physiotherapy, it can be assumed that physiotherapy care would be within the context of the intervention. Most authors failed to describe the physiotherapy component in detail, simply describing the intervention as *an exercise program delivered to the home, with follow-up telephone calls from a participating clinician*, with the assumption that this is a form of treatment rather than an umbrella term encompassing a range of interventions. This suggests that there is insufficient evidence to guide physiotherapists on how to effectively deliver an mHealth intervention, as supported by 4% (1/28) of the studies in this review [52].

This review highlights a lack of qualitative research on mHealth interventions as most evidence was quantitative in nature. The importance of understanding the experiences of those delivering and receiving these interventions is not to be understated and can be a vital part of enhancing the delivery of future interventions [54]. This can provide useful insights from both clinicians and patients on how to continually innovate mHealth and increase engagement and better patient care, as the value of qualitative research provides a richer insight into the lived experience [79]. This review has shown that the continents of North America, Asia, Europe, and Oceania currently have the strongest research output in support of the development of future mHealth interventions. It can be concluded that mHealth interventions are being implemented in high-income countries because of access to high-quality resources, infrastructure, and time to develop more effective and engaging interventions, including aspects such as gamification [80].

Study Limitations

Although most evidence within this review was conducted within the past 10 years, we excluded articles that were non-English articles, implying the possibility of excluding relevant articles from non–English-speaking countries (eg, China, Japan, and South Korea), where technology is well-advanced [81]. In addition, a consultation stage was not included in the review process through which we may have gained more insight, and study authors were not contacted for additional information. When compared with systematic reviews, the absence of a strong quality assessment of papers in scoping reviews makes any findings difficult to generalize and presents challenges in weighting the effectiveness of studies [44]. Despite this, we believe that the breadth of the evidence presented is sufficient for the aims of this review.

Research Opportunities and Recommendations

With the onset of the COVID-19 pandemic, alternatives to face-to-face musculoskeletal physiotherapy have become a priority. Future smart device–based mHealth interventions should focus on implementing evidence-based strategies in research design and using more innovative health care technologies to help enhance and expand the practice of mHealth. To aid in the development of the rapidly expanding market of mHealth, future research should look to develop evidence-based rehabilitation programs for acute and chronic conditions using the latest technologies and provide adequate training for clinicians.

Conclusions

It appears that mHealth has some beneficial effects on treatment adherence and can be as effective as the usual physiotherapy care and potentially more cost-effective. Currently, communication with a clinician via telephone or videoconferencing appears to be the most widely accepted among patients, as this helps maintain confidence in their rehabilitation because of ongoing feedback. This feedback loop between the clinician and the patient potentially leads to positive outcomes regarding pain and self-management because of increased adherence to the rehabilitation program.

The limitations identified in this review provide an outline for future studies. This review has shown the main limitations to mHealth uptake from clinicians, primarily as a lack of knowledge and confidence in their judgment when using mHealth interventions and a preference toward an evidence-based clinical technique [57]. Researchers have suggested more widely available training for clinicians implementing mHealth interventions in the future. The barriers to uptake among patients are related to the user-friendliness and aesthetics of the intervention, as it is likely that patients will discontinue use after a short period because of the lack of an efficient design [82]. What constitutes an efficient mHealth design is not adequately described within this review, with the only exception suggesting the use of videos within an app to promote engagement; therefore, we propose further research with a focus on designing an implementation framework and designing trials investigating long-term adherence and the effect of clinicians trained in mHealth implementation on long-term treatment outcomes.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search Strategy.
[PDF File (Adobe PDF File), 75 KB - rehab_v9i1e33609_app1.pdf]

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Abbreviations

mHealth: mobile health
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews
ROM: range of motion

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Original Paper

Patient Outcomes and Lessons Learned From Treating Patients With Severe COVID-19 at a Long-term Acute Care Hospital: Single-Center Retrospective Study

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Abstract

Background: With the continuation of the COVID-19 pandemic, shifting active COVID-19 care from short-term acute care hospitals (STACHs) to long-term acute care hospitals (LTACHs) could decrease STACH census during critical stages of the pandemic and maximize limited resources.

Objective: This study aimed to describe the characteristics, clinical management, and patient outcomes during and after the acute COVID-19 phase in an LTACH in the Northeastern United States.

Methods: This was a single-center group comparative retrospective analysis of the electronic medical records of patients treated for COVID-19–related impairments from March 19, 2020, through August 14, 2020, and a reference population of medically complex patients discharged between December 1, 2019, and February 29, 2020. This study was conducted to evaluate patient outcomes in response to the holistic treatment approach of the facility.

Results: Of the 127 total COVID-19 admissions, 118 patients were discharged by the data cutoff. At admission, 29.9% (38/127) of patients tested positive for SARS-CoV-2 infection. The mean age of the COVID-19 cohort was lower than that of the reference cohort (63.3, 95% CI 61.1-65.4 vs 65.5, 95% CI 63.2-67.8 years; *P*=.04). There were similar proportions of males and females between cohorts (*P*=.38); however, the proportion of non-White/non-Caucasian patients was higher in the COVID-19 cohort than in the reference cohort (odds ratio 2.79, 95% CI 1.5-5.2; *P*=.001). The mean length of stay in the COVID-19 cohort was similar to that in the reference cohort (25.5, 95% CI 23.2-27.9 vs 29.9, 95% CI 24.7-35.2 days; *P*=.84). Interestingly, a positive correlation between patient age and length of stay was observed in the COVID-19 cohort (r^2=0.05; *P*=.02), but not in the reference cohort. Ambulation assistance scores improved in both the reference and COVID-19 cohorts from admission to discharge (*P*<.001). However, the mean assistance score was greater in the COVID-19 cohort than in the reference cohort at discharge (4.9, 95% CI 4.6-5.3 vs 4.1, 95% CI 3.7-4.7; *P*=.001). Similarly, the mean change in gait distance was greater in the COVID-19 cohort than in the reference cohort (221.1, 95% CI 163.2-279.2 vs 146.4, 95% CI 85.6-207.3 feet; *P*<.001). Of the 16 patients mechanically ventilated at admission, 94% (15/16) were weaned before discharge (mean 11.3 days). Of the 75 patients admitted with a restricted diet, 75% (56/75) were discharged on a regular diet.

Conclusions: The majority of patients treated at the LTACH for severe COVID-19 and related complications benefited from coordinated care and rehabilitation. In comparison to the reference cohort, patients treated for COVID-19 were discharged with greater improvements in ambulation distance and assistance needs during a similar length of stay. These findings indicate that other patients with COVID-19 would benefit from care in an LTACH.

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KEYWORDS

COVID-19; SARS-CoV-2; post–COVID-19; subacute COVID-19; postacute care; long-term acute care hospital; pulmonary; speech therapy; speech-language pathology; rehabilitation; physical therapy; occupational therapy; respiratory therapy

Introduction

Patients hospitalized with severe COVID-19 caused by SARS-CoV-2 infection may face a long hospital length of stay (LOS), making it unreasonable to expect a direct discharge to home [1]. Indeed, COVID-19 is predicted to result in significant morbidity for some patients, with the need for medical and rehabilitation services for 6 months or longer after the initial diagnosis [2].

Long-term acute care hospitals (LTACHs) can provide these postacute care and rehabilitation services in the post-COVID phase. They can also provide an alternative to conventional short-term acute care hospitals (STACHs) for active COVID-19 treatment, thereby reducing the burden on the STACH system when resources are already limited [3,4].

LTACHs are certified acute care hospitals equipped to provide long-term (average LOS of 25-28 days) acute level care to medically complex patients. LTACHs are able to treat patients who require a higher level of care than what other rehabilitation facilities may be able to provide. Medically complex patients are often transferred to the LTACH setting as soon as they are found to be hemodynamically stable. Once at the LTACH, an interdisciplinary care plan, including continued treatment for underlying conditions and targeted holistic rehabilitation, is started. While it is the hope that each patient is able to be discharged to home, patients may also be transferred to other facilities such as skilled nursing facilities to continue their recovery if necessary.

It has been proposed that patients with severe COVID-19 may benefit from the inpatient respiratory, functional, and neurological rehabilitation provided at LTACHs [5]. Early rehabilitation may also reduce disability and improve clinical outcomes in patients with COVID-19 [6-9].

Here, we report on patient characteristics, clinical management strategies, and patient outcomes from an LTACH caring for patients with severe COVID-19, as well as make comparisons with the typical medical population cared for at the LTACH.

Methods

Study Design, Setting, and Study Population

This retrospective study was conducted at Gaylord Specialty Healthcare, a rehabilitation-focused LTACH in the Northeastern United States. COVID-19–related data were collected from March 19, 2020, through August 14, 2020. The study data are for 117 individuals who were treated in regional STACHs for acute COVID-19 and then discharged to the LTACH for post–COVID-19 care and rehabilitation. Due to STACH readmissions for acute decompensation, 8 of the 117 individuals accounted for 10 additional admissions, for a total of 127 admissions. Of the 127 total admissions/readmissions, there were 118 total discharges by the data cutoff of August 14, 2020, with 9 admissions remaining as active patients.

Data from a historical reference cohort (control population) consisting of 157 individuals discharged from December 1, 2019, through February 29, 2020, were also collected. Similar to the COVID-19 cohort, some individuals required temporary readmission to a STACH before being readmitted to the LTACH setting. Ten of the 157 individuals accounted for 13 additional readmissions in the reference cohort, for a total of 170 admissions and discharges. Although this led to uneven population sizes, the 2-month time frame for the historical control was selected to normalize potential seasonal variances and minimize the effect of annual regulatory and insurance changes.

When describing patient demographics, we compared the 117 individual patients admitted for COVID-19–related rehabilitation and the 157 individuals admitted during the reference time frame. When comparing LOS, we used the LOS for the 118 total COVID-19 discharges and the LOS for the 170 total reference cohort discharges. For all other comparisons, we used data from the total admissions or subpopulations.

Protocols for Patients With Confirmed or Suspected SARS-CoV-2 Infection

Similar to arrangements made by other LTACH facilities with regional hospitals, patients who required postacute care for COVID-19–related issues and those who were still SARS-CoV-2 positive were accepted from STACHs to help unburden those facilities [10]. Additionally, when available beds in the LTACH facility were scarce, health care workers and other first responders were prioritized for admission to ensure other regional health care facilities were able to be adequately staffed during the pandemic.

Patients with active or prior SARS-CoV-2 infection were housed on separate floors of the hospital, similar to the practical arrangements of other postacute care facilities [11]. Patients with confirmed or suspected SARS-CoV-2 infection were housed in negative-pressure rooms or in rooms with portable or ceiling-mounted air scrubbers.

Personal protective equipment protocols for the COVID-19 cohort included the use of face shields, N95 particulate respirator

masks or duck bill surgical masks, scrub caps, and boot covers, as well as uniform laundering at an outside facility. Powered air-purifying respirators were available if needed. Due to a facility shortage of N95 respirator masks (ie, unknown/unstable resupply chains), these masks were sterilized for reuse by an outside facility.

To decrease personnel exposure to patients with suspected or confirmed SARS-CoV-2 infection and conserve personal protective equipment, we developed multidisciplinary "COVID-19 teams" responsible for patient isolation, testing, implementation of droplet precautions, and cluster care. Further, a dedicated respiratory therapist and intubation box were used to treat patients with active SARS-CoV-2 infection requiring mechanical ventilation or having a tracheostomy.

Typical Care for Patients With a Pulmonary Condition

Using standardized measures and functional assessments, interdisciplinary clinical teams evaluated patients to determine functional impairments at admission. When applicable, a speech-language pathologist assessed patients for voicing, swallowing, and cognitive-communication impairments. Patients were mobilized throughout the day, including chair positioning of the bed, transfer to a bedside chair, and other exercises/ambulation as appropriate.

Within 24 hours of admission, patients with a tracheostomy were assessed for in-line speaking valve use. As patients progressed with the speaking valve, they were transitioned to tracheostomy capping and placed on the decannulation protocol (Multimedia Appendix 1). When appropriate, patients being mechanically ventilated were considered for the ventilator weaning protocol (Multimedia Appendix 2). Interdisciplinary rounds occurred weekly for patients being mechanically ventilated.

COVID-19–Specific Respiratory Therapy Considerations

SARS-CoV-2–positive patients completed self-directed exercises in their rooms, were seen for individual or co-treatment sessions in their rooms, and, once SARS-CoV-2 negative, participated in group pulmonary exercise therapy and education classes.

Patients who were desaturating or acutely decompensating were placed in the prone position by a multidisciplinary team (including physical therapy, nursing, and respiratory therapy). Prior to placing patients in the prone position, staff participated in training sessions on how to safely prone and reposition patients, manage leads and lines, and perform cardiopulmonary resuscitation while in the prone position. Patients who were functionally capable or were previously placed in the prone position during acute care, were educated on how to safely put themselves in the prone position and encouraged to do so when appropriate.

Speech-Language Pathology

Many patients in the COVID-19 cohort presented with cognitive-communication deficits, potentially as a result of COVID-19–induced hypoxia, prolonged intubation, or sedation [12]. When appropriate, cognitive-communication assessments were performed by a speech-language pathologist on the COVID-19 team. Using tools, such as the Bioness Integrated Therapy System, worksheets, and group therapy sessions, speech-language pathology sessions focused on attention, memory, functional skills, and compensatory strategy use. The National Outcomes Measurement System (NOMS) assessment was used to summarize the overall cognitive communication status of the COVID-19 cohort at admission and discharge. The NOMS scale was developed by the American Speech-Language-Hearing Association, and consists of 15 functional communication measures used for adult health care [13-15]. These 15 measures were designed to describe functional abilities over time and to be diagnosis specific, meaning that patients would only be given the measures specific to their case. These measures are scored using a 7-level system based on speech-language pathologist clinical observations of the individual's communication and swallowing ability. The diagnosis-specific functional communication measures used to describe the patients treated for postacute COVID-19 in this study included the following: attention, memory, problem solving, spoken language comprehension, spoken language expression, swallowing, and voice following tracheostomy.

For the purpose of this study, the functional communication measure scores were used to assign an overall cognitive-communication status, including the following: unable to assess, profound impairment, severe impairment, moderate-severe impairment, moderate impairment, mild-moderate impairment, mild impairment, within functional limits, or baseline. To facilitate statistical analysis, these statuses were then given a numerical value ranging from 1 (unable to assess) to 9 (baseline cognition). Due to the retrospective nature of the study, similar values were not readily available for the reference cohort and were not included.

Due to the correlation between prolonged intubation and dysphagia, speech-language pathology interventions also targeted swallowing dysfunction [16]. Dysphagia management comprises several aerosol-generating procedures, including oral mechanism examination, cough testing, reflexive cough, swallowing trials, and secretion management. Given the proximity and prolonged exposure to aerosols during instrumental evaluations and the need for multiple staff members, procedures, such as fiberoptic endoscopic evaluation of swallow and modified barium swallow study, were minimized. Thus, speech-language pathologists heavily relied on clinical swallowing evaluations for patients with active SARS-CoV-2 infection. Additionally, some patients in the COVID-19 cohort consented to performing clinical swallowing evaluations via telehealth to reduce potential SARS-CoV-2 exposure and transmission.

Gait/Functional Status Assessment and Rehabilitation

At admission, physical therapists evaluated patient ambulatory status by assessing functional ability and gait distance. Patients received standard individualized physical therapy, and their gait quality and distance were challenged for progression as tolerated. Hypotension or tachycardia was present in some patients in the COVID-19 cohort. For these individuals, therapy was aimed at improving tolerance and progression. Functional Independence Measure (FIM) assistance level scores and gait

distance were used to describe the functional ability of patients throughout recovery. With a mean interrater reliability ranging from 0.89 to 1.00, the FIM is a 2-domain (ie, motor function and cognitive function) 18-item assessment. This measure uses a 7-point ordinal scale to measures the amount of assistance provided by the therapist during treatment [17-20]. Here, we are only reporting the assistance level associated with the FIM scores for ambulation under the locomotion subscale [17-20]. The assistance level associated with FIM was analyzed separate to the gait distance component. We felt that analyzing assistance and gait distance separately was the best way to look at the functional status of the subject amidst infection control restrictions, potentially limiting patients to their rooms and potentially limiting ambulation distances.

Statistical Analysis

Data were analyzed using GraphPad Prism version 9.0.0 (GraphPad Software). Prior to analysis, data were tested for normality using the Shapiro-Wilk test. Each data set was found to have one or more nonnormally distributed groups, and nonparametric tests were used accordingly. For hypothesis testing between 2 unpaired groups, the Mann-Whitney rank comparison test was conducted. For paired 2-group testing, the Wilcoxon matched-pairs signed-rank test was conducted. For hypothesis testing between 3 groups, the Kruskal-Wallis analysis of variance (ANOVA) test with the Dunn multiple comparison posthoc test was conducted.

To compare the proportions of racial demographics of the reference and COVID-19 cohorts, we subdivided the individuals into either self-reported White/Caucasian or non-White/non-Caucasian (Black/African American, Asian, bi/multiracial) racial demographics. The rationale behind this was 2-fold. First, since the start of the pandemic, there has been a reported disparity in the number of White and non-White individuals being infected with SARS-CoV-2. By comparing these proportions, we wished to determine if this was also reflected in our population. Second, due to their lower representation in our population, individuals who self-reported as bi/multiracial in the COVID-19 cohort did not meet the criteria to conduct reliable chi-square testing across more than 2 groups. We were left with the option to either exclude these individuals or combine them. While combining Asian and bi/multiracial individuals into 1 category would have worked, we opted to combine and compare all non-White/non-Caucasian (Black/African American, Asian, bi/multiracial) individuals to White/Caucasian individuals. Doing this also allowed us to conduct the Fisher exact test, which is preferred to the approximation calculated with chi-square testing. Additionally, the odds ratios (ORs) for the proportions and the respective 95% CIs (Baptiste Pike testing) were calculated. Moreover, the Fisher exact test, ORs, and Baptiste Pike test were used to compare the proportions of male and female individuals between the cohorts.

Nonlinear regression analysis was conducted to determine the correlation between 2 conditions using least-squares regression; 95% CIs are reported. An extra sum-of-squares F test was performed to evaluate the calculated slope of each regression against a hypothetical slope of 0.

When data from multiple time points and two or more groups were present, a 2-way mixed effects model ANOVA was used. This was to evaluate for the presence or absence of time effects independent of the cohort, cohort effects independent of time, and the effects of time and cohort combined. The Šídák multiple comparisons test was then used to calculate all in-group and between-group comparisons. Included in this analysis were the admission and discharge values for ambulation assistance (ie, FIM scores) and gait distance travelled. Changes in FIM scores and gait distance were compared using Mann-Whitney *U* tests.

Ethics Approval

This study was written in compliance with our institutional privacy policy, the Health Insurance Portability and Accountability Act, and the standards set by the Declaration of Helsinki. Prior to beginning, this retrospective study was reviewed and given an exempt status by the Gaylord Specialty Healthcare Institutional Review Board.

Results

Patient Demographics

During the study period, 117 individuals, accounting for 127 total admissions, were admitted for COVID-19 or post–COVID-19 care as described above (Figure 1). COVID-19 admissions first peaked during May 2020 (Figure 2A), approximately 4 weeks later than in the New England/New York City area [21,22]. Of the 127 total admissions/readmissions, there were 118 total discharges by the data cutoff, with 9 admissions still receiving care. The COVID-19 cohort represented 17.2% (127/737) of the hospital census during the 4.5-month/148-day study period. For the 127 total COVID-19 admissions, the mean STACH LOS prior to LTACH admission or readmission was 34.3 (95% CI 30.6-37.9) days. The mean LTACH LOS for the 118 total discharges was 25.5 (95% CI 23.2-27.9) days. Regression analysis indicated that there was no correlation between STACH LOS and LTACH LOS (r^2=0.03, *P*=.09; Figure 2B). Further, the mean COVID-19 cohort LOS was similar to the reference cohort LOS of 29.9 (95% CI 24.7-35.2) days (*P*=.84; Figure 2C).

Figure 1. Study cohorts (COVID-19 cohort and reference cohort). FIM: Functional Independence Measure; NOMS: National Outcomes Measurement System.

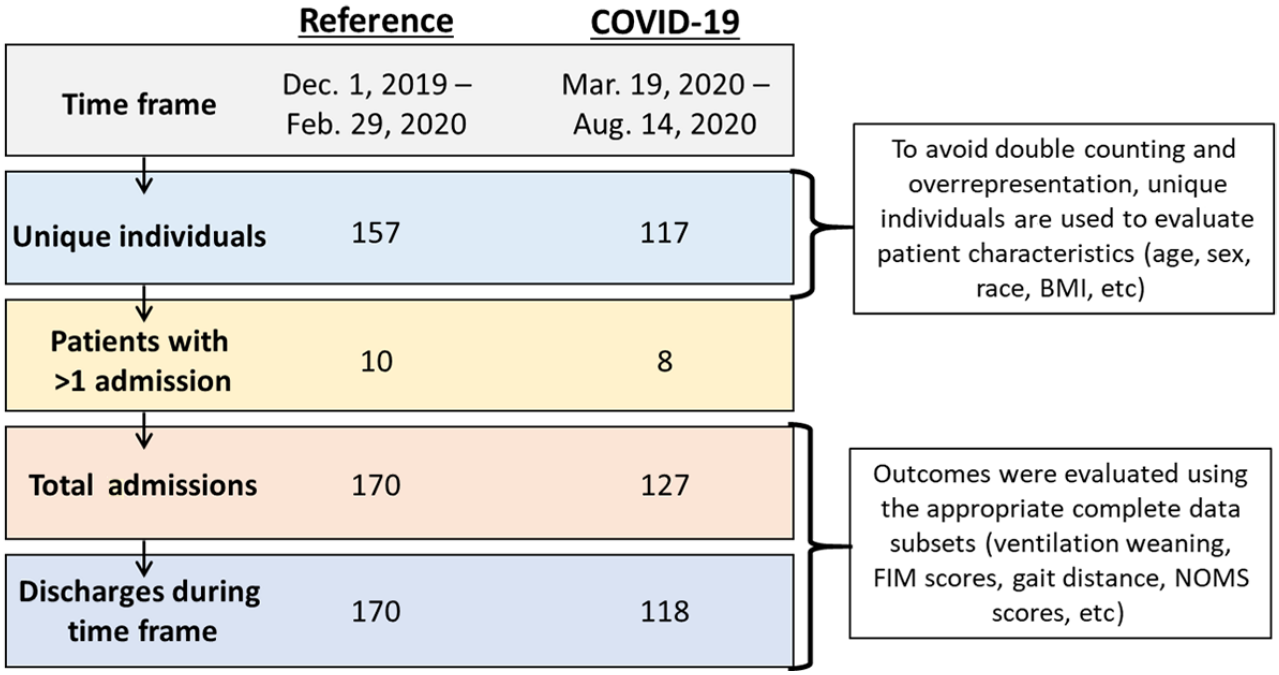
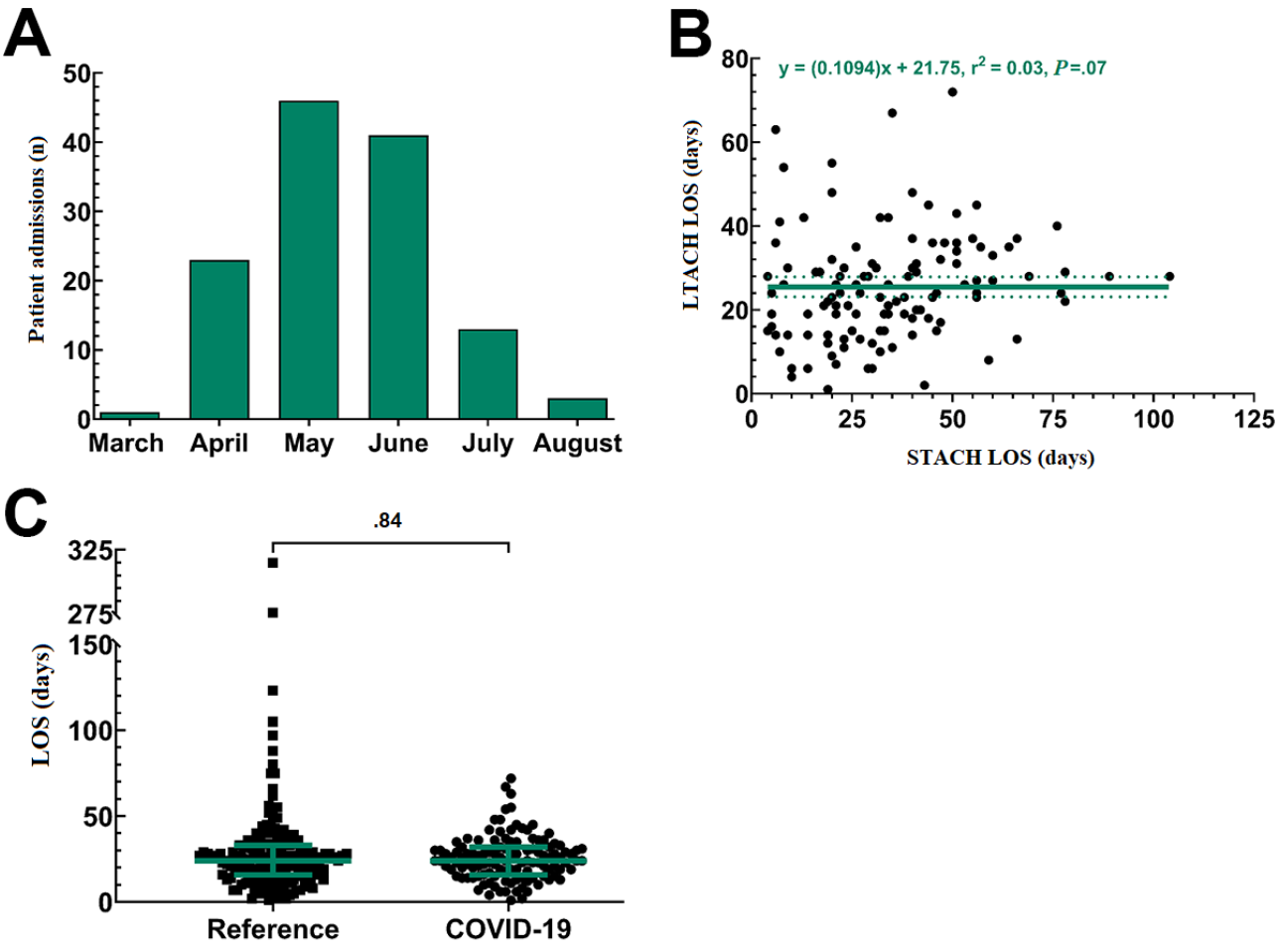


Figure 2. Trends in patient admission and length of stay (LOS) during the COVID-19 pandemic. (A) Patient admission from March 19, 2020, to August 14, 2020. (B) Nonlinear regression analysis for the correlation between patient long-term acute care hospital (LTACH) LOS and short-term acute care hospital (STACH) LOS. The solid regression line shows the correlation coefficient, and the dotted lines show the 95% CI. (C) Scatter plot for the comparison of the LTACH LOS between the reference and COVID-19 cohorts. The colored lines represent the median and interquartile range.



Compared to the reference cohort (n=157 individual patients), the COVID-19 cohort (n=117 individual patients) had a similar ratio of males to females (OR 0.79, 95% CI 0.49-1.3; *P*=.38), was younger (difference of medians=−4.0, 95% CI −6.0 to 0.0; *P*=.04; Figure 3A; Table 1), and had a greater representation of non-White racial demographics (32.5% vs 15.9%; OR 2.79, 95% CI 1.5-5.2; *P*=.001; Table 1). At admission, the most prevalent comorbidities in the COVID-19 cohort were hypertension (53.0%), hyperlipidemia (42.6%), dysphagia (38.3%), and type II diabetes mellitus (35.7%; Table 1).

At discharge, the most common discharge destinations of the reference cohort included home with health services (53/170, 31.2%), skilled nursing facility (43/170, 25.3%), emergent transfer to a STACH (38/170, 22.4%), and home without health services (11/170, 6.5%). The COVID-19 cohort discharge destinations were similar in nature and included home with health services (58/127, 45.7%), skilled nursing facility (35/127, 32.5%), home without health services (18/127, 14.2%), and emergent transfer to a STACH (14/127, 11.0%) (Table 1). Using chi-square testing, the distributions of the discharge destinations of the 2 cohorts were compared, and it was observed that the distributions were significantly different (χ^2_5=21.93; *P*<.001).

Figure 3. Age as a risk factor for prolonged COVID-19 illness. (A) Scatter plot showing the age distribution in the reference and COVID-19 cohorts. The colored lines represent the median and interquartile range. (B) Nonlinear regression analysis showing the correlation between patient age and long-term acute care hospital length of stay (LOS) in the overall COVID-19 cohort. Solid regression lines show the correlation coefficient surrounded by the 95% CI as dotted lines. (C, D) When evaluated by sex, this pattern was also observed in COVID-19 males alone (C), but was not present in COVID-19 females alone (D). Solid regression lines show the correlation coefficient surrounded by the 95% CI as dotted lines.

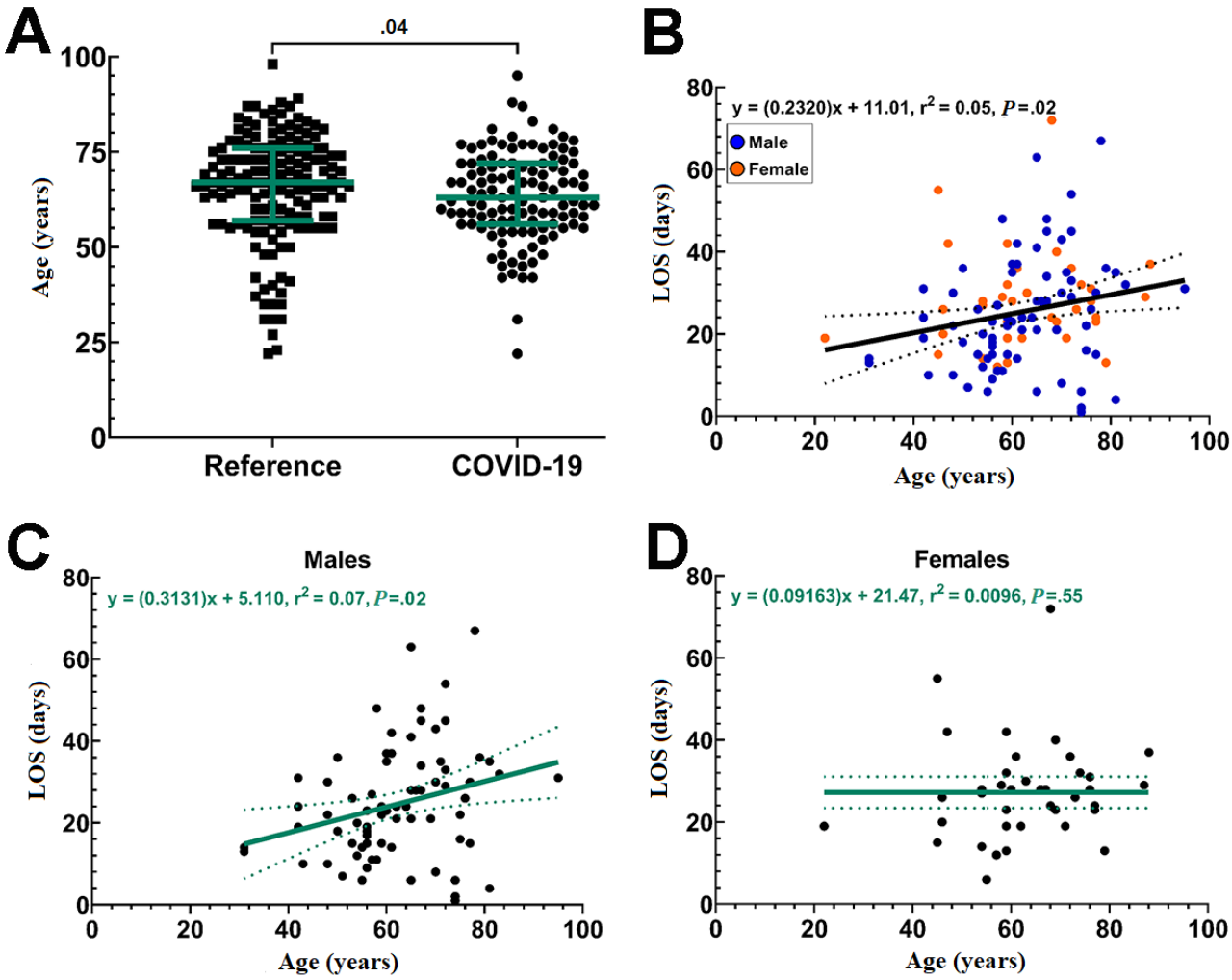


Table 1. Patient demographics and comorbidities at long-term acute care hospital admission.

Characteristic	Reference cohort[a]	COVID-19 cohort[b]	Group difference (95% CI) or chi square (*df*)	*P* value
Cohort age (years), mean (95% CI), n[c]	65.5 (63.2 to 67.8), 157	63.3 (61.1 to 65.4), 117	−4.0 (−6.0 to 0.0)[d]	.04
Sex			0.79 (0.49 to 1.3)[e]	.38
Male, n[c] (%)	92 (58.6)	75 (64.1)		
Female, n[c] (%)	65 (41.4)	42 (35.9)		
Male age (years), mean (95% CI), n[c]	64.0 (61.3 to 66.8), 92	63.2 (60.5 to 65.8), 75	−4.0 (−6.0 to 2.0)[d]	.30
Female age (years), mean (95% CI), n[c]	67.6 (63.7 to 71.6), 65	63.5 (59.5 to 67.4), 42	−6.5 (−11.0 to 0.0)[d]	.04
BMI (kg/m^2), mean (95% CI), n[c]	27.2 (26.0 to 28.4), 157	29.9 (28.7 to 31.2), 117	3.2 (1.3 to 4.5)[d]	<.001
Length of stay (days), mean (95% CI), n[c]	29.9 (24.7 to 35.2), 170	25.5 (23.2 to 27.9), 118	0.0 (−3.0 to 3.0)[d]	.84
Race[f], n[c](%)			2.79 (1.5 to 5.2)[e]	.001
White/Caucasian	132 (84.1)	79 (67.5)		
Non-White/non-Caucasian	21 (15.9)	35 (32.5)		
Black/African American	15 (9.2)	27 (23.7)		
Asian	4 (2.4)	7 (6.1)		
Bi/multiracial	2 (1.2)	1 (0.9)		
Discharge destination[g], n[c](%)			21.93 (*df* 5)	<.001[e,h]
Home with health services	53 (31.2)	58 (45.7)		
Skilled nursing facility	43 (25.3)	25 (19.7)		
Home without health services	11 (6.5)	18 (14.2)		
Emergent transfer to an ACH[i]	38 (22.4)	14 (11.0)		
Planned transfer to an ACH	8.8 (8.8)	2 (1.6)		
Other	10 (5.9)	10 (7.9)		
Acute rehabilitation	0 (0.0)	1 (0.8)		
Hospice/palliative care	6 (3.5)	0 (0.0)		
Deceased	4 (2.4)	0 (0.0)		
Patient at data cutoff	0 (0.0)	9 (7.1)		
COVID-19 cohort comorbid conditions at LTACH[j] admission[k], n (%)			N/A[l]	N/A
Primary hypertension	N/A	61 (53.0)		
Hyperlipidemia	N/A	49 (42.6)		
Dysphagia	N/A	44 (38.3)		
Type II diabetes mellitus	N/A	41 (35.7)		
Acute kidney failure	N/A	25 (21.7)		
Urinary tract infection	N/A	22 (19.1)		
Severe obesity	N/A	14 (12.2)		

[a]The reference cohort included medically complex patients cared for at the facility from December 1, 2019, to February 29, 2020. Data from 170 admissions, consisting of 157 individuals, were included.

[b]The COVID-19 cohort included all COVID-19–related admissions from March 19, 2020, through August 14, 2020. Data from 127 admissions, consisting of 117 individuals, were included; 118 of the 127 admission cases were discharged by the data cutoff.

[c]The listed "n" value indicates the sample size analyzed to obtain each of the reported *P* values.

[d]Nonparametric Mann-Whitney test is used; group difference and reported 95% CI are based on differences of the medians.

[e]Fisher exact test is used to compare proportions of the self-reported demographics by group; group difference and reported 95% CI are calculated using

odds ratios and Baptiste-Pike testing.

[f]Breakdown of self-reported demographics. For analysis of race-related demographics, groups were divided as either White/Caucasian or non-White/non-Caucasian. Individuals who elected to not report were not included in this analysis.

[g]Breakdown of recorded discharge destinations for all admissions in both the reference (n=170) and COVID-19 (n=127) cohorts. For analysis, the destinations of acute care hospital rehabilitation, hospice/palliative care, deceased, and patient at data cutoff were grouped.

[h]Chi-square testing was used to compare the distribution of discharge destinations for both cohorts.

[i]ACH: acute care hospital.

[j]LTACH: long-term acute care hospital.

[k]Comorbid conditions in the COVID-19 cohort were identified by International Classification of Diseases 10th revision (ICD-10) diagnosis codes available in the patient's medical record at discharge from the short-term acute care hospital and admission to long-term acute care.

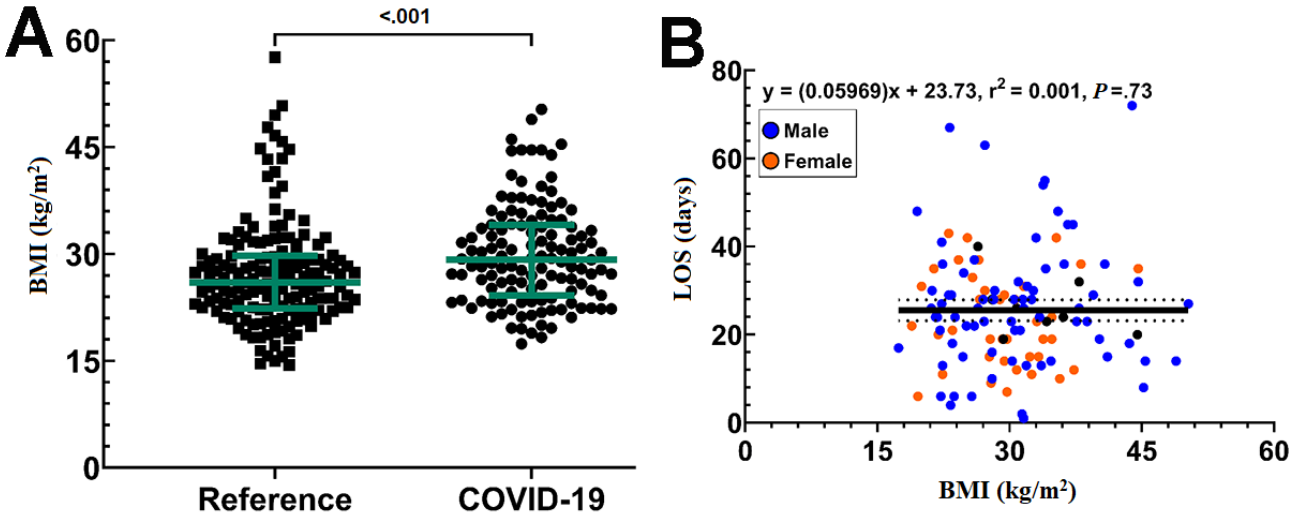
[l]N/A: not applicable; data was not readily available through retrospective review.

Outcomes

Using LOS as a read out for disease severity (ie, the more severe the COVID-19 illness, the longer the LOS in rehabilitation), regression analyses were performed to determine if patient sex, age, or BMI affected LOS, all of which have been noted to increase the risk of severe or prolonged COVID-19 illness [23,24]. Examining age as a potential risk factor for longer LOS and prolonged COVID-19 rehabilitation, we observed a positive correlation among COVID-19 patients (r^2=0.05; *P*=.02; Figure 3B). No such correlation was observed in the reference cohort (data not shown). When each sex was analyzed separately, we observed a positive correlation between LOS and age among males in the COVID-19 cohort (r^2=0.07; *P*=.02; Figure 3C), but not among females (r^2=0.001; *P*=.55; Figure 3D).

BMI was greater in the COVID-19 cohort than in the reference cohort (Figure 4A, Table 1). Using regression analysis, no correlation was observed between BMI and LOS overall in the COVID-19 cohort (r^2=0.001; *P*=.73; Figure 4B). Similarly, no such correlation was observed for males or females separately in the COVID-19 cohort (data not shown) or in the reference cohort (data not shown).

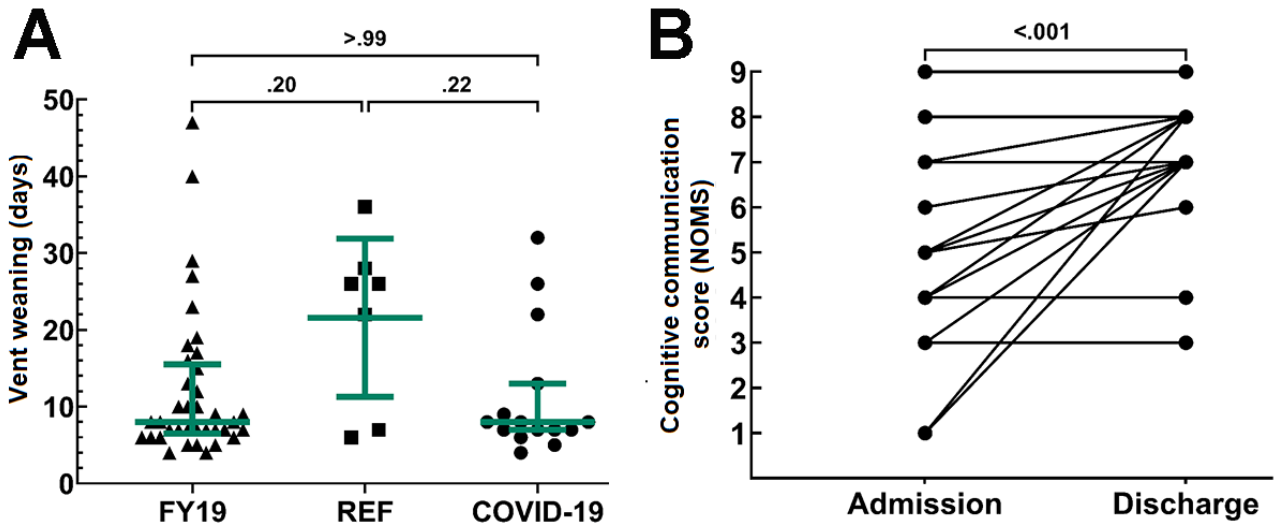
Figure 4. BMI as a risk factor for prolonged COVID-19 illness. (A) Scatter plot showing the distribution of BMI in the reference and COVID-19 cohorts. Lighter colored lines represent the median and interquartile range. (B) Nonlinear regression analysis showing the correlation between COVID-19 patient BMI and long-term acute care hospital length of stay (LOS). Solid regression lines show the correlation coefficient surrounded by the 95% CI as dotted lines.



Respiratory Therapy

Of the 43 patients admitted with a tracheostomy, 37.2% (16/43) required mechanical ventilation and 62.8% (27/43) did not; 93.8% (15/16) of mechanically ventilated patients in the COVID-19 cohort were weaned by the data cutoff. Compared to the reference cohort, the mean ventilator wean time in the COVID-19 cohort tended to be shorter (21.5, 95% CI 11.3-31.9 vs 11.3, 95% CI 6.6-15.9 days; *P*=.23). Given the small number of patients being mechanically ventilated in the reference cohort (n=7), we also compared the COVID-19 cohort wean time to that of all patients for fiscal year 2019 (ie, October 2018 through September 2019) in the LTACH (12.2, 95% CI 8.9-15.5 days; n=37) and found no difference between the 2 groups (*P*>.99; Figure 5A). For those weaned from mechanical ventilation, it was an additional mean duration of 15.1 (SD 13.3) days until tracheostomy decannulation. In comparison, for those not mechanically ventilated, the mean time from admission to tracheostomy decannulation was 16.3 (SD 11.4) days.

Figure 5. COVID-19 patient respiratory and cognitive-communication outcomes. (A) Scatter plot showing the comparison of ventilator wean times among patients mechanically ventilated during fiscal year 2019 (October 2018 through September 2019) (n=37), the reference cohort (n=7), and the COVID-19 cohort (n=15). The colored lines represent the median and interquartile range. (B) Evaluation of the cognitive communication score of COVID-19 patients recommended for speech-language pathology services (n=75) at admission and discharge. NOMS: National Outcomes Measurement System.



Speech-Language Pathology

In the COVID-19 cohort, 59% (75/127) of admissions were recommended for speech-language pathology evaluation. Of those, 81% (61/75) were admitted with a modified diet or instructions for nothing by mouth or nil per os (NPO). Following a dysphagia evaluation, most patients were upgraded from NPO to a regular consistency diet. At discharge, 75% (56/75) of patients were consuming a regular consistency diet. Further, 49% (37/75) of patients evaluated by a speech-language pathologist were admitted with a tracheostomy, with or without mechanical ventilation, and 73% (27/37) were found to have some form of voicing disorder, including aphonia (13/37), dysphonia (13/37), or dysarthria (1/37). At discharge, only 35% (13/37) of patients had voicing limitations.

Speech-language pathologists also evaluated patients for cognitive-communication deficits using the modified NOMS scale shown in Table 2. At admission, 58% (44/75) of patients were rated as either baseline or within functional limits, 37% (28/75) were found to have impairments ranging from mild to severe, and 4% (3/75) could not be assessed. The mean cognitive-communication score at admission was 7.2 (95% CI 6.7-7.6). Deficits primarily affected the areas of attention, processing speed, short-term memory, and complex executive functioning skills. Many patients showed improvement by discharge, with 72% (54/75) being at baseline or within functional limits; 21.3% (16/75) having only mild residual cognitive deficits needing minimal cues or memory aides for maintaining attention, completing tasks, or problem solving; and 6.7% (5/75) continuing with moderate-to-severe cognitive deficits. At discharge, the mean cognitive-communication score was 7.8 (95% CI 7.6-8.0), which is a modest yet significant improvement from admission (P<.001; Figure 5B). Continued speech-language pathology services were recommended for 39% (29/75) of patients after discharge. Due to the retrospective nature of the study, similar values were not readily available for the reference cohort and were not included.

Table 2. Cognitive-communication status scoring in the COVID-19 cohort.

Description	Admission (N=75)	Discharge (N=75)
Scoring[a], n		
Unable to assess (score 1)	3	0
Profound impairment (score 2)	0	0
Severe impairment (score 3)	2	1
Moderate-severe impairment (score 4)	3	1
Moderate impairment (score 5)	5	0
Mild-moderate impairment (score 6)	3	3
Mild impairment (score 7)	15	16
Within functional limits (score 8)	28	38
Baseline (score 9)	16	16
Mean score (95% CI)	7.2 (6.7-7.6)[b]	7.8 (7.6-8.0)[b]

[a]To better analyze patient outcomes, a modified National Outcomes Measure System scale was used for speech-language pathology cognitive-communication status evaluations.

[b]The nonparametric Wilcoxon matched pairs test was used, and the group difference (based on differences of the means) was 0.64 (95% CI 0.30-0.98; $P<.001$).

Physical and Occupational Therapy

Due to wheelchair dependence prior to STACH admission, emergent readmission to a STACH, continuing care at the time of data cutoff, and incomplete data collection, complete (ie, admission and discharge) gait and functional status data (FIM scores and gait distance) were only available for 99 of 127 total COVID-19 admissions and 90 of 170 reference cohort admissions. At admission, 44% (40/90) of patients in the reference cohort and 53% (52/99) of patients in the COVID-19 cohort were unable to ambulate or required maximum assistance (Table 3). The majority of patients in both the reference (69/90, 77%) and COVID-19 (88/99, 89%) cohorts displayed functional status improvement from admission to discharge, with many patients showing an increase in functional ability by 4 or more levels. These measurements were then evaluated using 2×2 two-way mixed effects ANOVA tests.

Table 3. Functional Independence Measure assistance scoring for ambulation.

Description	Reference cohort		COVID-19 cohort	
	Admission (N=90)	Discharge (N=90)	Admission (N=99)	Discharge (N=99)
Scoring[a], n (%)				
Unable/dependent[b] (score 1)	36 (40)	19 (21)	51 (52)	11 (11)
Maximal assistance[c] (score 2)	4 (4)	2 (2)	1 (1)	0 (0)
Moderate assistance[d] (score 3)	6 (7)	3 (3)	6 (6)	3 (3)
Minimal assistance[e] (score 4)	36 (40)	18 (20)	35 (35)	14 (14)
Supervision[f] (score 5)	8 (9)	30 (33)	6 (6)	29 (29)
Modified independence[g] (score 6)	0 (0)	13 (14)	0 (0)	28 (28)
Independence[h] (score 7)	0 (0)	5 (6)	0 (0)	14 (14)
Mean score (95% CI)	2.7 (2.4-3.1)[i]	4.1 (3.7-4.7)[i]	2.4 (2.1-2.7)[i]	4.9 (4.6-5.3)[i,j]

[a]To track patient functional ability, Functional Independence Measure scoring was used to assess the level of assistance required for ambulation at patient admission and discharge.

[b]Patient is either unable to ambulate or is only able to perform 24% of activity.

[c]Patient can perform 25%-49% of activity.

[d]Patient can perform 50%-74% of activity.

[e]Patient can perform at least 75% of activity.

[f]Patient does not need physical assistance but does require hands-on guidance, supervision for safety, cueing, coaxing, or set up.

[g]Patient does not need the physical presence of a second person, but requires equipment or takes more than reasonable time, or there are safety concerns.

[h]Patient does not require any equipment or the physical presence of a second person.

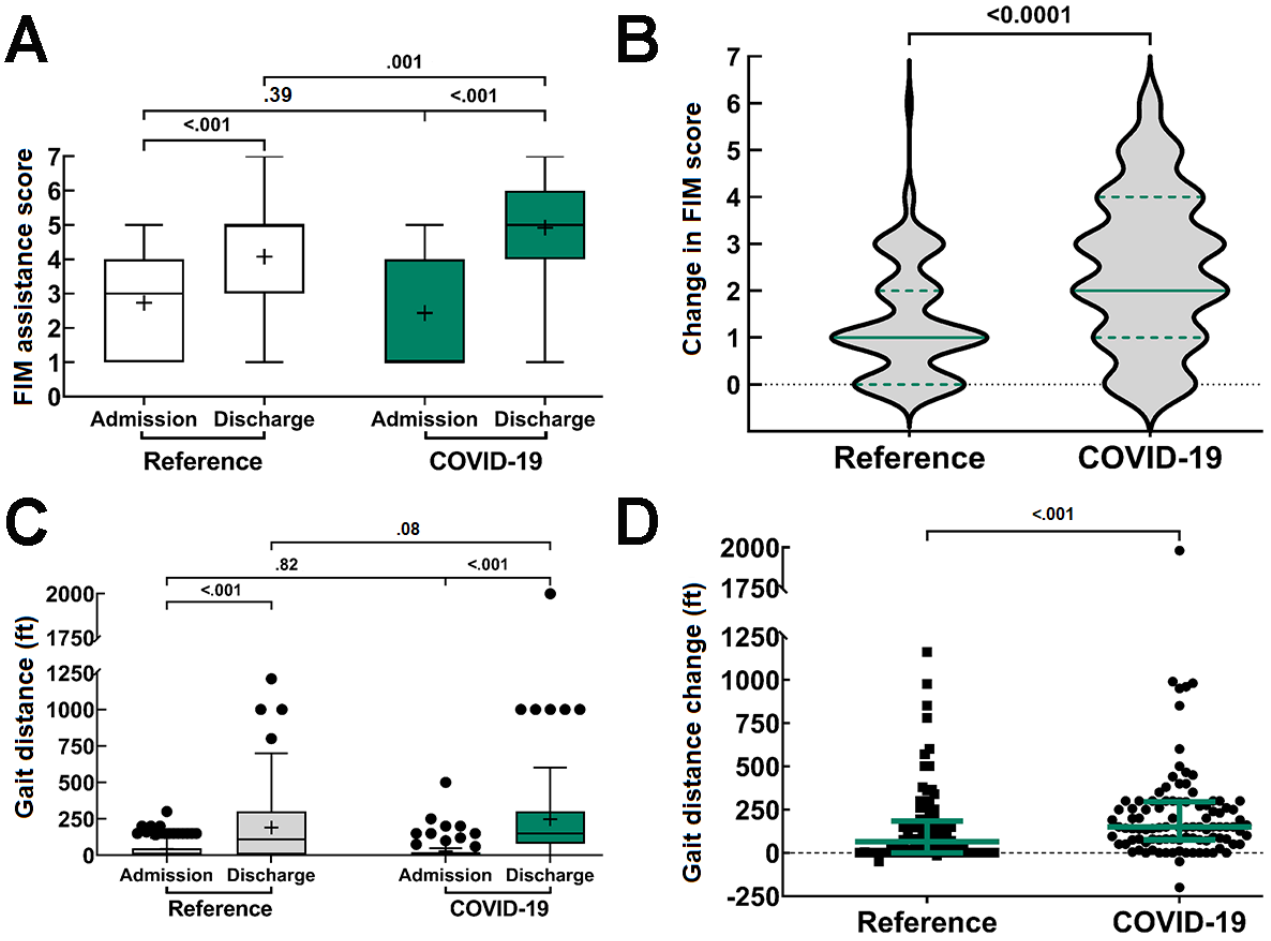
[i]The Šídák multiple comparisons test was used to compare in-group differences (based on differences of the means) between admission and discharge. The group difference was 1.3 (95% CI −1.7 to −1.0; P<.001) in the reference cohort and 2.5 (95% CI −2.8 to −2.2; P<.001) in the COVID-19 cohort.

[j]Significantly different compared to the mean discharge Functional Independence Measure score in the reference cohort; mean difference is −0.841 (95% CI −1.39 to −0.297; P=.001).

For ambulation FIM scores, the mean ambulation assistance scores increased in both the reference (2.73, 95% CI 2.4-3.1 to 4.1, 95% CI 3.7-4.7) and COVID-19 (2.4, 95% CI 2.1-2.7 to 4.9, 95% CI 4.6-5.3) cohorts (Table 3). Two-way mixed effects ANOVA showed a significant main effect associated with time ($F_{1,187}$=335.7; P<.001) on FIM scores, with overall discharge scores (mean=4.498) being greater than admission scores (mean=2.584). Although we also observed a significant interaction effect between time and cohort designation ($F_{1,187}$=29.78; P<.001), we did not observe a significant main effect of cohort designation ($F_{1,187}$=1.538; P=.22) on FIM scores alone. The pooled mean FIM score of the reference cohort (mean=3.406) was marginally lesser than that of the COVID-19 cohort (mean=3.677).

Using the Šídák multiple comparisons test, we then tested to see what in-group and between-group comparisons were significantly different. In-group comparisons for both cohorts showed a significant increase in FIM scores between admission and discharge (P<.001), further highlighting the main time effect noted in the 2-way mixed effects ANOVA (Figure 6A; Table 3). Between-group comparisons revealed that, with a mean difference of 0.299 (95% CI −0.245 to 0.843), there was no difference in FIM scores at admission between the 2 cohorts (P=.39) (Figure 6A; Table 3). This indicates that patients in both cohorts required the same or similar levels of assistance at admission. Comparing the FIM scores at discharge revealed that, with a mean difference of −0.841 (95% CI −1.39 to −0.297), the mean discharge FIM scores were significantly greater in the COVID-19 cohort than in the reference cohort (P=.001) (Figure 6A; Table 3). Together, we interpret these data to indicate that while both cohorts had similar FIM scores at admission and both improved over time, the discharge FIM scores were greater in the COVID-19 cohort than in the reference cohort.

Figure 6. Functional Independence Measure (FIM) assistance scores and gait distances as measures of functional ability. (A and C) For both the reference (n=90) and COVID-19 (n=99) cohorts, FIM assistance scores and gait distances were collected at admission and discharge. In-group and between-group comparisons were made using the Šídák multiple comparisons test following a 2×2 two-way mixed effects analysis of variance test for main effects associated with group and time. Box plots represent the median and the 25% and 75% quartiles. The whiskers extend 1.5 and -1.5 of the interquartile range; circle symbols reflect data points beyond the 1.5 interquartile ranges; and the "+" symbol represents the mean. (B and D) Changes in FIM assistance scores and gait distances were then compared using a nonparametric Mann-Whitney U test. B, Violin plot with medium smoothing to show the distribution of FIM score changes; the colored lines represent the median and interquartile range. D, Scatter plot, with the colored lines representing the median and interquartile range.



We then compared the mean FIM assistance score change from admission to discharge in the 2 groups. The score change was greater in the COVID-19 cohort than in the reference cohort (2.5, 95% CI 2.2-2.8 vs 1.3, 95% CI 1.1-1.6 points; difference of medians=1.0, 95% CI 1.0-2.0; *P*<.001; Figure 6B).

The same analysis was conducted for gait distance (feet). The mean gait distance increased in both the reference (43.3, 95% CI 29.8-57.0 to 189.9, 95% CI 139.0-240.8 feet) and COVID-19 (27.5, 95% CI 14.1-40.9 to 248.7, 95% CI 191.1-306.4 feet) cohorts (Table 4). Two-way mixed effects ANOVA showed a significant main effect associated with time ($F_{1,187}$=97.15; *P*<.001) on gait distance, with the pooled discharge distance (mean=219.3 feet) being greater than the pooled admission distance (mean=35.5 feet). Although a significant interaction effect was observed between time and cohort designation ($F_{1,187}$=4.02; *P*=.046), a significant main effect related to cohort designation ($F_{1,187}$=0.9994; *P*=.32) on gait distance was not observed, with the pooled gait distance being marginally lesser in the reference cohort (mean=116.7 feet) than in the COVID-19 cohort (mean=138.1 feet).

Table 4. Gait distance at patient admission and discharge.

Variable	Reference cohort	COVID-19 cohort	Between-group difference, mean (95% CI); *P* value
Admission distance (feet)[a], mean (95% CI)	43.4 (29.8 to 57.1)	27.53 (14.1 to 40.9)	15.9 (−48.0 to 79.8); *P*=.82[b]
Discharge distance (feet)[a], mean (95% CI)	189.9 (139.0 to 240.8)	248.7 (191.1 to 306.4)	−58.9 (−122.7 to 5.0); *P*=.08[b]
Within-group difference (feet), mean (95% CI); *P* value	−146.4 (−207.3 to −85.6); *P*<.001[b]	−221.1 (−279.2 to −163.2); *P*<.001[b]	74.8 (2.0 to 147.6); *P*<.001[c]

[a]Complete admission and discharge gait distances were only available for a subset of the total admissions for both the reference (n=90) and COVID-19 (n=99) cohorts.

[b]Calculated using the Šídák multiple comparisons test following a mixed effects analysis of variance.

[c]Comparison of group differences calculated using the Mann-Whitney *U* test.

Using the Šídák multiple comparisons test, we again tested to see what in-group and between-group comparisons were significantly different. In-group comparisons for both cohorts showed a significant increase in gait distance between admission and discharge (*P*<.001), further highlighting the main time effect noted in the 2-way mixed effects ANOVA (Figure 6C; Table 4). Between-group comparisons showed that, with a mean difference of 15.9 (95% CI −48.0 to 79.8), there was no difference in gait distance at admission between the 2 cohorts (*P*=.82) (Figure 6C; Table 4). This indicates that patients in both cohorts were able to ambulate the same or similar distances at admission. Comparing the gait distances at discharge revealed that, with a mean difference of −58.9 (95% CI −122.7 to 5.0), the mean discharge gait distances were nearly significantly greater in the COVID-19 cohort than in the reference cohort (*P*=.08).

Further, we compared the mean change in gait distance from admission to discharge in the 2 groups. The gait change was greater in the COVID-19 cohort than in the reference cohort (221.2, 95% CI 164.8-277.6 vs 142.5, 95% CI 95.9-189.1 feet; difference of medians=90, 95% CI 25.0-100.0; *P*<.001; Figure 6D; Table 4).

Additional Wound Care, Physical Therapy, and Medical Service Considerations

With prone positioning becoming the standard of care for COVID-19–related respiratory failure and pneumonia, many patients in the COVID-19 cohort developed atypical facial pressure injuries during their STACH stay. Patients in the COVID-19 cohort were admitted with approximately 69 total body pressure injuries (stage 3 or 4) requiring consultation; 30% were located on the face, usually on both cheeks, with one more severe than the other and having thick eschar development. Conservative treatment without sharp debridement resolved most cases of facial pressure injuries. New injuries were prevented by implementing adhesive foam cushioning to facial pressure areas. Patients were also likely more hemodynamically stable during LTACH care and therefore somewhat less likely to develop pressure injuries.

Unilateral and bilateral wrist and foot drop were also observed in some patients, potentially due to prolonged prone positioning in the STACH causing peripheral nerve compression. Patients with wrist drop showed some improvement, though some required orthoses or occupational therapy after discharge. Some COVID-19 patients presented conditions atypical for respiratory diseases, such as neurological findings, peripheral nerve injuries, paresthesia, and cognitive impairment. Neurological symptoms may have resulted from the use of paralytics or prolonged prone positioning during STACH treatment [12,25].

Discussion

Principal Findings

The emergence of the novel coronavirus SARS-CoV-2 has resulted in a worldwide pandemic with 281 million infections and 5.4 million deaths as of this writing [26]. For other facilities to reference now or in the future when treating patients with COVID-19, the goal of this retrospective study was to summarize and report the observations, experiences, and methods used by clinicians at our LTACH and how these practices impacted patient outcomes. Using our holistic treatment strategy, we focused on all aspects of patient recovery, with the majority of our patients with severe active COVID-19 or post–COVID-19 showing significant improvement through this coordinated care.

During the study period, 93% of patients admitted on mechanical ventilation were weaned, and 96% of patients admitted with a tracheostomy without mechanical ventilation were decannulated. Though many patients had functional limitations and were nonambulatory at admission, the COVID-19 cohort showed significant functional improvement by discharge, including a 149% greater change in gait distance travelled compared to the reference cohort. While both cohorts had similar FIM assistance scores at admission and both improved over time, the FIM assistance scores of the COVID-19 cohort were significantly greater than those of the reference cohort at discharge. Patients receiving speech-language therapy also showed improvements during their LTACH treatment, with 40.5% fewer patients having voicing limitations at discharge and only 28% having residual cognitive-communication deficits. Together, these observations indicate the potential benefits of individualized, focused, and holistic rehabilitation in a population severely affected by COVID-19 [27].

Though not significant, the COVID-19 cohort ventilator wean time (10.4 days) was shorter than historical facility wean times (12.2 days in 2019, 20.6 days in 2018, and 14 days in 2017) [28]. Based on our clinical observations, the COVID-19 cohort generally presented fewer complicated pulmonary and cardiac comorbidities than typical patients with tracheostomy, with or without mechanical ventilation. This may have contributed to the shorter ventilator wean time. These observations support the idea that pulmonary rehabilitation could play an important role in COVID-19 treatment and recovery [29]. Further, compared to patients with chronic pulmonary conditions, the COVID-19 cohort patients, who were generally new to respiratory deficits, improved rapidly with appropriate respiratory management.

In regard to patient susceptibility and risk for severe COVID-19 illness, we observed a positive correlation between patient age and patient LOS. In contrast to what has been reported, we did not observe a correlation between patient BMI and disease severity/LOS [23,24]. These differences could be attributed to several factors, including better pre–COVID-19 health status compared to that of patients typically cared for at the facility, current employment status at the time of COVID-19 diagnosis (many of the patients in the cohort were health care workers or first responders), and motivation to return home (as visitation was restricted).

The quick progression in cognitive-communication skills during LTACH stay was also likely multifactorial, involving discontinuation of sedatives, improved metabolic status, awareness of deficits, and an ability for patients to carry over compensatory strategies learned in therapy. However, ongoing cognitive-communication impairment is possible in patients who have had COVID-19, and these individuals may benefit from continued therapy services after discharge [30].

Many of our patients were admitted on a modified diet or NPO because of their inability to participate in swallowing assessments at acute care, the severity of their medical condition, or limited access to instrumental assessments during speech-language pathology evaluations due to droplet precautions. The prompt advancement of diet in the LTACH setting was mostly the result of clinical swallowing evaluations showing minimal residual weakness within the oropharyngeal swallowing mechanism. Therefore, it is possible to largely rely on clinical swallowing evaluations for patients with COVID-19, thus minimizing the risk of viral exposure by limiting aerosol-generating instrumental assessments [27]**.** To protect from aerosols when assessing patients with unknown or suspected positive SARS-CoV-2 status, speech-language pathologists should consider the continued use of clear face masks, face shields, and other eye protection during therapy sessions.

Patients also likely received emotional benefit from the formation of inpatient COVID-19 support groups. These groups, facilitated by a physical therapist and a social worker, were a collaborative effort to provide patients who were recovering from COVID-19 with the opportunity to speak with other patients experiencing similar concerns during their hospital course. With guidance from the group facilitators, patients were encouraged to ask questions and share their experiences in an open discussion format, which ultimately generated insightful feedback for the staff on patient care during the pandemic. Conversation topics focused on processing the initial illness onset and acute hospital stay; acknowledging and learning to cope with their physical, respiratory, emotional, and social changes; and preparing for their future after LTACH discharge. Participation was capped at 6 patients per meeting, and multiple meetings were convened as necessary to accommodate all interested patients.

Limitations

When evaluating these findings, several limitations need to be considered. First, as this was a retrospective study, *a priori* power analysis and sample size estimation were not conducted. Further, as this was a single-center study, the findings may or may not fully reflect the expected findings of other LTACHs or similarly structured institutions. Additionally, in an effort to create a reference for comparison of this unique population, a retrospective historical control was used. As such, all outcome measures could not be compared (ie, the NOMS was only readily available for the COVID-19 population). This also resulted in the population sizes being uneven despite the COVID-19 data being collected over 5 months versus 3 months for the reference.

There is also a possibility that the COVID-19 cohort received treatment at a slightly less intensity due to initial droplet precautions and isolation to the room. However, due to similarities in the baseline status (ie, assistance scores and gait distances), we are confident the populations were generally comparable as department standards for treatment and therapy doses for medically complex patients were followed in both cohorts.

It needs to be considered that the best treatment practices were actively being developed and implemented during the study period. Thus, the first COVID-19 patients admitted and treated may not have benefited from the knowledge gained over time. For example, as testing guidelines, isolation procedures, and intubation and ventilation recommendations changed, so did the treatment practices.

This study is strengthened by the breadth of quantitative outcomes and the detailed descriptions of potential presentations and complications that can be expected for patients with COVID-19 being treated in a LTACH setting. The goal of this study was to discuss typical symptom presentation and recovery patterns for the COVID-19 population in the LTACH setting so as to guide treatment planning choices at other similar facilities.

Mitigating SARS-CoV-2 Transmission in the Non–COVID-19 Patient Population

Patients cared for at LTACHs typically have complex medical conditions and are at increased risk for infection and fever; thus, there was a pressing need to isolate any potential source of SARS-CoV-2. Despite what symptoms have been described as “typical” COVID-19 symptoms, patients presented with a spectrum of respiratory symptoms, ranging from asymptomatic to respiratory distress. Consequently, all febrile patients were required to undergo SARS-CoV-2 testing and were isolated

with droplet precautions until ruled out. With only 1 exception, all non–COVID-19 patients tested negative for SARS-CoV-2 during this time, indicating that our protocols effectively isolated the 37 patients who were admitted with active SARS-CoV-2 infections. Our observation supports preemptive testing in LTACHs and other health care facilities to lower the incidence of SARS-CoV-2 transmission [31]. Given the documented issues of SARS-CoV-2 transmission in some long-term care facilities, it is possible to imagine what the alternative may have been without preemptive testing [32-34].

One limiting aspect of care during this period of the pandemic was the length of time it took to obtain SARS-CoV-2 test results for patients who were admitted with an active infection, so they could come off droplet precautions, which was over 2 months in many cases [35]. On May 20, 2020, Connecticut Department of Public Health released a memo supporting their agreement with the findings of the Centers for Disease Control and Prevention that the live virus was undetectable after 9 days of infection, allowing for the use of a symptom-based strategy rather than a test-based strategy [36,37]. We implemented a more conservative approach, requiring at least 14 days since diagnosis and 5 days without fever or evolving symptoms. Further, given the low facility infection rate of the non–COVID-19 population, the facility policy changed around the same time from transferring patients under investigation to the COVID-19 floor, to ruling-out in place with the use of droplet precautions and a portable room air scrubber. Coming off droplet precautions was instrumental in getting patients out of their rooms and having full access to therapy.

It was also evident early on that regular, clear, and transparent communication was, and still is, vital for staff acceptance of the constantly changing situation, guidelines, and personal protective equipment protocols. To support this, department directors and managers devoted time each day to discussing COVID-19–related patient issues. These directors then met weekly with key staff members to further discuss the issues and disseminate information. Further, emails were frequently sent to all employees detailing COVID-19–related changes, statistics, and other topics of interest. In-person communication was also helpful in correcting rumors and serving as a forum for establishing best practices in the ever-changing situation.

Conclusion

To alleviate crowded and overwhelmed STACH facilities, we envision the strategic use of LTACHs earlier in a patient's hospital course to treat and rehabilitate those with severe COVID-19. With a greater understanding of rehabilitation progression, clinical care can be adapted to maximize the recovery of this population.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Gaylord Hospital tracheostomy decannulation protocol.
[DOCX File , 26 KB - rehab_v9i1e31502_app1.docx]

Multimedia Appendix 2
Gaylord Hospital mechanical ventilation weaning protocol.
[DOCX File , 24 KB - rehab_v9i1e31502_app2.docx]

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Abbreviations

ANOVA: analysis of variance
FIM: Functional Independence Measure
LOS: length of stay
LTACH: long-term acute care hospital
NOMS: National Outcomes Measurement System
NPO: nil per os (nothing by mouth)
OR: odds ratio
STACH: short-term acute care hospital

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Original Paper

Comparison of the Impact of Conventional and Web-Based Pulmonary Rehabilitation on Physical Activity in Patients With Chronic Obstructive Pulmonary Disease: Exploratory Feasibility Study

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Abstract

Background: Pulmonary Rehabilitation (PR) increases exercise capacity, with less clear evidence regarding physical activity (PA). The World Health Organization recommends at least 150-300 minutes of moderate-intensity or 75-150 minutes of vigorous-intensity aerobic PA per week to reduce the risks of chronic disease.

Objective: The objective of this study was to assess the effectiveness of conventional PR versus web-based PR with respect to changes in PA.

Methods: Patients with COPD were randomized to either conventional PR classes (n=51) or a web-based PR program (n=52) for 7 weeks in a feasibility study. Accelerometers (Sensewear) were worn before and after the intervention, and PA was measured as steps per day and mean bouts of moderate activity for ≥2, ≥5, ≥10, and ≥20 minutes. Measures were derived for patients with ≥8 hours of data per day for ≥4 days, using the R package for statistical analysis. Variables were explored to examine their relationships with bouts of activity.

Results: Baseline characteristics did not differ significantly between groups. Complete PA data were available for the groups receiving web-based (n=20) and conventional (n=34) PR interventions. The web-based PR group demonstrated a nonsignificant increase in the number of steps per day, which mainly comprised short bouts of moderate to vigorous intensity PA when compared to the conventional PR group (P=.20). The conventional PR group demonstrated increased 20-minute bouts of PA by 49.1%, although this was not significant (P=.07). At baseline, age (r=–0.21, P=.04), BMI (r=–0.311, P=.004), and FEV_1 (forced expiratory volume in 1 second; % predicted; r=–0.248, P=.048) were significantly correlated with 10-minute bouts of PA; however, this was not observed post intervention.

Conclusions: The analysis revealed a nonsignificant difference in the pattern of PA between groups receiving conventional vs web-based PR—the former being associated with an increase in 20-minute bouts, while the latter having demonstrated an increase in the number of steps per day. There appears to be a differing response emerging between the two interventions.

Trial Registration: International Clinical Trials Registry ISRCTN03142263; https://tinyurl.com/y4dmfyrb

(JMIR Rehabil Assist Technol 2022;9(1):e28875) doi:10.2196/28875

KEYWORDS

SPACE for COPD; internet; web-based; chronic obstructive pulmonary disease; pulmonary rehabilitation; physical activity; exercise; chronic disease; COPD; rehabilitation

Introduction

Background

Individuals with chronic obstructive pulmonary disease (COPD) have poor exercise capacity and low physical activity (PA) levels [1], which are associated with an increased risk of hospital admission, poor quality of life, and increased mortality [2]. While pulmonary rehabilitation (PR) focuses on improving functional exercise capacity, this does not necessarily translate into increasing PA, the latter defined by the World Health Organization as "any bodily movement produced by skeletal muscles that requires energy expenditure" [3]. A recent study attempted to increase the amount of time patients were physically active by using pedometers as an adjunct to PR. However, the addition of step count targets during a PR program did not improve moderate-intensity PA levels [4].

PA is considered a modifiable risk factor for morbidity and mortality in people with COPD and those with other long-term conditions [2]. Although there are known benefits of pulmonary rehabilitation (PR) in terms of exercise capacity, psychological functioning, and quality of life, a recent review showed poor evidence about determinants of PA, including the impact of treatment or interventions in people with COPD [5]. National guidelines recommend that older adults should accumulate 150-300 minutes of moderate-intensity or 75-150 minutes of vigorous-intensity aerobic PA per week [6]. Achieving these targets is difficult when exercise capacity is reduced owing to shortness of breath and reduced muscle strength. In addition, the availability and access to pulmonary rehabilitation programs in the United Kingdom is limited, and attrition rates are often high [7]. To address this issue, there is an increasing appreciation among clinicians to offer wider choice in the delivery of rehabilitation.

Home-based rehabilitation has recently been shown to be an alternative to center-based PR. Grosbois et al [8] have shown home-based PR consisting of unsupervised physical exercises, therapeutic patient education, and self-management to be effective in the short, medium (6 months), and long term (12 months) at improving exercise capacity, mood, and quality of life [8]. Furthermore, an internet-based walking program for patients with COPD, which focused exclusively on step counts, increased the daily number of steps by >1000 over 3 months [9], and a randomized controlled trial of a pedometer-based program versus a standard program of PA encouragement alone increased step counts by 3080 (SD 3254) compared to 138.3 (SD 1950), respectively [10].

The effectiveness of PA interventions is determined by an improvement of >600 steps per day [11]. The evidence for home- or web-based PR to increase PA, however, is less well-established in COPD but has been demonstrated to be effective in cardiac rehabilitation [12]. A recent home-based PR trial has revealed a reduction in the amount of time during which all patients are sedentary (mean change -44 minutes) and an increase in the amount of time patients are performing bouts of moderate to vigorous PA (mean change 16 mins) following a home program [13]. However, there were no significant between group differences. Within our department, a *Self-Management Programme of Activity, Coping and Education*, "*SPACE for COPD*" has been developed (manual version) [14]. This program has been shown to be effective in primary care [15], where there were significant between-group differences in steps at 6 weeks in favor of the home training program and was recently shown to also be comparable to conventional rehabilitation in improving exercise performance and perceived dyspnea [16]. We have since developed a web-based provision of this program, SPACE for COPD. The protocol for the interactive web-based feasibility trial has been published previously [17]. Details of the nonclinical feasibility data and primary outcome of the main study are reported in a separate publication [18]. Significant within-group changes were observed in exercise capacity and quality of life, but there were no significant differences between groups. The study utilizes the pre-existing SPACE for COPD manual but in a web-based format. In brief, the study identified an improvement in both quality of life and endurance walking times.

Aims

The purpose of this secondary exploratory analysis was to compare the impact of the two interventions on PA with respect to bouts of total activity and to determine whether the response to the center-supervised and remotely supervised program differed in terms of the individuals' PA profiles and responses to an exercise training program. The relationship between PA and routinely collected clinical data at baseline and after the intervention was also explored.

Methods

Ethics Approval

Participants were recruited between 2013 and 2015, and ethical approval was granted by Northampton Ethics Committee of the UK National Research Ethics Service (12/EM/0351). All study participants signed an informed consent form prior to their enrollment. Individual patients could not be identified through the information presented in this analysis.

Eligibility Criteria

Participants were eligible to partake if they had a confirmed diagnosis of COPD, defined as having a postbronchodilator FEV_1 (forced expiratory volume in 1 second) of <80% and a predicted FEV_1 forced vital capacity ratio of ≤0.70 (GOLD stage 2-4) and a Medical Research Council Dyspnoea Scale score of 2-5. Patients had to be willing to partake in either arm of the study. Patients were required to have had access to the internet for more than 3 months, the ability to navigate a variety of websites (eg, uses e-shopping or e-banking websites), and use email regularly. Patients also had to be able to read and write in English.

Patients were excluded if they were unable to participate in the exercise component of the rehabilitation program owing to other comorbidities or had undergone PR in the previous 12 months.

Randomization

Randomization was performed using a web-based program [19]. Participants were allocated on a 1:1 ratio to either a standard care (conventional PR program) or an intervention group (web-based PR program).

Trial Interventions

Intervention Group: Web-Based PR Program

Following randomization to the intervention group, the participants attended a standardized introductory session where they were provided a password-protected secure log-in to the website as well as written instructions on website navigation. There are 4 stages to the program, each with a number of mandatory tasks to complete before moving onto the next task or stage. A description of the different stages is provided in Textbox 1. Upon completion of an information needs questionnaire at registration, gaps in knowledge were identified, and patients were signposted to relevant educational topics. Participant's progress was monitored and reviewed on the internet regularly and through weekly contact with a health care professional. As in conventional PR, patients were encouraged to exercise daily at home and record their progress in the web-based exercise diary section. The exercise program consisted of both aerobic and strength training. Patients were advised to walk at the pace that was determined from the baseline maximal exercise walking tests performed in the initial assessment, increasing the amount of time they walked for each day. Strength training comprised both upper and lower limb exercises using hand-held weights. Both exercise components progressed while maintaining a visual analogue scale (VAS) rating of 4-7. It was anticipated from previous work [20] that it would take approximately 6-8 weeks to work through the web-based program.

Textbox 1. Stages of the web-based pulmonary rehabilitation program.

Stages:

- Stage 1: introduction to exercising and goal setting, exercise safety quiz, and reading educational material
- Stage 2: introduction to the aerobic exercise program, setting walking targets, and reading educational material
- Stage 3: introduction to the strength training program, setting strength targets, continuing aerobic training, and reading education material
- Stage 4: maintaining strength and aerobic training, reviewing educational material, and a knowledge quiz

Standard Care Group: Conventional PR Program

Patients randomized to standard care commenced conventional rehabilitation, as described by the British Thoracic Society's guidelines [21], in accordance with the standard care at their referred site, which was either hospital- or community-based. The hospital-based program was of 7 weeks (4 weeks supervised and 3 weeks unsupervised) in total. Any sessions that were missed could be completed later because it was a rolling program. In the community-based programs, patients could attend a maximum of 12 sessions within the closed program.

Conventional PR programs at either referral site consisted of 2 weekly sessions, each lasting 2 hours, which were divided into an hour for exercise training, consisting of both aerobic and resistance training, and an hour for an education session covering a variety of relevant self-management topics.

The trial interventions for both the web-based and conventional pulmonary rehabilitation groups have previously been described in detail [18].

Physical Activity

All participants wore a Bodymedia Sensewear triaxial accelerometer (APC Cardiovascular). Algorithms within the software convert the data to produce meaningful outcome variables, which include the number of steps, energy expenditure in metabolic equivalence to tasks (METs): a multiple of the resting rate of oxygen consumption per minute (one MET is equal to that of the O_2 consumption at rest, which is approximately 3.5 mL/kg/minute) and PA duration (vigorous >6, moderate 3-6 METs, and light >1.5 METs intensity).

Accelerometer data were collected for 7 days at baseline and a further 7 days following discharge. None of the data were collected while the patients were participating in either intervention. Measures were derived for patients with ≥8 hours of data per day for ≥4 days [22] at each time point using the R package for statistical analysis [23]. The Sensewear accelerometer has been previously validated in COPD [24,25], and 4 days was proven sufficient to demonstrate treatment effects.

Data Analysis

Sample Size

Owing to the original study being a feasibility study, a formal sample size calculation was not required to detect between-group changes. We aimed to recruit around 100 patients within the timeframe of the operational phase of the trial. This was based on previous studies carried out in the PR service and deemed a reasonable number to assess the recruitment or retention rate and inform the planning of a subsequent randomized controlled trial. This is in line with recommendations by Lancaster et al [26] on the number of participants required in a feasibility study to estimate a parameter. Furthermore, in a recent audit of feasibility studies in the United Kingdom, it was found that a median sample size for a 2-arm trial was 36 and 30 per arm, respectively, for dichotomous and continuous endpoints [27]. Although the data in this exploratory study, based on secondary and per protocol analysis, fell slightly below this in the number

of participants in the web-based PR group (n=20), the data from the original study were collected for 103 participants (web-based care, n=51; usual care, n=52).

Statistical Analysis

Baseline characteristics were compared between groups using a 2-tailed independent samples *t* test. A 2-tailed paired samples *t* test was used to compare within-group changes, and a 2-way repeated measures analysis of variance (ANOVA) was used to compare the differences between the two treatment groups in the number of steps and PA pattern at the two time points. All *t* tests, repeated measures ANOVA, and factor analysis were performed using the SPSS (version 22; SPSS Inc) with a level of significance set at $P<.05$. The change in time in bouts (2-20 minutes) expressed as a percentage change, the mean change in bout length of moderate to vigorous PA (MVPA), daily MET level, and percentage time in moderate activity were explored.

Correlations between routinely collected clinical data and PA were explored using the Spearman rank correlation coefficient.

Patient and Public Involvement

A preprotocol award from the National Institute of Health Research (NIHR) East Midlands Research Design Service enabled us to conduct a focus group with current and ex-PR patients to gain feedback on the prototype website, with particular regard to features that would increase the interactivity and usability for service users as well as addressing any concerns such as data security. The website has undergone practical "road-testing" by members of the focus group and other members of the departmental patient and public involvement (PPI) group to ensure that participants can access the website and navigate the site easily. A member of the PPI group attended the study and steering group meetings, and a strategy for disseminating the results was thus coordinated.

Results

Results Overview

The flow of eligibility, screening, randomization, and follow-up in the study is shown in Figure 1. The baseline characteristics of participants with complete PA data are shown in Table 1. There were no significant differences in age, BMI, FEV_1, smoking status, and home oxygen usage between the web-based and conventional PR groups. Exercise capacity at baseline was similar in both groups. For participants assigned to the web-based PR group, the mean number of weeks to complete the program was 11.5 (SD 4.1), and the mean stage reached for those in the web-based PR group, who withdrew from the intervention, was stage 3 (IQR 1-4). The total number of complete accelerometer data sets for PA was 34 for the conventional PR group and 20 for the web-based PR group.

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram of participation. COPD: chronic obstructive pulmonary disease, MRC: Medical Research Council, PR: pulmonary rehabilitation.

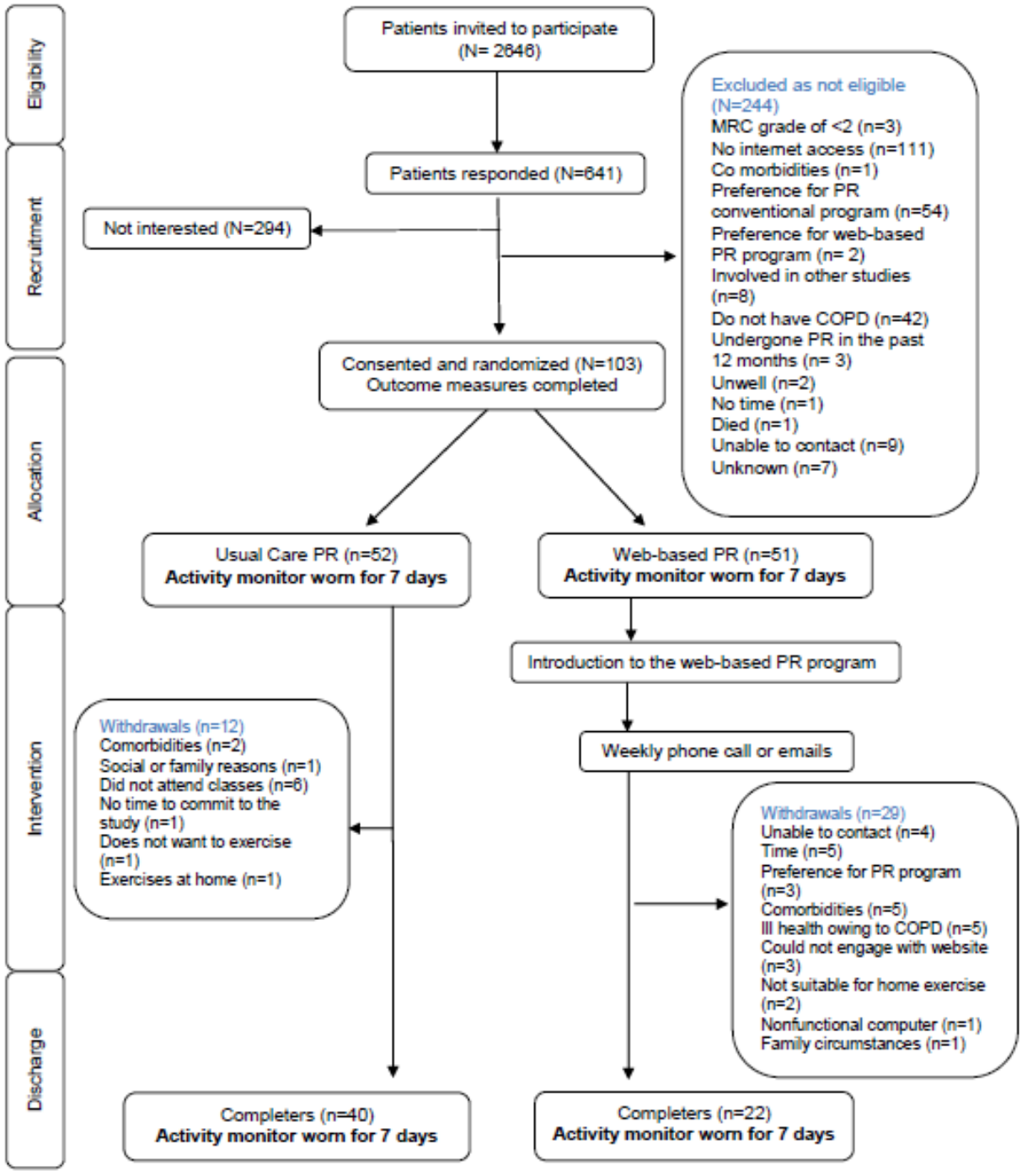


Table 1. Baseline participant characteristics (N=54).

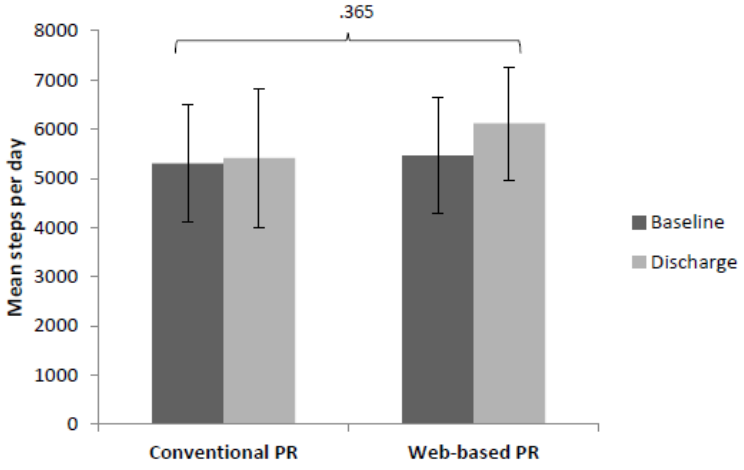
Characteristics	Web-based pulmonary rehabilitation group (n=20)	Conventional pulmonary rehabilitation group (n=34)	Between-group differences, *P* value
Gender (males/females), n	18/2	19/15	.009[a]
Age (years), mean (SD)	68.3 (6.5)	67.4 (8.6)	.60
BMI (kg/m^2), mean (SD)	27.2 (5.5)	29.8 (6.6)	.13
Forced expiratory volume in 1 second (L), mean (SD)	1.52 (0.7)	1.47 (0.6)	.84
Forced expiratory volume in 1 second (% predicted), mean (SD)	54.2 (26.9)	55.8 (19.4)	>.99
Smoking status: current, n (%)	3 (15)	3 (8.8)	.92
Nonsmoker	0 (0)	3 (8.8)	
Ex-smoker	17 (85)	26 (76.5)	
Unknown	0 (0)	2 (5.9)	
Home oxygen usage, n (%)			.83
Yes	4 (20)	6 (17.6)	
No	16 (80)	28 (82.4)	
Medical Research Council Dyspnoea Scale score, median (IQR)	3 (2-4)	3 (2-4)	.62
Medical Research Council grade, n (%)			.62
2	9 (45)	15 (45.5)	
3	5 (25)	8 (24.2)	
4	5 (25)	10 (30.3)	
5	1 (5)	0 (0)	
Incremental shuttle walking test (m), mean (SD)	338.5 (185.7)	286.8 (159.4)	.28
Endurance shuttle walk test (seconds), mean (SD)	263.9 (250.1)	256.2 (157.1)	.89

[a]Significant at $P<.05$ between groups.

Number of Steps Per Day

There were no significant differences in PA, in terms of steps per day, between the groups at baseline ($P=.86$). There was a nonsignificant increase ($P=.20$) in the number of steps per day from 5465 to 6112 (12%) in the web-based PR group compared with the conventional PR group ($P=.80$; n=5300-5409, 2%; Figure 2).

Figure 2. Comparison of the mean number of steps per day during waking hours between the conventional and web-based pulmonary rehabilitation groups at baseline and post intervention. PR: pulmonary rehabilitation.



PA Pattern of Accumulation

The increase in the number of steps observed in the web-based PR group was accumulated mainly through an increase of 2-minute bouts of PA (Figure 3). In contrast, the conventional PR group displayed increased 20-minute bouts of PA by 49%, although this was not significant (*P*=.07). The mean bout length of PA was similar between both groups (2.7-2.8 minutes) and did not significantly change following either intervention. Although the percentage of time in moderate activity was greater in the web-based PR group than in the conventional PR group (9.43 vs 8.14, respectively), this was not increased post intervention. Daily METs were similar in both groups, with those in the web-based PR group increasing only slightly at discharge (Table 2).

Figure 3. Comparison of the percentage change in physical activity between the conventional and web-based pulmonary rehabilitation groups. MET: metabolic equivalence to task, MVPA: moderate to vigorous physical activity, PR: pulmonary rehabilitation.

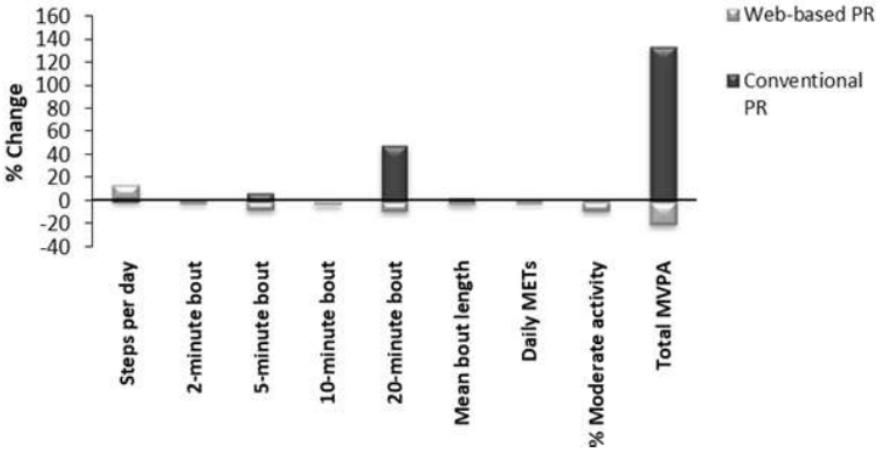


Table 2. Physical activity pattern before and after the intervention.

Activity pattern	Web-based pulmonary rehabilitation group (n=20)		Conventional pulmonary rehabilitation group (n=34)	
	Baseline, mean (SD)	Discharge, mean (SD)	Baseline, mean (SD)	Discharge, mean (SD)
Steps per day	5464.6 (3013.3)	6111.7 (2464.2)	5300.1 (3402.7)	5409.4 (3377.7)
Daily metabolic equivalence to tasks	1.52 (0.3)	1.54 (0.2)	1.44 (0.4)	1.42 (0.4)
Percentage of moderate activity	10.25 (8.8)	9.43 (4.2)	8.07 (5.9)	8.14 (7.3)
Mean bout length	2.8 (0.8)	2.7 (0.7)	2.7 (0.9)	2.8 (1.0)
Number of 2-minute bouts	21.1 (18.5)	21.4 (8.9)	18 (12.7)	17.9 (14.6)
Number of 5-minute bouts	7.2 (8.5)	6.7 (4.0)	5.5 (4.8)	5.9 (6.0)
Number of 10-minute bouts	2.11 (2.8)	2.1 (1.8)	1.6 (2.1)	1.6 (1.9)
Number of 20-minute bout	0.47 (0.7)	0.43 (0.4)	0.26 (0.4)	0.38 (0.5)
Total moderate to vigorous physical activity	82.03 (69.9)	65.7 (39.7)	102.9 (78.5)	241.1 (69.4)

Correlation Between Clinical Data and PA

As there were no significant differences between groups, the groups were collapsed and correlations between routinely collected clinical data and PA were explored. The variables age (r=–0.21, P=.04), BMI (r=–0.311, P=.004), and FEV_1 % predicted (r=–0.248, P=.048) significantly correlated with 10-minute bouts of PA at baseline. This effect was eliminated post intervention for age and FEV_1, but not for BMI (Table 3).

Table 3. Correlations between age, BMI, and FEV_1 (forced expiratory volume in 1 second) and physical activity before and after the intervention.

Variables	Preintervention		Postintervention	
	r	*P* value	*r*	*P* value
Age	–0.21	.04[a]	0.037	.78
BMI	–0.311	.004[a]	–0.449	<.001[a]
FEV_1 (forced expiratory volume in 1 second; % predicted)	–0.248	.048[a]	–0.034	.84

[a]Significant at $P<.05$.

Discussion

Principal Findings

One of the main outcomes of the European Respiratory Society task force on PA in COPD was to understand how improvements in exercise capacity, dyspnea, and self-efficacy following PR might translate into PA [28]. PR is well known to improve exercise capacity and quality of life, but the data are inconsistent for PA [28-30]. This may be a consequence of heterogeneity of interventions and measurements of PA, making it difficult to compare studies [31], or in fact suggests that the traditional focus of PR programs is on improving functional capacity, not necessarily PA.

The results from this study show that web-based PR increased the number of steps (Figure 2) by 12%; although this was not significant, it is most likely a reflection of the small sample size. The number of steps increased by 647 in the web group, in line with the suggested Minimal Clinically Important Difference for pedometer steps in COPD, estimated at 600-1181 steps [11]. Further analysis showed that the increased step count in the web-based PR group mainly comprised 2-minute bouts of PA (Figure 3), with very few 5-, 10-, and 20-minute bouts of PA. On the other hand, participants in the conventional PR program showed a trend to increase 20-minute bouts of activity, but this was not reflected in the overall step count.

Although the time spent in moderate-intensity PA was greater in the web-based PR group than in the conventional PR group, this did not translate into an increase in the total amount of MVPA. The pattern of PA is more sporadic in the web-based PR group, whereas the conventional PR group elicits a change through more prolonged bouts of PA (Figure 3). Participants in the conventional PR group were able to increase their 20-minute bouts of moderate PA by 49.1% (Figure 3); although not significant, this may be clinically meaningful. This may suggest that a more supervised approach is needed to achieve longer bouts of PA at the level of ≥3 METs. These data are interesting and suggest that although the increase in steps is a potentially positive outcome of an intervention, the web-based PR participants did not as a group improve their prolonged bouts of activity as was observed and anticipated in the conventional PR group. These data suggest that for this population, to improve exercise behaviors (ie, prolonged bouts of MVPA), supervision is required. In comparison to this, a study using a smartphone-based PA telecoaching approach [32] found that patients requiring more contact from health care professionals experienced less PA benefits. However, patients in our study do appear to have increased their overall PA in the absence of any supervision, and this translated to a significant change in endurance walking times, which was seen in both groups. This is in line with a study by Demeyer et al [33], which showed that a 12-week semiautomated telecoaching intervention, which included an exercise booklet and step counter, significantly increased the amount (29% from baseline in terms of steps per day) and intensity of PA in patients with COPD. In comparison, our study also showed an increase, although small, in the number of steps per day of 12% in the web-based PR group from baseline. The physiological benefits gained from interval training have been shown to translate into clinically meaningful improvements in daily activity levels [34]. Louvaris et al [34] reported a 27% increase in the number of steps per day in the interval training group, which remained significantly greater 12 weeks following completion of PR, suggesting that this mode of training may be better to impact activities of daily living. A recent review challenges the relevance of PA patterns in patients with COPD, stating which is more important, “more time spent in higher intensity PA or less time spent in a sedentary state?” [31].

The American Thoracic Society/European Respiratory Society policy statement recommends alternative approaches—for example, step counters or telerehabilitation—may be best placed as a maintenance strategy for PR [35]. Using these strategies have not only shown to increase patients step counts and PA but also reduced the risk of exacerbations and hospital admissions [36].

Factors associated with PA have largely been cross-sectional, and from our data, moderate correlations in PA show a trend with respect to age, BMI, and FEV_1 (% predicted) at baseline (Table 2), which is consistent with the existing literature [37-39]. There is a lack of data examining the direction of association and limited postintervention data describing these associations.

It is interesting to note that post intervention, the programs appear to have overcome the negative association between age and FEV_1 on PA but not on BMI, which has a more significant correlation at baseline. This suggests that rehabilitation programs can potentially reverse the negative impact of FEV_1 and age on PA, but this requires further exploration.

BMI remains highly significantly associated after PR, suggesting that in a population with obesity, additional interventions may be required to influence BMI. These data and those from previous studies, where BMI was used as a prognostic measure in COPD, have shown that both PR and PA have no influence on BMI, and as a result, a PR program was shown to be effective across the BMI spectrum; therefore, it is recommended that

patients are referred irrespective of their BMI [40]. This may also be true for PA improvements.

Other studies have found factors such as respiratory and metabolic variations to be associated with PA [41]. Interestingly these changes did not differ across the GOLD stages. When attempting to stratify patients, which may improve in their PA post PR, exercise tolerance was found to be the strongest baseline independent factor to predict an improvement in PA [42]. In this study, it appears that those who gained more in terms of number of steps had a higher exercise capacity at baseline, although this was not true for those who increased their MVPA overall.

Limitations

The main limitation of this study is that it is an exploratory analysis and is based on secondary analysis, and, per protocol, had a small sample size. Furthermore, there is a high risk of bias and a risk of overestimating any likely effect since this study only performed per protocol analysis. This was a highly selected group as the patient's needed to be web literate and willing to follow the web-based program; therefore, this selection bias may limit external validity. There was also a high withdrawal rate from the web-based PR group, which is an important limitation when interpreting the results. This was mainly due to challenges experienced around a technology-based intervention. Loeckx et al [32] reported that approximately 8% of patients reported difficulty using technology. In this study, it was found that the exercise component of the web-based program was difficult, but once it was simplified after obtaining patient feedback, completion rates improved. There were no significant differences between the groups even though more participants withdrew from the web-based PR group. A previous study in 2010 [43] suggested that levels of daily activity may be vulnerable to seasonal variations. The progression of physical inactivity in patients with COPD has also been studied with respect to climate conditions (eg, temperature, day length, and rainfall) [44]. A significant decrease in PA was seen over a period of 1 year, which was further affected by the hours of rainfall. Activity monitors were worn in our study during different time points of the year, depending on recruitment; therefore, seasonal variation may also have been a factor influencing PA. Nevertheless, this is a novel exploration of 2 interventions for individuals with COPD, which appear to have different effects based on the level of supervision.

Clinical Implications

When advising patients to increase their PA, promoting either multiple short bouts or long single bouts may be equally beneficial. Alternative approaches to increase PA may be more beneficial as a maintenance strategy.

Conclusions

The combination of a highly selected group of participants and the exploratory analysis approach renders it difficult to make generalizations. However, there was a nonsignificant difference in the pattern of PA between conventional and web-based PR groups. Conventional PR was associated with an increase in 20-minute bouts of PA. Effects of age and FEV_1 on PA can be overcome by taking part in rehabilitation, but BMI remains unaffected. This study shows a novel analysis of PA data, which could potentially be used as part of stratifying interventions based on measurements of PA and exercise capacity for individuals with COPD [45]. The data show that focusing on the number of steps alone can result in missing important messages about the pattern of PA.

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Authors' Contributions

All authors contributed to writing of the paper. SS, EC, and LH-W were involved in the design and intervention work. AVB and CN analyzed and interpreted the data.

Conflicts of Interest

None declared.

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Abbreviations

COPD: chronic obstructive pulmonary disease
FEV_1: forced expiratory volume in 1 second
MET: metabolic equivalence to task
MVPA: moderate to vigorous physical activity
NIHR: National Institute of Health Research
PA: physical activity
PPI: patient and public involvement
PR: pulmonary rehabilitation
SPACE for COPD: Self-Management Programme of Activity, Coping and Education for chronic obstructive pulmonary disease

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Original Paper

Accuracy of Heart Rate Measurement by the Fitbit Charge 2 During Wheelchair Activities in People With Spinal Cord Injury: Instrument Validation Study

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Abstract

Background: Heart rate (HR) is an important and commonly measured physiological parameter in wearables. HR is often measured at the wrist with the photoplethysmography (PPG) technique, which determines HR based on blood volume changes, and is therefore influenced by blood pressure. In individuals with spinal cord injury (SCI), blood pressure control is often altered and could therefore influence HR accuracy measured by the PPG technique.

Objective: The objective of this study is to investigate the HR accuracy measured with the PPG technique with a Fitbit Charge 2 (Fitbit Inc) in wheelchair users with SCI, how the activity intensity affects the HR accuracy, and whether this HR accuracy is affected by lesion level.

Methods: The HR of participants with (38/48, 79%) and without (10/48, 21%) SCI was measured during 11 wheelchair activities and a 30-minute strength exercise block. In addition, a 5-minute seated rest period was measured in people with SCI. HR was measured with a Fitbit Charge 2, which was compared with the HR measured by a Polar H7 HR monitor used as a reference device. Participants were grouped into 4 groups—the no SCI group and based on lesion level into the <T5 (midthoracic and lower) group, T5-T1 (high-thoracic) group, and >T1 (cervical) group. Mean absolute percentage error (MAPE) and concordance correlation coefficient were determined for each group for each activity type, that is, rest, wheelchair activities, and strength exercise.

Results: With an overall $MAPE_{all\ lesions}$ of 12.99%, the accuracy fell below the standard acceptable MAPE of –10% to +10% with a moderate agreement (concordance correlation coefficient=0.577). The HR accuracy of Fitbit Charge 2 seems to be reduced in those with cervical lesion level in all activities ($MAPE_{no\ SCI}$=8.09%; $MAPE_{<T5}$=11.16%; $MAPE_{T1–T5}$=10.5%; and $MAPE_{>T1}$=20.43%). The accuracy of the Fitbit Charge 2 decreased with increasing intensity in all lesions ($MAPE_{rest}$=6.5%, $MAPE_{activity}$=12.97%, and $MAPE_{strength}$=14.2%).

Conclusions: HR measured with the PPG technique showed lower accuracy in people with SCI than in those without SCI. The accuracy was just above the acceptable level in people with paraplegia, whereas in people with tetraplegia, a worse accuracy was found. The accuracy seemed to worsen with increasing intensities. Therefore, high-intensity HR data, especially in people with cervical lesions, should be used with caution.

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KEYWORDS

Fitbit Charge 2; heart rate; accuracy; photoplethysmography; spinal cord injury

Introduction

Background

Spinal cord injury (SCI) is a result of a partial or complete disruption of the neuropathways in the spinal cord, causing loss of motor and sensory function and a disturbed autonomic nervous system (ANS). Wheelchair users with SCI have one of the lowest daily activity levels compared with other groups with chronic physical conditions [1], negatively affecting their daily activity energy expenditure. In addition, their resting energy expenditure is often decreased because of multiple factors, with a reduced fat-free mass as a major contributor [2-5]. Together with the reduced activity energy expenditure, this leads to a lower total daily energy expenditure. As a consequence, approximately 68% of the people with SCI are overweight or obese, associated with increased risks of cardiovascular disease and mortality [6,7]. Therefore, maintaining or achieving an active lifestyle is even more crucial in people with SCI than in the able-bodied population. There are several tools that can help to stimulate or maintain an active lifestyle. Currently, activity trackers are a popular way to get insight on and monitor one's personal activity level. Activity trackers include many features, such as estimations of activity levels, exercise intensity or daily energy expenditure, often based on recorded movement via accelerometry and heart rate (HR).

HR is one of the most important and often used physiological parameters, as it is directly related to oxygen consumption and energy expenditure. The delivery of oxygen-rich blood required in the circulation system is controlled by the ANS by modulating both the HR and stroke volume [8,9]. For this reason, HR is used to monitor exercise intensity or as a derivative to estimate, for example, maximal oxygen uptake (VO_2max), or energy expenditure [10]. Over the last 4 decades, HR during exercise has mainly been measured using HR monitors that make use of a chest belt, transmitter, and receiver. Owing to the rapid development of sensor technology in recent decades, it is now possible to record and track HR in an even less invasive and easier way. One of the most popular and commonly used methods to determine HR in daily life is photoplethysmography (PPG), a simple and low-cost technique that can be integrated in a wrist-worn activity tracker [11,12].

PPG is a technique in which blood volume changes are detected in the microvascular bed of tissue by infrared light reflected from the tissue, such as the ear lobe, finger, or wrist [11]. The change in blood volume after a heartbeat is proportional to the reflected light, allowing pulse wave detection in the wrist, which can be used as a derivative to determine HR [13]. HR recording with this technique, however, is more susceptible to motion artifacts caused by hand-arm movements and blood flow dynamics and can, therefore, lead to a lower accuracy [14,15]. Studies have shown acceptable validity and accuracy (<10%) in HR recordings during sleep or across a 24-hour period in a free-living environment in able-bodied individuals with a mean absolute percentage error (MAPE) of <10% [16,17]. However, when tested during activities of higher intensities or dynamic situations, the accuracy dropped (MAPE>10%) [18-20]. Owing to the developments in HR recording with activity trackers, they are being included in clinical settings for medical purposes, such as mobile health monitoring, noninvasive medical surveillance, or even detecting first signs of health issues [21-23]. As information gathered by activity trackers is more often used for clinical and health purposes, the importance of accurate data is growing. However, as measurement techniques rely on physiological properties and responses, measurement outcomes can differ if physiological responses are altered, for instance, because of medical conditions. Therefore, it is important to investigate the accuracy of HR measurement within different populations, such as in people with SCI, as their physiological responses can be severely altered [24].

Objectives

The accuracy of HR determined by PPG depends on blood pressure changes which is, among other things, influenced by HR variability [25]. Both, the blood pressure of the upper limbs and HR are regulated by the ANS, of which the sympathetic outflow occurs between the first thoracic (T1) spinal cord segment and the fifth thoracic (T5) spinal segment. After an SCI, neural signal transmission is partially or fully lost at and below the lesion level. In case of an SCI at or above the T5 spinal cord segment, neural signaling and, therefore, the balance between the parasympathetic and sympathetic systems are often altered. Sympathetic hypoactivity usually occurs, resulting in possible low HR, low resting blood pressure, disturbed vascular regulation, and altered responses in these systems during rest or during physical activities [24]. Owing to the changes in HR response and blood pressure control, the accuracy of HR determined by PPG could be affected when a lesion occurs above T5. Because of possible impaired or altered vascular regulation, artifact-reducing algorithms may not apply and might subsequently compromise HR accuracy. The ANS is even more affected in cervical lesions, as the imbalance between the parasympathetic and sympathetic systems increases with lesion level [26]. Therefore, the aim of this study is to evaluate whether Fitbit Charge 2 can accurately record HR in wheelchair users with SCIs and to investigate how lesion level affects accuracy. In addition, the effect of intensity on accuracy is determined during wheelchair activities and strength exercise, as a higher intensity is expected during strength exercise compared with wheelchair activities and during wheelchair activities compared with rest. It is hypothesized that the HR accuracy of the Fitbit Charge 2 is lower in people with lesions at or above T5 because of the possible affected ANS, compared with people with lesions below T5 or without SCI. A further reduction in accuracy is expected in people with a cervical lesion compared with those with a lower lesion level or without SCI, because of an enlarged imbalance between the parasympathetic and sympathetic

systems. Furthermore, the accuracy is expected to decrease with increasing intensities.

Methods

Study Design

Data on body composition and energy expenditure in people with SCI were collected in a larger cross-sectional study. All participants were invited for a one-time visit to the Amsterdam Nutritional Assessment Center laboratory of the Amsterdam University of Applied Sciences. HR of the participants was recorded during rest, wheelchair activities, and a 30-minute strength exercise block with both the Fitbit Charge 2 and Polar H7 HR monitor. All participants provided signed informed consent before participating. The study was approved by the medical ethical committee of Slotervaart Ziekenhuis—Reade (METc nr. P1805).

Participants

Overall, 48 participants were recruited to participate in this study, 38 (79%) with SCI and 10 (21%) without SCI. Recruitment took place through advertisements via the Dutch SCI patient association, social media, rehabilitation center Reade in Amsterdam, and the social network of the involved researchers. Participants were included if the following inclusion criteria were met: age between 18 and 75 years; chronic SCI (time since injury >1 year), not ventilator-dependent; and wheelchair-dependent for longer distances. Exclusion criteria were as follows: presence of a pacemaker, severe edema, progressive illness, pressure ulcers, metabolic diseases, severe comorbidities, psychiatric disorders, pregnancy, and insufficient understanding of the Dutch language to understand the study. Participants without SCI were selected based on the same inclusion and exclusion criteria, except for the SCI-related criteria. Personal and lesion characteristics were obtained through a questionnaire and interview. A conservative sample size target was chosen and set on ≥40 samples of each device for each group for each activity based on the method comparison guideline [27].

The participants were divided into 4 groups—the without SCI group and based on their lesion level they were divided into the cervical (>T1), high-thoracic (T1-T5), and midthoracic and lower (<T5) groups, to test the influence of lesion level on PPG accuracy. Heart and upper-body blood vessels are sympathetically innervated from segments T1-T5 and interact with the parasympathetic system to provide a balanced regulation of the cardiovascular system. In people with an SCI at T5 and above, sympathetic innervation is likely to be affected to a certain extent, which causes altered HR response and blood pressure regulation, possibly affecting PPG recordings compared with lower lesions. In addition, the lesion groups T5 and above were divided into the following lesion subgroups: lesion above T1 and lesion between T1-T5, with a larger imbalance in the ANS expected in the first group and thus a more severe cardiovascular dysfunction [28]. In people with an SCI above T1, arm function might be impaired, as well as a more severed impaired sympathetic innervation of the heart and upper-body vessels compared to lower lesions, which could lead to a lower HR accuracy in those with a cervical lesion [29].

Materials

Fitbit Charge 2

The Fitbit Charge 2 (2017 version, Firmware version 22.55.2, Fitbit Inc) is a commercially available activity tracker with multiple sensors, such as a 3-axis accelerometer, an altimeter, and a PPG sensor to record HR. In the Fitbit Charge 2 PurePulse, HR technology is used as an investigational device, which constantly reads the changes in the blood volume at the wrist. An algorithm converts these data into continuous HR data. The smartwatch was tightly positioned according to instructions on Fitbit on the wrist of participants on which normally a watch would be worn, usually the nondominant side. Intraday data collection was requested and approved by Fitbit for research purposes, allowing us to obtain the data on the highest possible sampling rate for the time period in which all activities were performed through an application programing interface. Output frequency of the HR data varied between 0.2 Hz and 0.06 Hz. Data collected by the Fitbit were transferred through Bluetooth Low Energy to the Fitbit App and downloaded.

Polar H7 HR Monitor

The Polar H7 chest strap HR monitor (Bluetooth Low Energy version, Polar Electro) was used as a reference device to measure HR; it is an accurate (intraclass correlation coefficient=0.98) alternative for a 3-lead electrocardiography (ECG), which is considered as the gold standard for measuring HR [30]. The strap was moistened to improve conduction between the skin and the sensor before it was secured tightly around the chest. HR recording was connected with a Cortex Metamax 3B (Cortex Biophysik GmbH) portable indirect calorimetry system, used in the larger study, which collects data at each full breathing cycle. Therefore, the output frequency of the Polar H7 HR data was determined by the breathing frequency of the participants during the protocol. The HR output given after each breathing cycle was the average HR measured over the entire breathing cycle.

Measurement Protocol

After ensuring that all sensors were positioned correctly, the measurement protocol started with a 5-minute seated rest, followed by wheelchair activities, consisting of eleven different wheelchair tasks executed for 1 minute, namely: (1) wheelchair propulsion on a low-resistance surface on a slow, (2) normal, and (3) high speed; (4) handcycling on an armcrank ergometer; (5) rummaging in a bag while being pushed; (6) setting the table; (7) doing dishes; (8) typing on a laptop; (9) maneuvering the wheelchair; (10) wheelchair basketball; and (11) transfer from wheelchair to chair and back. No 5-minute seated rest data were available for the participants without SCI, as this was added to the measurement protocol after finishing the measurements of the participants without SCI. All tasks were performed for 1 minute, as this represents real-life situations better compared with longer steady-state situations. All tasks were timed, logged, and recorded using a camera. Between each task, a rest period allowed the HR to recover close to the resting level to ensure variability in measured HR between tasks. If the participant was not able to perform a wheelchair activity independently because of their impairment, the task was not

executed. After the activities were completed, a 30-minute upper-body strength exercise was performed. Exercises and resistances were chosen based on the participants' preferences and physical capabilities. All strength exercises were performed with sets of 8-12 repetitions, and each set was repeated 3 times in total. After each set, there was a rest period that lasted between 90 and 120 seconds before the next set was started. The strength exercise block was not executed if the participant was not able to perform strength exercises because of an upper-body injury or impairment.

Data Analyses

Missing Data and Synchronization

On the basis of expert evaluation, all data of 8% (4/48) individuals were excluded. Of the 4 individuals, data for 2 (50%) individuals were excluded because of poor Polar H7 HR monitor connection throughout the whole measurement, data for 1 (25%) were excluded owing to battery failure of the Polar H7 HR monitor, and data for 1 (25%) were excluded because of the loss of Fitbit Charge 2 data. In total, the HR data of 92% (44/48) of participants were analyzed. In addition, approximately 0.6% of the data were excluded from 13% (6/48) of participants because of invalid samples (temporary loss of Polar H7 HR monitor connection). In total, 21,732 valid HR samples from both devices were used for analysis. The data of the 2 devices with different sampling rates were synchronized by relating the HR monitored by the reference device (ie, Polar H7 HR monitor) to that of the investigational device (ie, Fitbit Charge 2) that was closest in time. Consequently, data were labeled with one of the three activity categories: rest, wheelchair activities (including resting time between the activities and before the strength exercises started), and strength exercises (including resting time between the exercises) based on logbook data and video recordings.

Statistical Analyses

All statistical analyses were performed in R (version 3.6.1; R Foundation for Statistical Computing) using R Studio (version 1.2.1335). To assess error, the mean difference between the Polar H7 HR monitor and Fitbit Charge 2 HR samples was calculated, resulting in the mean error. In addition, the mean absolute error (MAE) and the MAPE were evaluated. As stated by the American National Standards Institute, the accuracy of HR monitors should be within –10% to +10% of the input rate or –5 to +5 beats per minute (bpm), whichever is greater [31]. In alignment with these standards, we considered a MAPE of –10% to +10% as an acceptable error rate. Following Nelson and Allen [17], outliers were not removed to evaluate the accuracy of consumer use conditions. Bland-Altman plots with 95% limits of agreement (LoA) were produced using the BlandAltmanLeh R package [32]. The Bland-Altman plots and LoA are the suggested methods for analyzing the agreement between 2 measurement devices [33-36]. These plots were inspected to assess systematic biases over the entire HR range and to assess the magnitude of such biases and whether Fitbit Charge 2 overestimated or underestimated HR compared with the Polar H7 HR monitor. Finally, in line with previous wearable validation studies [17,33], Lin concordance correlation coefficients (CCCs) [37] were calculated using the DescTools R package [38]. These correlation coefficients provide information on the association and strength of the linear relationships between the reference device and investigational device. According to Nelson and Allen [17], the strength of agreement can be interpreted based on the following: CCC<0.5 indicates a weak association, CCC between 0.5 and 0.7 indicates a moderate association, and CCC>0.7 relates to a strong association.

Results

Descriptives

Table 1 shows the demographic characteristics of the 77% (34/44) wheelchair users with SCI and 23% (10/44) participants without SCI included in the analyses. Table 2 shows the descriptive statistics for the 21,732 HR samples measured by the Polar H7 HR monitor and the Fitbit Charge 2. These samples were taken during rest (1168 HR samples over a 5-minute period), wheelchair activities (12,016 HR samples), and strength exercises (8548 HR samples). In addition, the distributions in the HR samples are displayed visually in the violin plots shown in Figure 1. The violin plot displays the mirrored density plot in addition to the box plot, which displays summary statistics, such as the median and IQR. As shown in Table 2, the range of the HR samples from Polar H7 was wider than the HR estimates produced by the Fitbit Charge 2. The differences in the range of HRs became more pronounced when the lesion was above T5. However, further investigation showed that the range produced by the Polar H7 and Fitbit Charge 2 was quite similar for people with SCI above T1.

Table 1. Demographic characteristics of participants (N=44).

Characteristics	Lesion level					
	All lesions (n=34)	Below T5[a] (n=16)	T5 and above (n=18)	T1[b]-T5 (n=10)	Above T1 (n=8)	No SCI[c] (n=10)
Gender						
Female	9	5	4	2	2	3
Male	25	11	14	8	6	7
Age (years), mean (SD)	48.9 (12)	49.3 (13.7)	48.4 (10.9)	50.0 (9.9)	46.5 (12.5)	50.8 (10.1)
AIS (A/B/C/D)[d]	14/3/2/15	6/0/1/9	8/3/1/6	8/0/0/2	0/3/1/4	N/A[e]
Time since injury (years), mean (SD)	14.7 (11.6)	15.9 (13.3)	13.6 (10.1)	15.0 (11.7)	11.9 (8.1)	N/A
BMI, mean (SD)	24.2 (4.1)	23.5 (4)	24.7 (4.3)	25.7 (4.8)	23.6 (3.5)	26.0 (3.4)

[a]T5: fifth thoracic vertebrae.

[b]T1: first thoracic vertebrae.

[c]SCI: spinal cord injury.

[d]AIS: American Spinal Cord Injury Association Impairment Scale score.

[e]N/A: not applicable.

Table 2. Descriptive statistics of heart rate (HR) samples per activity, device, and lesion level.

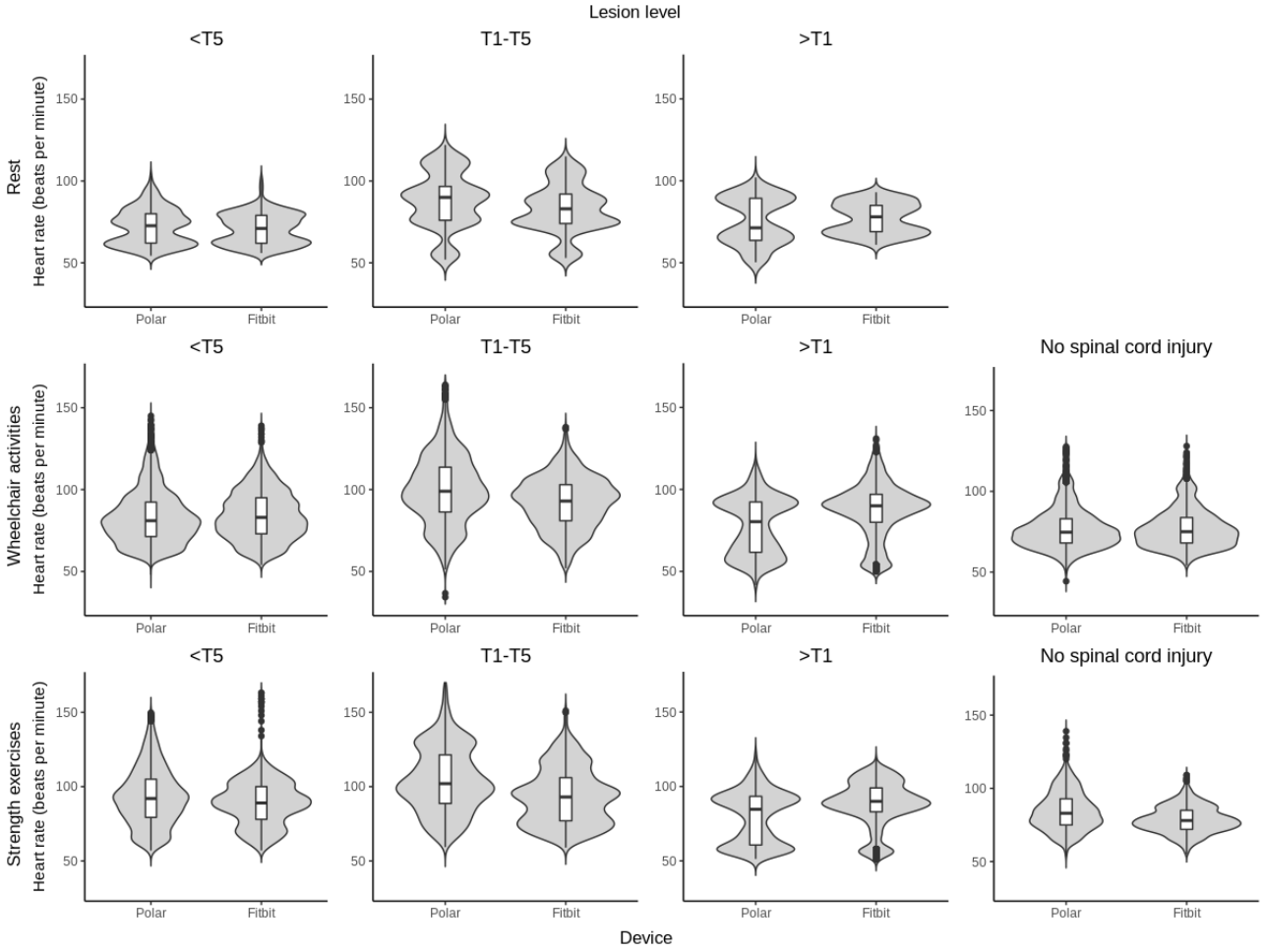
Lesion level	HR samples	Polar H7 HR monitor, mean HR (SD; range)	Fitbit Charge 2, mean HR (SD; range)
All activities			
All included	21,732	85.7 (19.7; 34.3-169.7)	85.6 (15.7; 50-163)
All lesions	17,211	89 (20.7; 34.3-169.7)	87.6 (16.2; 50-163)
<T5[a]	8172	86.3 (18.1; 48-149.7)	85.2 (15.3; 54-163)
>T5	9039	91.4 (22.4; 34.3-169.7)	89.9 (16.6; 50-151)
T1[b]-T5	5324	100.5 (21.2; 34.3-169.7)	91.8 (16.9; 52-151)
>T1	3715	78.3 (17.1; 41.7-121.7)	87.1 (15.7; 50-131)
No SCI[c]	4521	80.5 (13.3; 44.3-139)	77.8 (10.7; 54-128)
Rest			
All lesions	1168	78.2 (15.5; 50.3-122)	76.2 (12.7; 53-115)
<T5	538	72 (10.7; 54.3-103.3)	70.7 (9.3; 56-102)
>T5	630	83.6 (17; 50.3-122)	80.8 (13.4; 53-115)
T1-T5	397	88.3 (16.8; 52-122)	83 (14.8; 53-115)
>T1	233	75.6 (14; 50.3-102)	77 (9.3; 61-93)
Wheelchair activities			
All included	12,016	85.3 (19.2; 34.3-164)	85.4 (15.8; 50-139)
All lesions	9654	87.4 (20; 34.3-164)	87.5 (15.9; 50-139)
<T5	4434	83.1 (16.1; 48-145)	84.3 (15; 54-139)
>T5	5220	91 (22.2; 34.3-164)	90.2 (16.2; 50-138)
T1-T5	3119	99.8 (20.7; 34.3-164)	92.1 (15.8; 52-138)
>T1	2101	77.8 (17.3; 41.7-118.7)	87.3 (16.3; 50-131)
No SCI	2362	76.9 (12.5; 44.3-127.7)	77 (12; 54-128)
Strength exercises			
All included	8548	91.1 (20; 51.3-169.7)	87.1 (15.5; 51-163)
All lesions	6389	93.4 (21.4; 51.3-169.7)	90.0 (16.2; 51-163)
<T5	3200	93.6 (23.4; 51.3-169.7)	88.8 (14.9; 57-163)
>T5	3189	93.1 (19.2; 57-149.7)	91.2 (17.3; 51-151)
T1-T5	1808	104.4 (21.8; 59.3-169.7)	93.2 (18.6; 59-151)
>T1	1381	79.6 (17.3; 51.3-121.7)	88.5 (15; 51-119)
No SCI	2159	84.4 (13.1; 53.3-139)	78.6 (9.1; 55-109)

[a]T5: fifth thoracic vertebrae.

[b]T1: first thoracic vertebrae.

[c]SCI: spinal cord injury.

Figure 1. Violin plots of heart rate observations for Polar H7 and Fitbit Charge 2 divided by intensity from top to bottom in rest, wheelchair activities and strength exercise and divided by lesion level from left to right in lesion <T5, T1-T5, >T1, no spinal cord injury. Mean heart rate in beats per minute and IQRs are shown together with the distributions. T1: first thoracic vertebrae; T5: fifth thoracic vertebrae.



Mean Absolute Error

Overall, the Fitbit Charge 2 had a mean percentage error rate of 12.99% for people with SCI (Table 3), which is too high considering the standard acceptable MAPE is –10% to +10%. The MAPE of people with a lesion below T5 and between T1 and T5 was comparable with 11.16% and 10.16%, respectively, but for people with a lesion above T1, the MAPE was considerably higher (20.43%). People without SCI showed slightly better MAPE (8.09%) compared with people with lesions below T5 and between T1 and T5, as the MAPE was within the standard acceptable range of –10% to +10%. The MAPE was dependent on the type of activity performed by people with SCI. For rest, the overall MAPE was 6.5%, whereas the MAPE increased with the intensity of the activity to 12.97% for wheelchair activities and 14.2% for strength exercises. A similar trend was found in people without SCI, where the MAPE for strength exercise (8.39%) was slightly higher than the MAPE for wheelchair activities (7.82%). For each activity, a pattern exists where the MAPE increased with higher lesion levels. Taken together, the MAPE of the Fitbit Charge 2 only seemed within the acceptable range for people with SCI during rest. With higher lesion levels, Fitbit Charge 2 HR measurements were more off relative to the Polar H7 HR estimates.

Table 3. Device error statistics.

Lesion level	Heart rate samples	Error Fitbit Charge 2			Bland-Altman analysis	
		MAE[a]	MAPE[b] (%)	ME[c] (SD)	Lower LoA[d]	Upper LoA
All activities						
All included	21,732	10.2	11.97	−1.6 (16)	−32.9	29.7
All lesions	17,211	11.1	12.99	−1.3 (17.0)	−34.7	32.1
<T5[e]	8172	9.6	11.16	−1.1 (14.7)	−30	27.8
>T5	9039	12.4	14.64	−1.5 (18.9)	−38.5	35.5
T1[f]-T5	5324	11.6	10.6	−8.7 (15.7)	−39.3	22
>T1	3715	13.7	20.43	8.8 (18.4)	−27.3	44.8
No SCI[g]	4521	7	8.09	−2.7 (10.8)	−23.9	18.5
Rest						
All lesions	1168	5.2	6.5	−2.1 (9.0)	−19.7	15.6
<T5	538	4.1	5.41	−1.2 (8.3)	−17.4	14.9
>T5	630	6.2	7.43	−2.7 (9.5)	−21.4	15.9
T1-T5	397	6.2	6.27	−5.2 (9.2)	−23.3	12.8
>T1	233	6.2	9.39	1.5 (8.6)	−15.3	18.3
Wheelchair activities						
All included	12,016	9.9	11.96	0.1 (15.4)	−30.1	30.3
All lesions	9654	10.7	12.97	0.1 (16.4)	−32.1	32.3
<T5	4434	9.2	11.29	1.2 (14.3)	−26.8	29.1
>T5	5220	12	14.4	−0.8 (18)	−36.1	34.6
T1-T5	3119	10	10.33	−7.7 (14.2)	−35.6	20.2
>T1	2101	13.5	20.43	9.5 (18.2)	−26.3	45.2
No SCI	2362	6.3	7.82	0.1 (10.2)	−19.9	20.2
Strength exercises						
All included	8548	11.5	12.73	−4 (17.1)	−37.5	29.5
All lesions	6389	12.7	14.2	−3.4 (18.8)	−40.1	33.4
<T5	3200	11.1	11.94	−4.3 (15.6)	−34.9	26.3
>T5	3189	14.4	16.47	−2.5 (21.4)	−44.4	39.5
T1-T5	1808	13.8	12.03	−11.2 (18.5)	−47.5	25.2
>T1	1381	15.1	22.29	8.9 (19.5)	−29.3	47.1
No SCI	2159	7.7	8.39	−5.8 (10.6)	−26.6	14.9

[a]MAE: mean absolute error.

[b]MAPE: mean absolute percent error.

[c]ME: mean error.

[d]LoA: limits of agreement.

[e]T5: fifth thoracic vertebrae.

[f]T1: first thoracic vertebrae.

[g]SCI: spinal cord injury.

Bland-Altman Analysis and 95% LoA

Table 3 shows the results from the Bland-Altman analysis, and Multimedia Appendix 1 shows the Bland-Altman plots. Across all lesion levels and activities, the mean error of the Fitbit Charge 2 was −1.3 (SD 17) bpm (lower LoA-upper LoA: −34.7 to 32.1 bpm) and MAE was 11.1. People without SCI showed a slightly larger mean error of −2.7 (SD 10.8) bpm (lower LoA-upper LoA: −23.9 to 18.5 bpm) but a smaller MAE of 7. Less agreement was observed in the group with a higher lesion

level—mean error −1.1 (SD 14.7) bpm for the group with SCI lesions below T5 (lower LoA-upper LoA: −30 to 27.8 bpm), mean error −8.7 (SD 15.7) bpm (lower LoA-upper LoA: −39.3 to 22 bpm) for the group with SCI lesions between T1 and T5, and mean error 8.8 (SD 18.4) bpm (lower LoA-upper LoA: −27.3 to 44.8 bpm) for those with SCI lesions above T1. Although there were some outliers, Fitbit Charge 2 did not seem to systematically overestimate or underestimate HR values during rest in people with SCI. For the group with SCI lesions below T5, all outliers shown in Bland-Altman plots in Multimedia Appendix 1 during all 3 activities were from 3 separate participants. During rest, the overall mean error for people with SCI was −2.1 (SD 9) bpm (lower LoA-upper LoA: −19.7 to 15.6 bpm). Here, the agreement seemed lowest for the group with an SCI between T1-T5 with a mean error of −5.2 (SD 9.2) bpm (lower LoA-upper LoA: −23.3 to 12.8 bpm) compared with a mean error of −1.2 (SD 8.3) bpm (lower LoA-upper LoA: −17.4 to 14.9 bpm) for those with an SCI below T5 and a mean error of 1.5 (SD 8.6) bpm (lower LoA-upper LoA: −15.3 to 18.2 bpm) for those with an SCI above T1. In contrast, investigation of the plots presented in Multimedia Appendix 1 showed that during wheelchair activities and strength exercises, a trend toward overestimation for values below 100 bpm and an underestimation for observations with higher bpm was present. These trends seemed more pronounced during the strength exercises where the mean error was −3.4 (SD 18.8) bpm (lower LoA-upper LoA: −40.1 to 33.4 bpm) compared with an overall mean error of 0.1 (SD 16.4) bpm (lower LoA-upper LoA: −32.1 to 32.3 bpm) during wheelchair activities. A similar trend was found during strength exercise in those without an SCI, with a mean error of −5.8 (SD 10.6) bpm (lower LoA-upper LoA: −26.6 to 14.9 bpm) for strength exercise compared with a mean error of 0.1 (SD 10.2) bpm (lower LoA-upper LoA: −19.9 to 20.2 bpm) for wheelchair activities. Overall, Bland-Altman plots showed a trend toward overestimation of HR values for observations between 80 and 100 bpm in people with SCI lesions below T5. This was, to a lesser extent, also observed in general for people with SCI lesions above T1. In contrast, the Fitbit Charge 2 mostly underestimated the HR values of observations with ≥80 bpm in people with SCI between T1-T5.

Concordance Class Correlation

Overall, across all activities and all included groups, the Fitbit Charge 2 had a moderate agreement with the Polar H7 HR monitor (CCC=0.596, 95% CI 0.587-0.604). During rest, this agreement was stronger (CCC=0.791, 95% CI 0.770-0.810) and as intensity increased, this agreement became weaker; during wheelchair activities $CCC_{activities}$=0.615 (95% CI 0.605-0.626) and during strength exercises $CCC_{strength}$=0.531 (95% CI 0.517-0.545). Overall, the agreement was stronger for those with an SCI lower than T1 or no SCI and became much weaker for the group with SCI above T1: CCC_{noSCI}=0.585 (95% CI 0.567-0.603), $CCC_{<T5}$=0.613 (95% CI 0.599-0.626), $CCC_{T1–T5}$=0.605 (95% CI 0.590-0.620), and $CCC_{>T1}$=0.328 (95% CI 0.302-0.353). Agreement was weak for people with a lesion above T1 during wheelchair activities ($CCC_{>T1activities}$=0.354, 95% CI 0.321-0.386) and strength exercises ($CCC_{>T1strength}$=0.238, 95% CI 0.195-0.281). For lesions between T1 and T5 and lesions below T5, the agreement was moderate. Moderate ($CCC_{no\ SCI\ activities}$=0.653, 95% CI 0.629-0.675) to low ($CCC_{no\ SCIstrength}$=0.490, 95% CI 0.464-0.516) agreements were found for those without SCI, as shown in Table 4.

Table 4. Concordance class correlation based on lesion groups and activities.

Lesion level	Heart rate samples	Concordance class correlation (95% CI)
All activities		
All included	21,732	0.596 (0.587-0.604)
All lesions	17,211	0.577 (0.567-0.586)
<T5[a]	8172	0.613 (0.599-0.626)
>T5	9039	0.541 (0.527-0.554)
T1[b]-T5	5324	0.605 (0.590-0.620)
>T1	3715	0.328 (0.302-0.353)
No SCI[c]	4521	0.585 (0.567-0.603)
Rest		
All lesions	1168	0.791 (0.770-0.810)
<T5	538	0.659 (0.609-0.703)
>T5	630	0.792 (0.764-0.817)
T1-T5	397	0.788 (0.751-0.820)
>T1	233	0.736 (0.684-0.780)
Wheelchair activities		
All included	12,016	0.615 (0.605-0.626)
All lesions	9654	0.586 (0.573-0.599)
<T5	4434	0.577 (0.558-0.597)
>T5	5220	0.567 (0.550-0.584)
T1-T5	3119	0.645 (0.627-0.663)
>T1	2101	0.354 (0.32-0.386)
No SCI	2362	0.653 (0.629-0.675)
Strength exercises		
All included	8548	0.531 (0.517-0.545)
All lesions	6389	0.503 (0.486-0.520)
<T5	3200	0.567 (0.545-0.534)
>T5	3189	0.457 (0.431-0.482)
T1-T5	1808	0.505 (0.475-0.534)
>T1	1381	0.238 (0.195-0.281)
No SCI	2159	0.490 (0.464-0.516)

[a]T5: fifth thoracic vertebrae.

[b]T1: first thoracic vertebrae.

[c]SCI: spinal cord injury.

Discussion

Principal Findings

This is, to our knowledge, the first study to assess the HR accuracy of Fitbit Charge 2 in people with SCI, or more specifically, to assess the effects of lesion level on PPG-based HR accuracy. With an overall MAPE of 12.99% for the Fitbit Charge 2, the standard acceptable error of –10% to +10% was not met, and the outcomes were worse than in earlier research in able-bodied populations [17,20]. As the intensity of the activity increased, the HR accuracy of Fitbit Charge 2 worsened, which is in line with previous research [18-20]. Moreover, there seems to be a clear effect of lesion level, as the highest lesion group (>T1) showed drastically lower accuracy on Fitbit HR recordings on all intensities, compared with lower lesion level groups. This could possibly contribute to a more severely affected sympathetic innervation.

Compared with previous research in able-bodied individuals, our findings showed poorer outcomes for both MAPE and agreement rate during wheelchair activities and strength exercises. Previous research on the accuracy of HR

measurements of the Fitbit Charge 2 that included similar activities (seated rest, activities of daily living, strength exercises) showed a MAPE range of 5.93% to 9.88% in able-bodied individuals. A similar range was found in this study in people without SCI (7.82%-8.39%) [17,20]. In all people with SCI, the MAPE range varied between 6.5% and 14.2%. During seated rest, our findings showed a stronger association (CCC=0.791) between the Fitbit Charge 2 and Polar H7 HR monitor compared with a moderate association in previous research (CCC=0.561) [17]; however, agreement and error in all other activities showed poorer results and worsened as intensity increased in people with SCI. The reduced accuracy with increasing intensities is in line with the literature [18,19], but accuracy worsened more in people with SCI during wheelchair activities (CCC=0.586; MAPE 12.97%) and strength exercises (CCC=0.503; MAPE 14.2%) than in people without SCI during wheelchair activities (CCC=0.653; MAPE 7.82%) and strength exercises (CCC=0.490; MAPE 8.39%) and previous literature (activities of daily living: CCC=0.739; MAPE 8.29%; strength exercise: CCC=0.72; MAPE 9.8%; [17,20]). It could be argued that performing activities in a wheelchair could influence the agreement of HR recording in wrist-worn wearables in general as the CCC values in this study tend to be lower, even in people without SCI. To perform certain activities in a wheelchair, the wrist is often repetitively pressed and bumped against the rim of the wheel during propulsion, which could continuously affect the PPG connection as the pressure between the sensor and skin fluctuates [39]. This could, at least in part, explain the overall poorer accuracy of the Fitbit Charge 2 during wheelchair activities in people with and without SCI in this study compared with previous findings in able-bodied individuals. However, this would not explain the drastically decreased HR accuracy of the Fitbit Charge 2 in the higher lesion level (>T1) group. Therefore, it is very likely that a more severely imbalanced ANS negatively affects the accuracy [26].

It is remarkable that the T1-T5 group showed no clear difference from the <T5 group, as the sympathetic pathway is affected at lesion levels above T6 and an imbalance between the sympathetic and parasympathetic system is most likely present, which controls HR and blood pressure [24]. As there is a major difference between Polar H7 and Fitbit Charge 2 in the technique used to measure the obtained HR outcomes, it seems likely that this difference causes a drop in accuracy and agreement during the Fitbit Charge 2 HR recording. Because Fitbit Charge 2 HR recording is based on blood pressure differences, and autonomic control of the blood vessels in the upper body is controlled between segments T1 and T4, it was expected to observe differences in the T1-T5 group as well as in the >T1 group compared with the <T5 group. However, it appears that as long as there is some innervation left and not all sympathetic innervation of the blood vessels is affected, HR accuracy measured by PPG is only slightly reduced. The accuracy only seems to drop at lesion levels above T1, as there is possibly no sympathetic innervation left of the blood vessels in the lower parts of the upper limbs [40]. In addition, people with tetraplegia are more likely to show lower blood pressure compared with people with paraplegia or able-bodied individuals caused by reduced sympathetic activity [41]. Therefore, hypotension is a common phenomenon among people with tetraplegia, which could possibly influence the accuracy of PPG-based HR recordings as it deviates from the regular expected signal [42,43].

The severity of reduced sympathetic innervation is not necessarily related to neurological lesion completeness, which is often expressed using the American Spinal Cord Injury Association Impairment Scale score. This scale is based on the presence of motor or sensory function, where a complete injury is defined as the absence of both motor and sensory function below the lesion, and an incomplete lesion is defined as any reduced presence of motor or sensory function below the lesion [44]. However, research has shown that this classification does not necessarily include autonomic function, because sympathetic activity has been detected in athletes with complete cervical SCI lesions [45]. Although lesion level clearly influences the ANS and, therefore, Fitbit Charge 2 HR accuracy, the effect of completeness of the lesion on motor, sensory, and autonomic function remains unknown. Therefore, future studies should test autonomic function separately from neurological lesions in people with SCI to gain better insight on the effect of autonomic function on HR accuracy based on PPG signals.

Strengths and Limitations

A strength of this study was the relatively large sample size of people with SCI, in which the distribution among the different lesion level groups, which were based on physiological differences determined by the literature, was fairly even and the direct comparison between people with and without SCI [24,26,40]. Analyses were performed, when possible, according to the methodological approaches suggested by Nelson and Allen [17], van Lier et al [34], and Sartor et al [33]. Activities and exercises mimicked real-life situations, which increased the ecological validity. Participants with SCI performed the tasks in their own wheelchair, at their own speed in relatively short time bouts, representing real-life situations better than prolonged steady-state activities. A suitable wheelchair was provided to the participants without SCI. Outcomes were analyzed as a whole and divided by lesion group and rest, wheelchair activities, and strength exercises to gain insight on both the effect of intensity and lesion level on the accuracy.

However, there are some limitations to the design and analysis. The reference device used, a Polar H7 HR monitor, is not considered a gold standard. A 3-lead ECG HR monitor device would have served better as a reference device. However, the Polar H7 HR monitor shows a high correlation with a 3-lead ECG (Intraclass Correlation Coefficient=0.98) and is therefore a good alternative [30]. In addition, HR outcomes from both devices were provided without raw signals (raw ECG signals and interbeat intervals). Ideally, one would obtain all raw information as algorithms to convert raw signals into the reported HR are often confidential and unknown. Firmware versions were, therefore, reported to take into account any sealed changes in such algorithms and to allow for the replication of results. HR was collected at the highest possible sample rate for Fitbit Charge 2, as intraday time series access was provided by Fitbit for research purposes. As measurements were performed within a larger study on energy expenditure in people with SCI, the Polar H7 was connected to an indirect calorimetry

device during measurements. The output provided by this device was given on a breath-by-breath basis, meaning the HR sample rate for the Polar H7 varied per minute and was determined by the breathing rate of the participant, which eventually provided a lower HR sample rate than preferred. The number of data points available for each activity to analyze reduced when the lesion level increased, as several participants were not able to perform certain wheelchair activities or strength exercises because of the severity of their impairment, present injuries, or risks. In addition, no information was collected on the environmental conditions or skin information that could possibly affect the PPG signal [33]. However, because all measurements were performed at the same location within the same rooms, temperature and light were similarly regulated during all the measurements. Unfortunately, no blood pressure data were collected during the measurement to strengthen our findings. Therefore, it is advisable to combine HR recordings together with continuous blood pressure data in future research to confirm our findings.

Practical Implementations

HR data obtained with the PPG technique during activities, especially during high intensities in people with a high lesion level (>T1), could provide inaccurate HR data in people with SCI. Therefore, it is advised to avoid using PPG-based HR measurements for medical purposes in people with SCI with a cervical lesion level (>T1). However, despite a possible discrepancy in HR recordings, outcomes can still be of value in situations where the consequences of inaccurate HR data are low, for example, to get a global impression of energy expenditure and exercise intensity during physical activities in daily life.

Conclusions

The overall accuracy of the Fitbit Charge 2 HR measurements in people with SCI did not reach the standard acceptable error of –10% to +10%. With increasing intensity, the HR accuracy of the Fitbit Charge 2 was further reduced in people with SCI compared with its HR accuracy in able-bodied individuals. In addition, HR accuracy is related to lesion level, where a high SCI lesion (>T1) negatively affects HR accuracy. Accuracy seems to worsen more in high lesion levels with increasing intensities. A clear reduction in accuracy was found in the lesion group >T1 during wheelchair activities and strength exercises. This suggests that PPG-based HR accuracy is affected in people with SCI, as blood pressure responses during activity are possibly altered because of an affected ANS. Therefore, PPG-based HR measurements during activities should be taken with caution in people with SCI, especially in those with cervical SCI lesions.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Bland-Altman plots.
[PNG File , 145 KB - rehab_v9i1e27637_app1.png]

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Abbreviations

ANS: autonomic nervous system
bpm: beats per minute
CCC: concordance correlation coefficient
ECG: electrocardiography
HR: heart rate
LoA: limits of agreement
MAE: mean absolute error
MAPE: mean absolute percentage error
PPG: photoplethysmography
SCI: spinal cord injury
T1: first thoracic vertebrae
T5: fifth thoracic vertebrae

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Original Paper

Occupational and Physical Therapy Strategies for the Rehabilitation of COVID-19-Related Guillain-Barré Syndrome in the Long-term Acute Care Hospital Setting: Case Report

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Abstract

Background: Although several reports have described the diagnosis and treatment of patients with COVID-19-associated Guillain-Barré syndrome (GBS), there is a paucity of literature describing the occupational and physical therapy (OT and PT) strategies used in the long-term acute care hospital (LTACH) setting to rehabilitate these patients.

Objective: To expand this body of literature, we present a case report highlighting the treatment strategies used to rehabilitate and discharge an individual from an independent LTACH facility, following diagnosis and treatment of COVID-19-related GBS at a regional ACH.

Methods: A 61-year-old male was admitted to an LTACH for the rehabilitation of GBS following COVID-19 infection and intravenous immunoglobulin treatment. Rehabilitation in the LTACH setting uses a variety of skilled treatment interventions to meet patient-driven goals and maximize their function to the highest level possible in preparation of their discharge to a subacute or homecare setting. In this case, this was accomplished through individual OT and PT sessions, OT/PT cotreatment sessions, and targeted group therapy sessions focused on leg, arm, and fine motor coordination exercises.

Results: With the OT and PT standard of care, the patient's improvement was demonstrated by several outcome measures, including manual muscle testing, range of motion, grip strength, and the activity measure for postacute care. The patient was successfully rehabilitated and returned to the community after presenting with COVID-19-associated GBS.

Conclusions: This report highlights the complex rehabilitation needs patients require to regain independence after diagnosis of COVID-19-associated GBS.

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KEYWORDS

Gullian-Barre syndrome; COVID-19; SARS-CoV-2; occupational therapy; physical therapy; long-term acute care hospital; rehabilitation; case report; treatment; diagnosis

Introduction

Background

SARS-CoV-2 is a novel coronavirus strain that has led to the emergence of the COVID-19 pandemic [1] and over 5.3 million deaths as a result [2]. As with other infectious vectors, including coronavirus strains SARS-CoV and Middle East respiratory syndrome (MERS) [3-7], the immune response elicited by SARS-CoV-2 has been implicated in the etiology of several neurological disorders, such as stroke, and autoimmune diseases,

including Guillain-Barré syndrome (GBS) [5-11]. GBS is exceedingly rare, affecting 1-2 of every 100,000 people in the United States, or 0.001%-0.002% [12]; in contrast, a 0.42% incidence rate of GBS in individuals diagnosed with COVID-19 has been reported [10,13].

GBS, an acute autoimmune polyradiculopathy disorder characterized by symmetrical progressive ascending weakness, areflexia, and sensory loss closely resembling quadriplegia, is typically the result of molecular mimicry and the formation of autoantibodies targeting the proteoglycans common to the myelin sheath [3,4]; the specific autoantigen linked to SARS-CoV-2 infection and GBS is still under investigation [7,9].

In rare cases, GBS can lead to irregular heart rhythms, respiratory distress, heart attacks, or death; the GBS mortality rate ranges from 3% to 10% of infections [3,14,15]. Respiratory insufficiency further complicates COVID-19 and GBS outcomes, as both diagnoses can cause respiratory distress and shortness of breath. As symptoms overlap, it is advisable for clinicians to be aware of the less-common symptoms of GBS, including diplopia and paresthesia, so appropriate treatments can be initiated in a timely manner [10,16]. Given that GBS is diagnosed and treatment started early to avoid serious cardiac and pulmonary complications, and there are no serious secondary infections, patients typically recover well, with 60%-80 % walking after 6 months [14].

Although many reports have documented the diagnosis and treatment of GBS following COVID-19 [17-32], the literature documenting the rehabilitation process of these individuals is limited. At the time of writing, only 1 such paper exists to the best of our knowledge [33]. In that paper, the patient, having been treated for GBS associated with cerebral vasculitis, was admitted to the rehabilitation unit of the same acute care hospital (ACH) for further care and rehabilitation. To expand this body of literature, we present this case report highlighting the treatment strategies used to rehabilitate and discharge an individual from an independent long-term acute care hospital (LTACH) facility, following diagnosis and treatment of COVID-19-related GBS at a regional ACH.

The treatment strategies described here are informed by the LTACH's long history of treating patients with GBS. For example, between March 2019 and the start of March 2020, approximately 18 patients were treated for GBS at this facility. Since the start of the COVID-19 pandemic (March 2020-March 2021), this facility has treated 23 patients for GBS, 5 (21%) of which, including the case described here, were COVID-19-associated GBS cases.

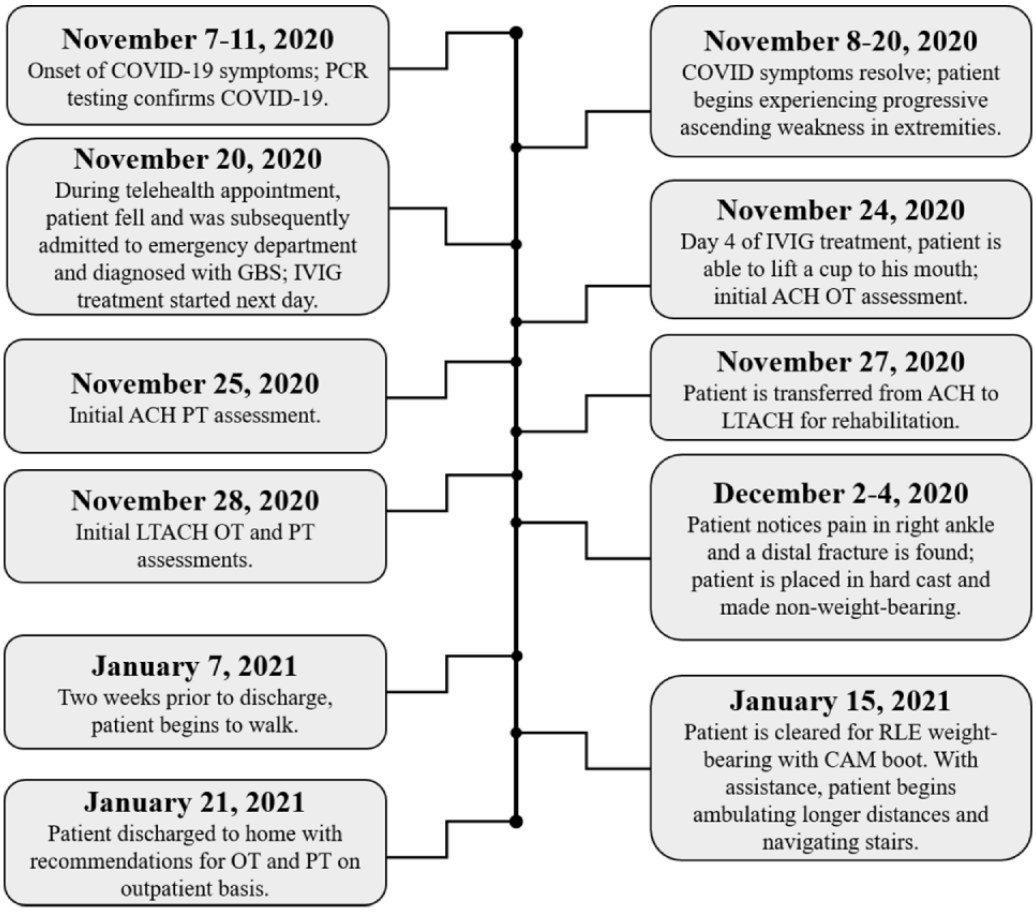
Case Presentation

On November 11, 2020, a 61-year-old Caucasian male tested positive for COVID-19 by polymerase chain reaction (PCR) testing, after developing shortness of breath and a low-grade fever on November 7, 2020 (Figure 1). By the time the patient received his test results, he was afebrile and his shortness of breath had begun to markedly improve. The patient then began developing progressive ascending weakness and numbness in both his upper and lower extremities (UEs and LEs). The weakness progressed to the point where it was increasingly difficult to ambulate and negotiate stairs; at this time, the patient began using a walker to assist with mobility.

Other than a history of hypertension and hyperlipidemia, the patient's past medical history was unremarkable prior to the diagnosis of COVID-19 infection. The patient's father is alive at 91 years old, and his mother passed away at 88 years old with a history of hypertension. He lives with his wife, who is a full-time caregiver to her mother, while the patient works full-time as an office shop manager. Prior to COVID-19 infection, he was independent with all activities of daily living (ADLs) and mobility.

On November 20, 2020, in lieu of an office visit due to state COVID-19 restrictions, the patient attended a telehealth appointment to discuss his symptoms. During the telehealth appointment, the patient fell when attempting to stand and was unable to get off the floor. Consequently, emergency medical services were called and the patient was brought to the emergency department under droplet precautions. At admission, the patient was awake and alert, with clear fluent speech and no facial asymmetry. His vital measurements were as follows: temperature, 36.9°C; blood pressure, 164/91 mm Hg; pulse, 105 beats per minute, oxygen saturation, 97% on room air; and respiratory rate, 18 breaths per minute. All laboratory tests collected were within normal ranges, including the following: white blood cell count, 7.8×10^3 cells/μL; hemoglobin, 15.4 g/dL; platelet count, 299×10^3 cells/μL; blood urea nitrogen, 9 mg/dL; creatinine, 0.6 mg/dL; aspartate aminotransferase, 21 IU/L; alanine aminotransferase, 34 IU/L; and albumin, 4.5 g/L. Upon physical examination, the patient presented with rapidly progressing UE and LE weakness with absent patellar and bicep reflexes.

Figure 1. Patient timeline. Starting November 7, 2020, the timing of the patient's diagnosis, treatment, rehabilitation, and other significant events are outlined until his discharge from the LTACH rehabilitation setting on January 21, 2021. ACH: acute care hospital; CAM: controlled ankle motion; GBS: Guillain-Barré syndrome; IVIG: intravenous immunoglobulin; LTACH: long-term acute care hospital; OT: occupational therapy; PCR: polymerase chain reaction; PT: physical therapy; RLE: right lower extremity.



Magnetic resonance imaging (MRI) of the brain ruled out acute infarction. Cervical MRI showed mild degenerative joint disease with disc desiccation from C2 to C7 discs without cord compression. A lumbar puncture was attempted on November 21, 2020, but was unsuccessful. The patient was ultimately diagnosed with postinfectious COVID-19-associated acute inflammatory demyelinating polyradiculoneuropathy (AIDP), a common GBS variant [10]. Once diagnosed, the patient was given a 5-day intravenous immunoglobulin (IVIG) cycle at 0.4 g/kg/day (November 21-26). On the fourth day of IVIG treatment, the patient was able to lift a cup to his mouth, which he was previously unable to do. After completing the day 5 IVIG treatment of the cycle, the patient presented with improving weakness in both UEs and LEs, while continuing to report pain in his UEs and tingling in both UEs and LEs. His positive response to IVIG treatment reinforced the GBS diagnosis.

Speech therapy was not requested at the ACH, as cognitive, swallowing, and communication deficits were not noted at that time. Additionally, since the progressive ascending weakness from GBS did not affect his respiratory system, and the shortness of breath secondary to COVID-19 had resolved prior to being admitted to the ACH, he did not require evaluation by respiratory therapy.

At the ACH, the patient's arm strength was assessed by occupational therapy (OT) using manual muscle testing (MMT) and was as follows [34] (Table 1):

- Right upper extremity (RUE): shoulder 2/5, elbow 3–/5, and hand grasp 3/5
- Left upper extremity (LUE): shoulder 2–/5, elbow 2+/5, and hand grasp 2/5.

With regard to ADLs, the patient required built-up utensils and setup assistance to perform self-feeding and moderate assistance for oral care. Therapists at the ACH attempted to stand the patient; however, he was unable to achieve a fully upright position. As a result, he required the use of a mechanical lift for out-of-bed transfers.

On November 27, 2020, 7 days after admission, the patient was discharged to an LTACH, Gaylord Specialty Healthcare (Wallingford, CT, USA), for inpatient rehabilitation. His goal upon admission was to return to an independent level of function.

Table 1. Occupational therapy upper extremity assessments.

Assessment	T0[a]	T1[b]	T2[c]
BUE[d] strength			
ROM[e]	WNL[f]	WNL	WNL
RUE[g] strength			
Shoulder	2/5	3+/5	5/5
Elbow[h]	3–/5	3+/5	5/5
Wrist[h]	—[i]	3+/5	5/5
Grip	—	15 lb	52 lb
LUE[j] strength			
Shoulder	2–/5	3+/5	5/5
Elbow[h]	2+/5	3+/5	5/5
Wrist[h]	—	3+/5	5/5
Grip	—	21 lb	70 lb
ADLs[k,l]			
Self-feeding, oral care	ModA[m]	D[n]	I[o]
UE[p] bathing, dressing	D	MinA[q]	DS[r]
LE[s] bathing, dressing	D	MaxA[t]	CG[u]
Toilet and shower transfers	D	MaxA	S[v]
AM-PAC[w] OT[x]	—	17 points; 50% impairment	20 points; 35% impairment

[a]T0: acute care hospital (ACH) OT admission assessment, November 24, 2020.
[b]T1: long-term acute care hospital (LTACH) OT admission assessment, November 28, 2020.
[c]T2: LTACH OT discharge assessment, January 20, 2021.
[d]BUE: bilateral upper extremity.
[e]ROM: range of motion.
[f]WNL: within normal limits.
[g]RUE: right upper extremity.
[h]Measurement of both flexion and extension.
[i]Not assessed at this time.
[j]LUE: left upper extremity.
[k]ADL: activity of daily living.
[l]ADL measurements based on a modified functional independence measure [35].
[m]ModA: moderate assistance required.
[n]D: dependent.
[o]I: independent.
[p]UE: upper extremity.
[q]MinA: minimal assistance required.
[r]DS: distant supervision required.
[s]LE: lower extremity.
[t]MaxA: maximal assistance required.
[u]CG: contact guard assistance required.
[v]S: supervision required.
[w]AM-PAC: activity measure for postacute care.
[x]OT: occupational therapy.

Initial Functional Status at the LTACH

Upon initial evaluation by LTACH physical therapy (PT), the patient's LE range of motion (ROM) was within normal limits (WNL), and his LE strength, assessed by MMT, was as follows (Table 2):

- Right lower extremity (RLE): hip flexion 3/5, hip abduction/adduction 2+/5, knee flexion 4/5, knee extension 3+/5, and ankle dorsiflexion 3/5
- Left lower extremity (LLE): hip flexion 3/5, hip abduction/adduction 2/5, knee flexion/extension 3/5, and ankle dorsiflexion 3–/5

Proprioception to bilateral great toes and ankles was absent, and the patient had diminished sensation to light touch in bilateral lower extremities (BLEs).

The patient's functional status was evaluated using a modified functional independence measure ranging from dependent to independent (Table 3) [35]. He required maximal assistance to perform bed mobility and out-of-bed transfers. He also required contact guard (CG) assistance to maintain sitting balance on the edge of the bed. The activity measure for postacute care (AM-PAC), a standardized assessment tool, was used to measure the patient's ability to complete ADLs and functional mobility [36]. The patient scored a 10 on the mobility segment during the initial PT evaluation, indicating 77% impairment (Table 2).

On initial evaluation by LTACH OT, the patient's UE passive ROM was WNL and his bilateral upper extremity (BUE) strength, assessed by MMT, was as follows: (both RUE and LUE) shoulder flexion, 3+/5; elbow flexion/extension, 3+/5; and wrist flexion/extension, 3+/5. By a dynamometer, the patient's right grip strength was 15 lb and 21 lb on the left (Table 1). His UE sensation was intact to light touch and deep pressure and had intact proprioception. However, he continued to endorse numbness and tingling in his hands. His coordination demonstrated dysmetria, as evidenced by decreased accuracy when performing a finger-to-nose assessment with occluded vision. The patient scored a 17 on the initial OT ADL portion of the AM-PAC evaluation, indicating 50% impairment (Table 1).

Upon admission to the LTACH, other than assistance to cut foods and open containers, the patient had progressed to requiring distant supervision for self-feeding and no longer required the use of built-up handles. Additionally, he required minimal assistance for upper body bathing and maximal assistance for lower body bathing at bed level. He required maximal assistance for upper body dressing and total assistance for lower body dressing at bed level.

All patients evaluated by OT at this LTACH facility are given the St. Louis University Mental Status (SLUMS) examination at admission to screen for possible cognitive impairments and to inform the treatment plan [37]. The patient scored a 25/30 on the SLUMS examination, indicating mild neurocognitive impairments in attention and short-term memory. The patient stated that his attention was a baseline impairment likely present prior to his GBS diagnosis but that his short-term memory was currently worse than his baseline status prior to hospitalization. Furthermore, the patient complained of blurry vision and difficulty reading since the onset of GBS. A formal vision assessment, performed by OT, confirmed blurriness in both eyes (right worse than left). The patient's near point of convergence was 12 inches, indicating convergence insufficiency and a marked impairment compared to the normal range, which is between 2 and 4 inches. Clinically, this observation is intriguing as ocular muscle weakness and paralysis are associated with the Miller Fisher syndrome variant of GBS, not the AIDP variant [38].

During an initial OT/PT cotreatment session to perform standing in the parallel bars on December 2, 2020, 5 days after LTACH admission, the patient's LE sensation began to improve and he complained of right ankle pain. Swelling and bruising of the right ankle was noted, and a fracture of the distal right fibula was diagnosed by radiography. This fracture was attributed to his fall prior to admission and was likely not found at the ACH due to his altered sensation and other medical challenges at the time. An orthopedic physician placed a hard cast, and the patient was made non-weight-bearing of the RLE for 6 weeks. To protect the fracture, the patient returned to requiring the use of a mechanical lift for out-of-bed transfers. Therefore, compensations, such as using slide board transfers, were initiated early on as it was known that the patient would be non-weight-bearing for at least 6 weeks. The patient was also educated on proper techniques for sit-to-stand and stand-pivot transfers so that when he was able to weight-bear through his RLE, it would not be a new concept.

Table 2. Physical therapy lower extremity assessments.

Assessment	T0[a]	T1[b]	T2[c]
BLE[d] strength			
ROM[e]	—[f]	WNL[g]	WNL
RLE[h] strength			
Hip flexion	—	3/5	4–/5
Hip[i]	—	2+/5	3/5
Knee[j]	—	4/5	5/5
Ankle dorsiflexion	—	3/5	—; CAM[k] boot
LLE[l] strength			
Hip flexion	—	3/5	3+/5
Hip[i]	—	2/5	3/5
Knee[j]	—	3/5	4+/5
Ankle dorsiflexion	—	3–/5	3/5
Function and mobility[m]			
Out-of-bed transfers	D[m]	MaxA[n]; D after fracture was found	S[o]
Sitting balance	MinA[p]	CG[q]	I[r]
Sit-to-stand	D	D	S with RW[s]
Ambulatory transfers	UA[t]	UA	S with RW
Ambulation	UA	UA	300 feet; CG with RW
Stairs	UA	UA	Able to clear six 4-inch stairs; CG with bilateral railing
AM-PAC[u] PT[v]	—	10 points; 77% impairment	20 points; 36% impairment

[a]T0: acute care hospital (ACH) PT admission assessment, November 25, 2020; patient LE strength at the ACH was not formerly assessed or not available at the time of writing. Function and mobility assessments were available.

[b]T1: long-term acute care hospital (LTACH) PT admission assessment, November 28, 2020.

[c]T2: LTACH PT discharge assessment, January 20, 2021.

[d]BLE: bilateral lower extremities.

[e]ROM: range of motion.

[f]Not assessed at this time.

[g]WNL: within normal limits.

[h]RLE: right lower extremity.

[i]Measurement of both abduction and adduction.

[j]Measurement of both flexion and extension.

[k]CAM: controlled ankle motion.

[l]Measurements based on the modified functional independence measure score [35].

[m]D: dependent.

[n]MaxA: maximal assistance required.

[o]S: supervision required.

[p]MinA: minimal assistance required.

[q]CG: contact guard assistance required.

[r]I: independent.

[s]RW: rolling-walker assistive device required.

[t]UA: unable to perform.

[u]AM-PAC: activity measure for postacute care.

[v]PT: physical therapy.

Table 3. Modified functional independence measure definitions and criteria.

Descriptor	Definition
Unable (UA)	The subject/patient is unable to perform.
Dependent (D)	Dependent mobility; the subject/patient providing less than 25% of the work.
Maximal assistance (MaxA)	The subject/patient performs 25%-49% of the work.
Moderate assistance (ModA)	The subject/patient performs 50%-74% of the work.
Minimal assistance (MinA)	The subject/patient performs 75%-100% of the work.
Contact guard (CG)	The subject/patient requires light hands-on assistance for balance, but no physical lifting is required.
Close supervision (CS)	The subject/patient requires the therapist to be close by in case the patient experiences a loss of balance, but does not need physical or hands-on assistance.
Supervision (S)	During supervision, the therapist provides supervision at more than an arm's length away.
Distant supervision (DS)	This is intermittent supervision. The therapist does not have to be in the room.
Modified independence (ModI)	The subject/patient is independent *with* the use of adaptive devices, techniques, or increased time.
Independent (I)	The subject/patient is independent *without* the use of adaptive devices, techniques, or increased time.

Methods

Therapy Details

During his inpatient stay, Monday through Friday, the patient participated in 5-6, 30-minute-long treatment blocks each day. These blocks consisted of a combination of individual PT and OT sessions, an OT/PT cotreatment session, LE and UE exercise group sessions, or a fine motor coordination group session focused on sensation and coordination. On Saturdays, he alternated weekly between a 30-minute LE or UE exercise group; treatment sessions were not conducted on Sundays.

During his early PT sessions, the patient worked on antigravity supine LE therapeutic exercises. He required skilled PT intervention to ensure the exercises were being performed properly and he was working at the appropriate workload. For example, the patient required assistance to perform hip flexion exercises in a side-lying position as, when he began to fatigue, he would compensate and recruit other muscles to facilitate the motion. As such, he required cues to stop and rest so that form was not compromised and he did not overfatigue the muscle. The patient also worked on wheelchair mobility and both static and dynamic sitting balance (ie, anterior weight shifting and reaching outside the base of support to prepare for transfers).

In early OT sessions, the patient worked on bed-level lower body ADLs, UE exercises seated on a mat, cognitive tasks addressing short-term memory, and hand-strengthening activities. Additionally, the patient began participating in OT convergence training exercises to address his convergence insufficiencies. Within a week of starting convergence training, the patient started to report improvements to the blurry vision and increased ability to read novels at his leisure.

UE exercises focused on using lighter resistance weights that the patient could tolerate for 10 repetitions without compromising body mechanics; the weight was gradually increased per the patient's tolerance. Due to shoulder weakness, passive ROM exercises were initiated to the joint end ROM to preserve joint integrity. In addition to performing daily OT tasks, which included self-ROM and hand-strengthening tasks with putty (eventually increasing to graded grippers), the patient was independent with a gentle bed-level exercise program.

The patient was educated on energy conservation during ADL performance, including taking rest breaks, utilizing adaptive equipment to improve independence without compromising functional activity tolerance, and preserving the ability to persist through daily therapies [16]. In his early cotreatment sessions, PT and OT worked together to assist the patient with bed mobility and basic slide board transfers to and from his wheelchair and bed. As the patient progressed, OT/PT cotreatments worked on slide board transfers to and from the car, tub, and commode.

On January 7, 2021, 18 days prior to discharge, the patient started progressive LE strengthening, sit-to-stand transfers, and ambulation during individual PT sessions. The individual OT sessions were able to focus on progressing UE therapeutic exercises, dressing at a wheelchair level, and bathing in the shower using a shower chair.

OT/PT cotreatment sessions also advanced the patient from standing to using a rolling-walker (RW) with a right sling attachment to support his RLE. This allowed him to weight-bear through the right knee to provide more stability while standing and ambulating and adhere to his weight-bearing restrictions. As the patient progressed, he no longer required cotreatment for standing and ambulation and was able to perform these activities with the assistance of 1 person. This allowed for an additional individual therapy session each day.

On January 15, 2021, 44 days after being placed in the hard cast, the patient was cleared for weight-bearing as tolerated through his RLE using a controlled ankle motion (CAM) walking boot and RW. To ensure he did not have a significant increase in pain with weight-bearing, the patient's ambulation distance was gradually increased. As he began tolerating ambulating further distances with the RW, he began climbing stairs with assistance.

During his PT LE exercise group session, the patient performed seated LE exercises, including hip flexion, hip

abduction/adduction, knee extension, and ankle ROM. To help his progression, ankle weights were added, as appropriate, per therapist discretion and the patient's tolerance. The patient was also able to utilize a recumbent cross-trainer using his LLE and BUEs during these sessions. Once cleared for weight-bearing with the CAM boot, he was able to effectively use all extremities on the cross-trainer. During his OT UE exercise group session, the patient performed seated UE exercises, starting without weights and gradually worked up to 4 lb in shoulder weights and 6 lb in elbow weights. In the fine motor coordination group session, the patient began with hand-strengthening and larger fine motor coordination tasks; he gradually transitioned to smaller tasks, including putting small objects (approximately 0.5 inches) together and pulling them apart.

Ethics Approval and Consent to Participate

This case report was written in compliance with our institutional privacy policy, the Health Insurance Portability and Accountability Act (HIPAA) policy, and the standards set by the Declaration of Helsinki. Institutional review board approval was not required by institutional policy as the report only describes 1 patient; the need for approval was therefore waived.

Consent for Publication

The patient described here gave his written permission for the authors to access his personal information and for his information to be used in writing and publishing this case report.

Results

Discharge Assessment

The patient's function was re-evaluated immediately prior to LTACH discharge. The patient's PT discharge assessment indicated that his LE coordination and ROM were now WNL and that his LE strength was as follows:

- RLE: hip flexion 4–/5, hip abduction/adduction 3/5, and knee flexion/extension 5/5
- LLE: hip flexion 3+/5, hip abduction/adduction 3/5, knee flexion 4+/5, knee extension 4–/5, and ankle dorsiflexion 3/5

The patient's right ankle was unable to be assessed as it was still in a CAM walking boot and not cleared for ROM assessments (Table 2).

The patient continued to endorse diminished sensation in his bilateral lower legs and feet, but his sensation to light touch had returned. Proprioception was WNL in his BLEs. Functionally, the patient was performing sit-to-stand and ambulatory transfers with an RW with supervision. By discharge, he had regained ambulation and was able to ambulate 300 feet with an RW and CG utilizing the CAM walking boot. Further, the patient was able to negotiate six 4-inch stairs with bilateral railings, step-to-pattern, and a CG. The patient scored a 20 on the AM-PAC at discharge, indicating a 36% impairment; this was a 41% improvement from admission (Table 2).

The patient's OT discharge assessment indicated that his BUE strength, coordination, and ROM were now WNL (Table 1). His grip strength was 52 lb on the right and 70 lb on the left, a 37 and 49 lb increase, respectively. Although the patient continued to demonstrate diminished sensation to light touch in BUEs, his proprioception remained intact. With regard to ADLs, the patient could now perform upper body bathing/dressing and lower body bathing with distant supervision; lower body dressing sitting upright in the wheelchair could be performed with a CG. He was also able to complete ambulatory transfers to the commode and transfer to a tub bench with supervision.

The patient's visual impairments were completely resolved upon discharge. With residual impairments to his short-term memory still present, the patient scored a 27/30 on the SLUMS examination, a 2-point improvement. He also scored a 20 on the AM-PAC at discharge, indicating a 35% impairment; this was a 15% improvement from admission (Table 1).

On January 21, 2021, 56 days after LTACH admission, the patient was discharged home, ambulatory with improved strength, self-care, and cognition.

Discussion

Principal Findings

Here we described the presentation and rehabilitation regimen of a patient diagnosed with COVID-19-associated GBS. During a telehealth appointment following a COVID-19 diagnosis, the patient fell. Being unable to stand up due to weakness in his LEs, the medical professional advised the patient to call for emergency medical services. He was then brought to a local regional ACH. There he was diagnosed and treated for GBS. Requiring functional rehabilitation, the patient was transferred to an independent rehabilitation-focused LTACH, where OT and PT regimens led to objective improvements in both UE and LE strength. Fine motor control and coordination were also markedly improved, as evidenced by the patient's ability to open containers, write, and self-feed. The patient's functional mobility improved from being dependent and unable to ambulate or perform transfers to ambulation with a CG and transfers with supervision. This led to functional improvements, independence with ADLs, improved AM-PAC scores for both the mobility and ADL sections, and a safe discharge home.

PT and OT interventions were structured to optimize the patient's independence at each stage of rehabilitation. Although the patient was challenged throughout the week, therapists were careful to not overfatigue the patient so as to avoid potential delays in his recovery and to allow for rest on weekends. When resuming therapy on Mondays, the patient had objectively notable increases in both his UE and his LE strength. It is important to provide patients with adequate rest in order to maximize functional recovery.

Strengths and Limitations

It is important to acknowledge the strengths and limitations of this report. This report was strengthened by the use of objective measures and standardized assessments to demonstrate the improvements this patient made at an LTACH level of care. Although GBS is an exceedingly rare disease, it is relatively common for patients with GBS to be treated at our facility each year. Although this report is based off 1 patient's case, our

facility has admitted and treated 5 patients with GBS related to COVID-19 at the time of writing. A limitation of this particular case is the absence of some diagnostic tests typically reported for GBS, namely cerebrospinal fluid analysis and electrophysiological nerve conduction studies. Being an independent LTACH, the records we were able to obtain from the ACH, where the patient was initially diagnosed and treated, were incomplete. However, given the abundance of literature already describing the diagnosis and treatment of COVID-19-related GBS, we reported what was available to us and focused on reporting the rehabilitation regimen used to treat this patient for COVID-19-related GBS. Additionally, nerve conduction studies could have been used to monitor the patient's recovery and rehabilitation. However, as this is not a common practice at our institution and the patient's recovery and rehabilitation were in line with expectations, follow-up nerve conduction studies were not conducted.

A challenge in this patient's recovery was that his ankle fracture left him non-weight-bearing for much of his rehabilitation. Although it is not typical for patients with GBS to also have weight-bearing restrictions, we thought reporting this unique case worthwhile as no 2 patients will require the same rehabilitation regimen. In fact, it is often the case that patients will arrive for rehabilitation with not 1 but multiple diagnoses that will influence their treatment plan. Being no exception, the patient's non-weight-bearing status influenced his treatment course and added challenges in his functional mobility progress that were addressed with an individualized therapeutic approach. These goals were centered on the patient becoming as mobile as possible, given his weight-bearing restrictions, while being careful to not overfatigue his muscles and creating additional problems. This patient's rehabilitation may have been complicated by this fracture and non-weight-bearing restrictions, but the patient made significant improvements in his time at this LTACH and recovered, as we would expect a patient with GBS to recover.

Patient's Perspective

Following the patient's discharge, he was asked to give his thoughts about his time in rehabilitation. From the first day the patient started therapy, he was motivated and had a positive attitude. The patient admits, "I did have some mental difficulties early on absorbing all that was happening to me." This was never shown outwardly, however, and the patient quickly moved away from this mindset. The patient states, "I was somewhat traumatized from the 8 days in the [acute care] hospital all alone, but once I realized that everyone at Gaylord was looking out for me, I was able to relax and just focus on getting better. I worked hard to maintain a positive attitude and to talk with other patients and staff to get encouragement and strength from them so I could reflect on it each night, which was the most difficult time for me." This mentality helped the patient to overcome the obstacles he faced during rehabilitation and make a remarkable recovery.

Conclusion

At the time of writing, this is the first report to the best of our knowledge to demonstrate the standard of care and strategies used in an independent LTACH setting to successfully rehabilitate and discharge a patient diagnosed with GBS following COVID-19 infection and the second report to describe these methods overall [33]. This successful rehabilitation was accomplished through intensive PT and OT regimens targeted at patient-specific deficits. This case report demonstrates how therapy interventions are effective in maximizing the functional potential of patients with COVID-19-associated GBS.

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Authors' Contributions

CC designed and conceptually conceived the case report, acquired the initial written consent to access and use the patient's information, wrote the first draft, and contributed to the revision process throughout. SM and HCH substantively contributed to subsequent drafts and revisions. All authors have approved the submitted version and have agreed to be personally accountable for the work presented here.

Conflicts of Interest

None declared.

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Abbreviations

ACH: acute care hospital
ADL: activity of daily living
AIDP: acute inflammatory demyelinating polyradiculoneuropathy
AM-PAC: activity measure for postacute care
BUE: bilateral upper extremity
CAM: controlled ankle motion
GBS: Guillain-Barré syndrome
IVIG: intravenous immunoglobulin
LE: lower extremity
LLE: left lower extremity
LTACH: long-term acute care hospital
LUE: left upper extremity
MERS: Middle East respiratory syndrome
MMT: manual muscle testing
MRI: magnetic resonance imaging
OT: occupational therapy
PCR: polymerase chain reaction
PT: physical therapy
RLE: right lower extremity
RUE: right upper extremity
SLUMS: St. Louis University Mental States
UE: upper extremity
WNL: within normal limits

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Original Paper

Speech and Language Practitioners' Experiences of Commercially Available Voice-Assisted Technology: Web-Based Survey Study

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Abstract

Background: Speech and language therapy involves the identification, assessment, and treatment of children and adults who have difficulties with communication, eating, drinking, and swallowing. Globally, pressing needs outstrip the availability of qualified practitioners who, of necessity, focus on individuals with advanced needs. The potential of voice-assisted technology (VAT) to assist people with speech impairments is an emerging area of research but empirical work exploring its professional adoption is limited.

Objective: This study aims to explore the professional experiences of speech and language therapists (SaLTs) using VAT with their clients to identify the potential applications and barriers to VAT adoption and thereby inform future directions of research.

Methods: A 23-question survey was distributed to the SaLTs from the United Kingdom using a web-based platform, eliciting both checkbox and free-text responses, to questions on perceptions and any use experiences of VAT. Data were analyzed descriptively with content analysis of free text, providing context to their specific experiences of using VAT in practice, including barriers and opportunities for future use.

Results: A total of 230 UK-based professionals fully completed the survey; most were technologically competent and were aware of commercial VATs (such as *Alexa* and *Google Assistant*). However, only 49 (21.3%) SaLTs had used VAT with their clients and described 57 use cases. They reported using VAT with 10 different client groups, such as people with dysarthria and users of augmentative and alternative communication technologies. Of these, almost half (28/57, 49%) used the technology to assist their clients with day-to-day tasks, such as web browsing, setting up reminders, sending messages, and playing music. Many respondents (21/57, 37%) also reported using the technology to improve client speech, to facilitate speech practice at home, and to enhance articulation and volume. Most reported a positive impact of VAT use, stating improved independence (22/57, 39%), accessibility (6/57, 10%), and confidence (5/57, 8%). Some respondents reported increased client communication (5/57, 9%) and sociability (3/57, 5%). Reasons given for not using VAT in practice included lack of opportunity (131/181, 72.4%) and training (63/181, 34.8%). Most respondents (154/181, 85.1%) indicated that they would like to try VAT in the future, stating that it could have a positive impact on their clients' speech, independence, and confidence.

Conclusions: VAT is used by some UK-based SaLTs to enable communication tasks at home with their clients. However, its wider adoption may be limited by a lack of professional opportunity. Looking forward, additional benefits are promised, as the data show a level of engagement, empowerment, and the possibility of achieving therapeutic outcomes in communication

impairment. The disparate responses suggest that this area is ripe for the development of evidence-based clinical practice, starting with a clear definition, outcome measurement, and professional standardization.

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KEYWORDS

speech and language therapy; voice-assisted technology; professional practice; rehabilitation; speech therapy; health technology; mobile phone

Introduction

Background

Speech and language therapy (SLT) is an allied health profession concerned with the assessment, diagnosis, and treatment of a range of both communication and swallowing disorders [1]. Speech and language therapists (SaLTs) support a broad range of people within pediatric and adult services (eg, early language development, learning disabilities, Parkinson disease, stroke, and traumatic brain injury) and work within a wide range of settings (eg, schools, homes, care homes, hospitals, and prisons) [2]. SaLTs are responsible for delivering a range of evidence-based therapeutic interventions to support the clinical needs of their service users, related to improving communicative ability and managing eating, drinking, and swallowing difficulties. The ultimate goal of any therapeutic program is the generalization of principles learned in the clinical context to a person's everyday life [3]. Despite providing a core service within rehabilitative and long-term care—particularly in acquired or degenerative neurological conditions—SLT, similar to many other services, has been affected by funding cuts. A survey by the Royal College of Speech and Language Therapists (RCSLT) suggests that over 80% of services in the National Health Service (NHS) face reduced staffing, narrowing scope of services and, in 8% of the services, abolishment of services altogether [4].

There is a potential for appropriate technology-based solutions to assist in reducing the burden on staff and widening access to care services. One of the key areas where technology has impacted SLT has been in the development of *augmentative and alternative communication* (AAC) devices. AAC is a term used to describe various methods of aided communication, including nonverbal strategies such as gestures or body language, the use of picture books or communication charts, or a range of different technologies that can act as a substitute vocal communication aid [5]. The types of technologies used for AAC are diverse with varying complexities—from equipment with simple text to speech functions, picture-based *buttons* that relay messages when pressed, to eye gaze technology for those who are physically unable to physically interact with a system. The development of AAC apps [6-8] that can be downloaded from commercial app platforms and installed on personal mobile devices has seen a recent rise in popularity, with the purpose of bringing the benefits of AAC to a wider range of individuals by reducing the associated costs.

Although AAC is a well-established field with clinically proven benefits, researchers have also been investigating other areas of technology innovation within the field of SLT, particularly those that exploit the benefits of low-cost, off-the-shelf consumer technology. For example, research has explored the role of technology in supporting SLT for people with aphasia—a communication difficulty affecting the expression or comprehension of spoken and written language [9-15]. One study explored an approach toward making paper-based resources, such as worksheets, stickers, and photographs more interactive by enabling therapists to customize content with personally meaningful and useful audio clips [11]. Another study developed a context-aware system that provided the user with relevant word lists to select from, depending on their location [15]. Similarly, Williams et al [13] explored the potential for providing in situ support for the access of vocabulary during conversation, using head-mounted wearable technologies, such as Google Glass, and wrist-mounted touchpads for easy navigation. In another study, Google Glass was used to provide volume training for people with Parkinson disease [16], providing real-time feedback on the users' speech volume by indicating that a predefined target was achieved. The participants provided positive feedback and described the benefits of the voice interaction functionality for technology access. These studies highlight the potential of technology-assisted SLT to address client needs cost-effectively.

Voice-Assisted Technology

Voice assistants are software applications (eg, Siri [17], Google Assistant [18], and Amazon Alexa [19]), which have become increasingly popular in smartphones, computers, tablets, and purpose-built speakers. They can interpret human speech and allow interaction with the technology through spoken commands, allowing users to complete a variety of tasks such as setting alarms, searching for information on the web, playing music, providing weather updates, and telling the time. These devices allow infinite attempts for the user to practice their speech and commands and will actively acknowledge if it has misunderstood the attempt, which can be a prompt to modify speech.

Recent figures show that almost 29% of the population in the United Kingdom [20] has access to a smart speaker. Another report suggests that the COVID-19 lockdown has increased interaction with voice assistants in the United Kingdom [21]. As such, the popularity of these devices is growing and they are being widely accepted. Similar smart speaker ownership has also been recorded in other countries, such as Australia [22] and the United States [23]. The older adult population (aged ≥60 years) accounts for approximately 20% of smart speaker ownership, with almost 60% of these consumers using the device every day [24]. The technology offers hands-free access and naturalistic voice interaction, a beneficial means of interacting with the device for those with physical disabilities or lower levels of technology literacy [25]. These features have motivated

research in the health care sector, and recent years have seen an emergence in research that explores the use of voice-assisted technology (VAT) to support people within these demographics.

Several studies have explored how diverse populations such as older adults [26], people with visual and physical disabilities [27-30], and people with speech impairments [31-33] use and interact with VAT. One study exploring the experiences of older adults' use of Alexa reported positive first interactions when using the device, owing to the simplicity of speech-based communication, but highlighted the need for better device training and the privacy, security, and financial concerns raised by the participants [26]. Studies exploring the experiences of people with disabilities [27,28] and health concerns [27] more broadly have also focused their attention on Alexa as a VAT of interest, with retrospective qualitative analyses being conducted on a significant number of consumer reviews of Alexa-enabled smart speakers on Amazon. These studies have demonstrated increased independence and empowerment when using the device. Although not the primary focus of their analysis, Pradhan et al [28] also explicitly described successful use in many cases of customers who had reported speech difficulties.

One recent study explicitly focused on VAT use among people with speech impairments. A survey conducted on 290 people with Parkinson disease (78% of whom were assessed to have mild to moderate speech impairment) explored their access and use of VAT, including whether they had noticed any changes to their speech because of using the device [32]. The authors found that as many as 25% of the participants reporting changes to their speech had noticed improvement, indicating a clear potential direction for future work exploring VAT as a tool to support outcomes relevant to SLT. Participants in this study, who were primarily in the range 65-74 years, also had high levels of success when using VATs (most used the device regularly and rarely had to repeat themselves), a finding further echoed by McNaney et al [29]. Further studies have investigated the success rates of different VATs (Cortana, Microsoft Inc; Alexa; and Siri) for people with dysarthria (a group of neurological speech disorders affecting intelligibility), finding recognition accuracy in the range of 50%-60% with single prerecorded samples [33]. They did not report on the severity or etiology of the speakers' dysarthria; however, the study was not conducted with live speakers in naturalistic settings, which would be required to accurately draw conclusions about how successful dysarthric users may be in voice interface interactions. Another study explored how the application of adaptive voice recognition (ie, systems that learn the user's voice over a series of sessions) could have promise for improving the accessibility of VAT for users with speech difficulties [31].

Therefore, although research into the space of VAT for people with impaired speech is emerging, most studies have focused on the end users' perceptions and how the device is used *out of the box*. To the best of our knowledge, there has been no previous work exploring the perceptions of VAT by SaLTs and its use in clinical practice.

Study Aims

The primary aim of this study is to gather a preliminary overview of how SaLTs and their clients have been using VAT. We wanted to understand the potential opportunities and challenges of VAT use from SaLTs' perspectives and gather an understanding of current use cases within SLT practice, whether this be directed by their client or explicitly used by therapists for clinical reasons. We aim to answer the following research questions: (1) If SaLTs have used VAT with their clients, what was their experience of its use? (2) If VAT was not being used currently, what were the possible reasons for this? (3) What are the perceived benefits, risks, and barriers to using VAT in SLT?

By addressing these questions, we aim to provide a foundation for future research, which will explore how VAT might be used in clinical practice, the types of clients it might be useful for, and the types of activities that clinicians might perform with VAT to support therapeutic delivery.

Methods

Survey Design

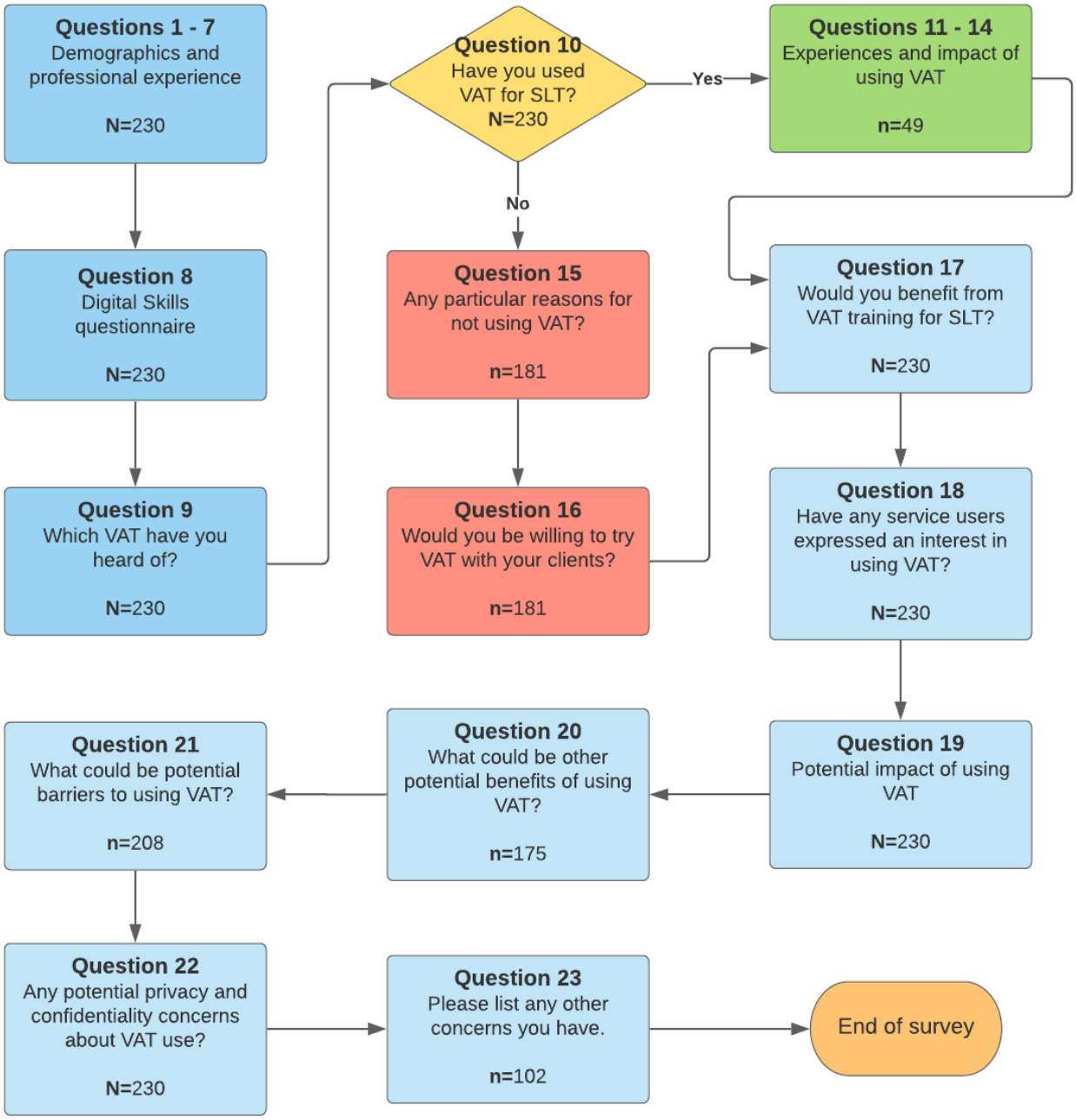
We developed a survey to gather the experiences of the SaLTs from the United Kingdom about how they and their clients had been using VATs to support their clinical needs and to understand the possible barriers and opportunities toward the future use of VATs in clinical practice. A draft survey was pilot-tested with 3 academic staff members at Ulster University and 2 SaLTs, with minor amendments to improve the clarity and flow of the questions based on their feedback.

The finalized version consisted of 23 questions (please note that participants were not required to respond to every question) and consisted of three sections:

1. Demographics, such as age, job title, years of experience, and clinical caseloads.
2. Digital skills assessment: this was adapted from The Tech Partnership's Basic Digital Skills framework (reuse permission was granted) [34]. The assessment provided statements describing 11 digital tasks spanning areas, including managing information, communicating, transacting, problem solving, and creating. For example, a *managing information* digital skill is *find a website I have visited before*. For each of the 11 statements, respondents were asked to indicate whether they could or could not complete the digital task described in the statement.
3. VAT familiarity, use, and the participants' opinions on the potential barriers, benefits, and impacts of using VAT to support client's needs in their clinical practice.

The survey questions were designed to obtain both quantitative and qualitative insights from the participants using a mix of checkbox and free-text questions. It was developed and distributed using Qualtrics, a web-based survey tool [35]. Figure 1 shows a breakdown of the questions asked during the survey.

Figure 1. Survey flow diagram: starting at the top left, the diagram shows elements of the survey with skip logic to avoid irrelevant directions of questioning (the number of respondents to each element have been provided). SLT: speech and language therapy; VAT: voice-assisted technology.



Study Ethics, Population, and Recruitment

The study was peer-reviewed, and ethical approval was obtained from the Ulster University Institutional Research ethics committee. The web-based survey was distributed to members of the RCSLT by advertising on their social media platforms (Facebook and Twitter) in January 2019. Following the social media recruitment phase, 111 clinical excellence networks in RCSLT were contacted in February 2019, and the survey was disseminated through their membership using a snowball sampling technique. Details of the study were presented on the welcome page of the survey, including information about the purpose of the study, the length of time required to complete it, data storage, and anonymity. The participants were informed that consent was provided through the completion of the survey.

The intended sample size was based on the number required to obtain 90% confidence with –5% to +5% margin of error in estimating proportions: the exact calculation was a sample size of 289.

Data Analysis

As the survey consisted of both checkbox and free-text responses, the study used a mixed methods approach for analysis. For each checkbox question, the total number of participants responding to each possible option (ie, count) was collected and the percentage (of overall respondents to that question) was provided. Summative content analysis [36] was used for qualitative free-text responses [37]. The responses from each free-text question were collated and analyzed separately by 2 researchers to identify the themes. Any disagreements were

resolved through discussion until a decision was made on the final set of themes. The themes were summarized, with several responses relating to each theme available for the analysis.

Results

Overview

The survey received responses from 261 respondents. Partially completed survey responses (31/261, 11.9%) were excluded, as ethically we only considered participants who completed the survey as fully consenting to the study. This left 230 fully completed surveys for the analysis. Most of the respondents (223/230, 96.9%) were women, with a large proportion (102/230, 44.3%) aged <35 years; 64 (27.8%) respondents were aged between 35 and 44 years, 41 (17.8%) respondents were aged between 45 and 54 years, and the remaining 23 (10%) respondents were aged >55 years.

Professional Experience Demographics

Most of the respondents (227/230, 98.7%) were practicing SaLTs, with varying years of experience in the field. Very few respondents (3/230, 1.3%) worked in academia, in research, and teaching. They reported a mean work experience of 13 years (SD 9.45 years). The majority (184/230, 80%) worked for the UK NHS: half of this population (92/184, 50%) were early career practitioners working in NHS bands 5 and 6, whereas the other half (92/184, 50%) were more experienced practitioners working in NHS bands 7 and above. The rest (46/230, 20%) did not work for the NHS. The respondents worked across a wide range of clinical caseloads (Table 1).

Some participants (27/230, 11.7%) reported *other* caseloads in the form of a free-text response, including social, emotional, and mental health (8/230, 3.5%); head and neck cancer (8/230, 3.5%); early language development (7/230, 3%); selective mutism (2/230, 0.9%); and general research (2/230, 0.9%).

Table 1. Reported clinical caseloads (N=230).

Caseload	Count, n (%)
Dysphagia (swallowing difficulty)	103 (44.8)
Augmentative and alternative communication	100 (43.5)
Acquired communication disorders	90 (39.1)
Learning disabilities	90 (39.1)
Autistic spectrum disorder	87 (37.8)
Progressive neurological conditions	70 (30.4)
Developmental language disorders	69 (30)
Speech sound disorders	67 (29.1)
Dementia	57 (24.8)
Dysfluency	47 (20.4)
Voice	34 (14.8)
Deafness	24 (10.4)
Cleft lip and palate	18 (7.8)
Others	27 (11.7)

Digital Skills

An adapted version of the digital skills questionnaire [34] was included in the survey. This consisted of 11 statements describing a range of digital skills. These skills ranged from using a search engine to look for information on the web to creating something new from existing web-based images, music, or videos. For each statement, respondents were asked to indicate whether they could or could not perform the technology-related activity the statement referred to, with the purpose of gauging the digital competence of the respondents. More than 95.7% (220/230) of the participants possessed 9 out of the 11 skills. The highest rated skills (229/230, 99.6%) were the following: *using a search engine to look for information online, download a photo you found online, find a website you have visited before, send a personal message to another person via email or online messaging service, buy items or services from a website, and complete online application forms which include personal details*. The skill *create something new from existing online images, music, or video* had the lowest number of participants indicating they could complete it (179/230, 77.8%).

VAT Awareness and Use

Alexa was the most common VAT that the participants had heard of (229/230, 99.6%), followed closely by Siri (226/230, 98.3%) and Google Assistant (201/230, 87.4%). Most of the participants (181/230, 78.6%) had not used VAT with their SLT clients but 92.7% (166/181) of these indicated that they would like to use it in the future. Most participants (198/230, 86.1%) also indicated that they would benefit from training using VAT with their SLT clients. Of these 198 participants, 167 (84.3%) participants provided additional information about their training needs, with many participants (97/167, 58.1%) discussing a need for general information and awareness training, some participants (25/167, 15%) wanting structured information about

using VAT with specific user groups and specific activities that could be conducted with the VAT, and few participants (9/167, 5.4%) interested in learning about how the technology is being used in the SLT community through real-world examples and in understanding the technical aspects of VATs and how they could improve the intelligibility of speech (6/167, 3.6%).

Participants who responded that they had never used VAT with their SLT clients were asked to provide the possible reasons for this (Table 2).

Table 2. Reasons for not using voice-assisted technology (N=181).

Reason	Count, n (%)
I have never had the opportunity to use it	131 (72.4)
I have not had any training	63 (34.8)
I do not know what technology is available	62 (34.2)
Technology is too expensive	32 (17.7)
I do not think there would be any benefit from speech and language therapy	20 (11)
Technology is too complicated	16 (8.8)
I am not interested in using technology	5 (2.8)
Other (please specify)	31 (17.1)

Other reasons were provided as free-text responses. These were mainly centered on barriers to accessing these types of technologies within the current digital infrastructure of the work environment (23/181, 12.7%), for example, “NHS IT puts up too many barriers to using with patients,” “Poor Wi-Fi in NHS premises,” and “lack of availability of up-to-date technology in my workplace.” Other reasons identified were reluctance to use technology by their clients (6/181, 3.3%) and privacy concerns (2/181, 1.1%). A small number of participants indicated that they had not used and would never want to use VAT with their SLT clients in the future (15/230, 6.5%).

Barriers to Using VAT

The entire cohort of the survey participants (N=230) was invited to provide free-text qualitative responses around what they perceived might be the potential barriers to using VAT in therapy. A total of 208 (90.4%) respondents provided further information.

Over half of these respondents (105/208, 50.5%) had concerns about the devices’ ability to understand SLT clients’ speech, which they felt could be demotivating: “If a client's speech is too unclear they may receive negative feedback which would be disheartening and may lead to low self-esteem” and “Accents, speech sound errors not recognised by a computer but would be recognisable to humans. Can negatively impact confidence.” Very few respondents (3/208, 1.4%) also stated that device use could reinforce incorrect speech or pronunciation, which was a genuine concern. One participant stated, “Sometimes there are subtleties to speech which we are working on *e.g.* lateralization. They could be understood by Alexa/Siri which may reinforce incorrect productions.”

Some of the respondents (56/208, 26.9%) mentioned the lack of technical skills and/or the ability to use the devices by them and their clients as barriers. They provided examples such as “My lack of technological knowledge, time in what is a very time-intensive area in terms of assessing, researching, liaison, implementation and monitoring” and “Inherent difficulties with technology - things not being plugged in correctly, set up correctly or carers not having sufficient skill to rectify any issues as they arise.” Similarly, psychological barriers were also identified by a few respondents (29/208, 13.9%). Older clients were considered potentially unwilling to use the technology because of unfamiliarity or being *scared* of technology use: “Older patients tend to be more resistant to using/learning new technology” and “Tech knowledge and confidence of service users and/or their supporters. Resistance to the concept of tech in some clients.” A few respondents (8/208, 3.8%) mentioned that learning trigger words could be challenging, stating:

> *The models available at the moment require very specific multi-word trigger phrases which lots of people with LD (learning disability) wouldn't be able to get right every time. Could lead to frustration if you need to repeat the phrase because it wasn't picked up originally.*

Another barrier that many respondents (73/208, 35.1%) identified was the cost and availability of the devices for therapy, providing examples such as “Expensive for NHS and patients to purchase” and “Access - often elderly patients may not have suitable equipment/devices.” A few respondents (30/208, 14.4%) also mentioned that setting up the infrastructure to support the devices could be challenging. Information technology support, internet, troubleshooting, and maintenance were some of the infrastructural challenges mentioned: “IT systems in Local Authorities and *NHS*. Poor internet speeds in rural areas” and “Resources, information governance, need to be appropriately used and managed.” Other respondents (11/208, 5.3%) had privacy and security concerns, which were seen to be a potential barrier to VAT use: “Some people refuse Alexa because they don’t want to feel ‘big brother’ is watching them all the time” and “believing that the device owner (*E.g.* Google/Amazon) are collecting and saving your data.”

Privacy and Security Concerns

We further explored possible privacy, security, and confidentiality concerns with all participants by asking them to rate their level of concern: not concerned (75/230, 32.6%),

slightly concerned (132/230, 57.4%), or very concerned (23/230, 10%). Participants were then asked to provide free-text responses highlighting any concerns they might have (102/230, 44.3% provided additional information).

Many respondents (38/102, 37.2%) discussed the *always on* nature of VAT and the fact that these devices are *always listening*:

> *I would be concerned that the microphone seems to be always listening to all conversations, therefore impacting on privacy.*
>
> *There are still reports of voice assistants being used as eavesdroppers, compiling information on users etc. I personally wouldn't have one in the house but can see use for people if they are happy to take that risk.*

Other respondents (21/102, 20.6%) were concerned about who had access to the data, especially considering these are commercial devices with data being collected and stored by large-scale technology companies: "It is unclear how that data is used, who has access to it and/or can purchase it." Some respondents (12/102, 11.8%) were also concerned about data use, stating, "Use of voice data is not clearly articulated by companies such as Amazon and Google." This was further elaborated, with 8.8% (9/102) of the respondents stating their concern over targeted advertisements: "They're always listening and then provide tailored adverts." In a similar sense, several respondents (21/102, 20.6%) were concerned about data storage and security: "VAT can make anyone vulnerable to leaks of personal information so an added difficulty in communicating could increase that person's vulnerability if not managed appropriately."

Regulatory and General Data Protection Regulation (GDPR) issues were also discussed (8/102, 7.8%):

> *I am concerned that organisations will put hurdles in the way which would prevent people benefiting from voice assisted technology. For example, being told that a device can't be purchased or used due to GDPR etc.*

Finally, some respondents (5/102, 4.9%) expressed their concerns over unsupervised access and accidental purchases using the devices: "children accessing internet with devices potentially unsupervised" and "buying products or apps without awareness."

Experiences of Using VAT in Clinical Practice

Overview

A total of 49 respondents reported that they had used VAT with their clients. These respondents were asked a set of free-text questions to gather details about their experiences. They were explicitly asked the following three questions:

1. Please provide some detail about your experience of using VAT for SLT. Please describe the types of service user you have used VAT with.
2. Please provide some detail about how you used VAT with service users.
3. What was the impact of using VAT with service users?

A total of 57 cases were discussed by the respondents, as some reported multiple use cases. There were 10 major client groups across adult and pediatric services that were discussed (Tables 3 and 4). Almost half of the respondents (28/57, 49%) had used the technology to support day-to-day tasks, such as setting reminders, playing music, and sending emails and text messages. Many respondents (21/57, 37%) reported using VAT specifically for SLT practice (ie, using it to support the training of explicit SLT strategies with their clients). Others reported using the devices for speech to text functionality (9/57, 16%), environment control (9/57, 16%), and to set up an AAC device (2/57, 3%). A handful of respondents also reported using it as a motivational tool for therapy (3/57, 5%), a tool for routine formation (1/57, 2%), and a tool for translation (1/57, 2%).

In terms of the impact of VAT use, the respondents reported a multitude of positive impacts. They reported increased client independence (22/57, 39%), accessibility (6/57, 10%), and confidence (5/57, 9%). Some respondents discussed the impact on their clients' speech. They mentioned that their clients received feedback on their speech (9/57, 16%) and reported increased client communication (5/57, 9%) and sociability (3/57, 5%). A full breakdown of the findings is presented in Tables 3 and 4. We then contextualized and drew out the respondents' experiences further through a narrative description of the data.

Table 3. Voice-assisted technology use cases.

Client group example and main use cases	Respondents, n (%)
Dysarthria (n=18)	
SLT[a] practice	10 (55)
Day-to-day tasks	5 (28)
Environment control	5 (28)
Speech to text	2 (11)
Augmentative and alternative communication (n=15)	
Day-to-day tasks	10 (67)
Environment control	4 (27)
Augmentative and alternative communication setup	2 (15)
Motivation tool	1 (7)
Aphasia (n=7)	
Speech to text	4 (57)
SLT practice	3 (43)
Day-to-day tasks	2 (28)
Learning disability (n=5)	
Day-to-day tasks	4 (80)
SLT practice	3 (60)
Mainstream school setting (n=3)	
Day-to-day tasks	3 (100)
Motivation tool	2 (67)
Speech to text	1 (33)
SLT practice	1 (33)
Traumatic brain injury (n=3)	
Day-to-day tasks	3 (100)
SLT practice	1 (33)
Apraxia (n=2)	
SLT practice	2 (100)
Speech to text	2 (100)
Cognitive communication disorder (n=2)	
SLT practice	1 (50)
Routine formation	1 (50)
Dementia (n=1)	
Day-to-day tasks	1 (100)
English as a second language (n=1)	
Translation tool	1 (100)

[a]SLT: speech and language therapy.

Table 4. Impact of using voice-assisted technology.

Client group example and reported impacts	Respondents, n (%)
Dysarthria (n=18)	
Increased independence	9 (50)
Feedback on speech	6 (33)
Increased engagement as technology is an everyday device	3 (17)
Increased speed of task	2 (11)
Increased quality of life	1 (5)
Increased accessibility	1 (5)
Augmentative and alternative communication (n=15)	
Increased engagement as technology is an everyday device	7 (47)
Increased independence	5 (33)
Increased accessibility	3 (20)
Increased quality of life	2 (13)
Increased communication	2 (13)
Increased sociability	1 (8)
Aphasia (n=7)	
Increased independence	3 (43)
Feedback on speech	2 (29)
Functional writing	1 (14)
Increased sociability	1 (14)
Increased confidence	1 (14)
Learning disability (n=5)	
Improved communication	3 (60)
Increased confidence	2 (40)
Increased independence	1 (20)
Increased engagement	1 (20)
Mainstream school setting (n=3)	
Increased engagement as technology is an everyday device	2 (67)
Increased confidence	1 (33)
Traumatic brain injury (n=3)	
Increased independence	2 (67)
Increased accessibility	2 (67)
Increased confidence	1 (33)
Apraxia (n=2)	
Increased independence	1 (50)
Increased sociability	1 (50)
Feedback on speech	1 (50)
Cognitive communication disorder (n=2)	
Increased independence	1 (50)
Increased engagement as technology is an everyday device	1 (50)
Increased independence	1 (50)
Dementia (n=1)	
Increased independence and sociability	1 (100)

Client group example and reported impacts	Respondents, n (%)
English as a second language (n=1)	
Improved communication with English as a second language student and time saving (as no need for a translator)	1 (100)

Dysarthria

Of the described use cases, dysarthria was the most common, with 18 therapists reporting using a range of VATs with their dysarthric clients. Dysarthria is a motor speech impairment caused by weakening or paralysis of the muscles used to produce speech. It often presents as slow or slurred speech, which can be difficult to understand. The therapists primarily discussed using VATs to support speech practice as a way to provide biofeedback to the client on their speech clarity. For example, 1 therapist described how a client "uses it to practice speaking with strategies to make her speech clearer because if Alexa understands her, she knows she is doing well"; another's client "uses it to monitor volume and intelligibility and finds it objectively helpful." One therapist discussed how their client had actively "identified the goal of being understood by Siri" as an outcome measure for their therapy. This process of enhancing the clients' practice of speech and the ability to give clients continuous feedback on their speech was seen as particularly beneficial for this user group.

Several therapists also explicitly described working with dysarthric patients with specific neurological conditions such as Parkinson disease ("speech therapy to improve accuracy of speech to text recognition software"), multiple sclerosis ("used an Alexa which was used as a switch device to control items in his environment e.g. curtains, fan...increased independence and reduced frustration"), and motor neuron disease ("sending text messages, memos, calendar, email, web search...it kept the patients using their phones and felt less medical- minimal training required"). The day-to-day functional outputs provided by VAT devices (eg, using speech to text to write memos, searching for web-based information, and writing shopping lists) and the ability to support those with comorbid physical impairments (eg, because of a neurological condition or paralysis post stroke) by enhancing their ability to control the environment were frequently outlined by the therapists as improving the independence of individuals within this client group.

Augmentative and Alternative Communication

The second most discussed use cases that were provided centered on AAC users. A total of 15 therapists described using VATs in varying degrees with this client group. AAC refers to any communication method used to supplement or replace spoken or written speech production; however, in our case, therapists explicitly discussed digital AAC devices. Most use cases discussed how the therapists had helped their clients set up their voice output devices to provide commands, primarily to Alexa, thereby allowing their clients to access the functionalities of VATs through a computerized voice. This enabled their clients to complete everyday tasks, such as searching for information on the web or listening to music as well as to control their environments. For example, 1 therapist described it as follows:

> *enabled voice output devices to liaise with voice assisted technology to enable control and information gathering and sharing, e.g. with Nest to control heating; used with shopping apps like Amazon; request information about news, local events; to access leisure activities like music, television, Netflix...many many ways.*

The therapist described how using the technology in this way "facilitated great independence [and] facilitated and maintained social contacts." Several therapists (n=3) also discussed nonverbal clients who were users of AAC devices controlled through eye gaze. One therapist described setting up *pages* on a client's device (ie, a visual page of icons or images on the device that the user can activate using eye gaze and blinking):

> *so that they can use Alexa to play music, or activate a disco ball (favourite toy)...enabled a little girl with progressive muscle weakness to control music and toys after losing hand function. Did this using mainstream technology [Alexa] that her parents were confident with and found acceptable and exciting to use.*

Therapists describing use cases in this theme were very positive about the impacts of VAT on their clients' lives, describing how it had "greatly improved their quality of life in all situations" and had led to improvements in the clients' independence and confidence. There were also many comments stating that clients were motivated to engage with the technology as it was an everyday device: "users love it as it's not a 'disability device'- it is something everybody is using."

Aphasia

Seven of the therapists described using VAT with clients with aphasia (a disorder affecting the ability to produce and comprehend spoken and written language). Primarily, it was used for its speech to text functionality to support written communication. One therapist described it as follows:

> *We used voice assisted tech for Google searching, writing emails and texts and writing stories...many of the reported increased confidence and self-esteem...Some of the people in the clinic even managed to get back into work as a result.*

However, several therapists also described using it as a tool to facilitate spoken language tasks. For example, 1 therapist used it to "practice spoken language in a 'real life' setting and also [to support] comprehension (e.g. playing games with Alexa skills where they listen to instructions and then give verbal commands)" and another described its use at helping clients "generate clear and accurate sentences, format questions without hesitancy and learn how to phrase to get the best results."

Learning Disability

Therapists working with people with learning disabilities (n=5) mainly discussed using VAT as a tool to support day-to-day tasks, such as playing music or searching for things on the web: "Alexa or Siri to enable music to be played or to search the web, used mainly with individuals with mild to moderate learning disabilities," which was seen to be "very positive, provides control/independence, boosts confidence and gives further topic conversation with staff/family [as well as] increasing awareness of [their] own speech and how this is interpreted by others/Alexa." Therapists also discussed using the device to specifically target language tasks such as phrase construction, supporting joint attention with a carer, and training conceptual understanding of cause and effect. One therapist described a specific activity that they had designed to use with Google Assistant: "service user makes a request 'moo', carer says 'OK Google, play the sound of a cow'. Other farm animals and vehicles were also used."

Mainstream School Setting

Similarly, within the mainstream school setting (ie, where therapists might have worked with children who had milder speech and language impairments or delays), we had 3 therapists using VAT primarily to keep the children engaged "as a motivation tool...students were more engaged as the technology is more relevant to their lives." One therapist described using the technology creatively to "ask Alexa to make silly noises or to tell us a joke during classroom-based sessions" but it was mainly described as being used to search for things on the web or to play music:

> *It's been incredible. The instant gratification has meant the children keep going back to use it. We had to get the school to buy an amazon music subscription.*

Traumatic Brain Injury

Three therapists had used VAT with clients with traumatic or acquired brain injury, which is caused by sudden trauma in the brain (eg, from a sports injury or car crash). This type of injury can cause a range of issues that might be supported by an SLT, relating to an individual's speech, language, writing, social communication, behavior, attention, planning, learning, and swallowing. All of the therapists were using VAT to support day-to-day activities, such as *turning on the radio, making phone calls, checking the weather, setting reminders, and calling* and reported improvements to confidence, independence, and access to technology. One therapist also used it to support *verbal reasoning/problem solving* by asking the client to find out and respond to information by using the device.

Apraxia

Similar to dysarthria, apraxia of speech can cause issues with speech intelligibility. Although both are motor speech disorders, apraxia is more concerned with the planning, sequencing, and coordination of speech production. Two therapists had used VAT (Alexa and Siri) to support speech therapy practice, in particular, "to provide biofeedback on how intelligible the clients' speech is." One therapist described it as follows: "Direct work on improving apraxia of speech, word production accuracy and improving impairment." The technology's ability to respond correctly to verbal commands was seen as a valuable way to *enable clients to practice clear speech at home with measurable outcomes.* Both therapists also used speech to text functions to enable their clients to create written notes, messages, and emails.

Cognitive Communication Disorder

There were 2 respondents who discussed use cases with clients experiencing cognitive communication disorders, which can cause difficulties in remembering information, staying on topic, and maintaining attention. One respondent used interaction with Alexa to support *generating clear and articulate sentence, formatting questions without hesitancy and learning how to phrase to get the best result* and the other respondent used it *as a way of helping them with their routines*, that is, *Alexa, tell me my schedule for today.* In this second case, the therapist noted how engagement with Alexa was seen to be particularly beneficial as "it is not a 'disability' device, it is something everybody is using."

Dementia

Remaining within the space of cognitive impairment, there was one example of a therapist who had used Alexa with *patients with different types of dementia as a tool to organize diaries, timetabling, reminders, shopping lists, music, and Alexa to Alexa calls to family.* Although they reported "varying success due to personal preference, but also the trigger word Alexa can sometimes be difficult to remember," they reported that the technology could be used successfully if individuals were supported, and the use of the device was modeled effectively. This therapist described "it can make a positive difference to them, maintaining independence, keeping in contact with people and for quality of life."

English as a Second Language

Finally, 1 therapist described using Google translator to support a case history taking exercise with a family with limited English (as the translator had failed to arrive in time), so they had *the option of understanding in their home language.* They said, "I was able to complete a case history and save time by not having to re-book the assessment. The parents were very happy." Although this example was not directly related to patient outcomes, it was a broader example of how this type of technology might be able to support the therapists themselves in their professional activities.

Reported Limitations

It is worth noting that although the reported use cases were vastly positive across the therapists, there were some instances where therapists discussed limitations with the technology (n=3). One therapist discussed how a client with Parkinson disease had "improved speed of task. However, fatigue impacted." Another, discussing a wheelchair user with traumatic brain injury, had variable success: "useful but needs clear speech which is sometimes not clear enough." Finally, 1 therapist discussed how 1 aphasic client they had been using Alexa with had "found it slightly useful but the quality of his wifi connection was poor and this impacted how well it worked for him."

Perceived Potential Benefits of VAT for the Wider SLT Community

We asked all 230 respondents, regardless of whether they had reported experiences of using VATs in their practice, whether they felt there were any possible (perceived) benefits of using VAT with their SLT clients. Although many participants remained unsure (potentially because of a lack of experience and training), the majority either agreed or strongly agreed that VAT could have a positive impact on their clients' speech and confidence (Table 5).

Table 5. Respondents' views on the potential impact of voice-assisted technology for their clients (N=230).

Statement	0 (strongly disagree)	1 (disagree)	2 (maybe, but I'm not sure)	3 (agree)	4 (strongly agree)
These technologies could have some impact on patients' speech, n (%)	2 (0.9)	12 (5.2)	90 (39.1)	99 (43)	27 (11.7)
These technologies could help patients speak louder, n (%)	0 (0)	11 (4.8)	99 (43)	92 (40)	28 (12.2)
These technologies could help patients speak more clearly, n (%)	1 (0.4)	23 (10)	97 (42.2)	88 (38.3)	21 (9.1)
These technologies could increase patients' confidence in their speech, n (%)	0 (0)	9 (3.9)	86 (37.4)	112 (48.7)	23 (10)

The respondents were asked to describe any other potential benefits that VAT could have on their clients; 175 (76.1%) of the 230 respondents provided additional information via free-text responses. Similar to the therapists who had experience using the technology, accessibility and independence, psychological benefits, and speech improvement were the major themes identified.

Many respondents (51/175, 29.1%) believed that VATs would enhance accessibility for their clients and give them more control over their environment. They provided examples, such as "It could help clients access online services, environmental controls and communication platforms to communicate face to face with others *e.g.* skype/facetime" and "It would also be beneficial if they were to have physical conditions which restrict their ability to stand to turn the TV/radio on." Many respondents (35/175, 20%) explicitly stated that the technology would make their clients more independent. For example, 1 respondent stated, "It can help someone to be more independent and not rely on another person to meet their requests." Improving their clients' organizational skills, by setting up reminders or diaries easily, was also identified as a benefit by some respondents (16/175, 9.1%). They provided examples, such as "I think they could be used for prompts to remember to do things. Easier for people to be able to access information" and "Most of my patients have cognitive impairments as well as communication impairments - these technologies have the potential to be very helpful to someone with poor memory and orientation."

Several respondents focused on the psychological benefits that VATs could have. Some respondents (19/175, 10.8%) stated that the devices provided a sense of normality and were not therapy devices, as they were something that everyone used. This reduced stigma and encouraged the clients to use the devices: "As the technology is mainstream, as is technology generally, it is more socially acceptable and less different and isolating for AAC users now than it has been in the past." A few respondents (18/175, 10.3%) also mentioned the enjoyment and motivation effect of these devices, stating "Enjoyment and expansion of communication for clients that are non-verbal. It provides a sense of freedom outside of the structured AAC device." Some respondents (11/175, 6.3%) also believed that the devices could enhance their clients' communication and community engagement. They provided examples, such as *improved ability to communicate with others* and *communication at home/between family members/engaging more with the younger generation.*

Many respondents stated that the devices can have a direct impact on the speech of their clients. A few respondents (18/175, 10.3%) stated that using the devices could make speech more intelligible and clearer, by providing examples, such as "Encourages increased volume/clarity of speech" and "Enables users with degenerative conditions to maintain their voice for as long as possible." Other respondents (19/175, 10.8%) mentioned how these devices could provide feedback on their clients' speech and increase their self-awareness:

> *Impartial feedback from a non-human. If they haven't used speech sounds correctly then it's not a family member telling them. Enhances their own awareness of their intelligibility.*
>
> *Awareness of the need to speak more clearly to be understood, feedback on intelligibility.*

Finally, several others (15/175, 8.6%) stated how the devices could be used for home practice by their clients and provided examples, such as "Good for those who are socially isolated to practice speech" and "More inclined to practise at home where nobody else can hear them."

Discussion

Principal Findings

Overview

The aim of this survey is to understand the attitudes and experiences of SaLTs toward VAT use. Specifically, we wanted to (1) develop an understanding of their use experiences (if any) and any potential benefits they might see in using the technology in the future and (2) understand their reasons for not using the technology and uncover any potential barriers that could be addressed in the future (eg, training needs). There has been no previous study on how VAT was used in SLT clinical practice, or indeed clinical practice, among other health professions. As

such, the aim of this work is to gather a preliminary scoping overview of how SaLTs and their clients are currently using VAT. Our study findings will shape the future areas of research and identify potential clinical use cases that can be further developed.

Overall, 96.9% (223/230) of the respondents were women, which is unsurprising given that SLT is largely a female-dominated profession [38,39]. The respondents mostly worked within the UK NHS, with an even balance of early career and experienced practitioners. They demonstrated caseloads with service users possessing a diverse range of communication and swallowing needs. This indicates that the survey results expressed the views and experiences of a representative sample of SLT intervention areas. The respondents were very familiar with commercial VATs, with over 98.3% (226/230) having heard of Alexa and Siri. We found that over 21.3% (49/230) of our sample had already used VATs with a variety of different client groups and had a range of experiences to share.

Opportunities for VAT in SLT Practice

The therapists had already used VATs across 10 different client groups and provided detailed accounts of their use experiences and impacts. Almost half of these use cases involved using VAT to assist with day-to-day tasks, such as setting reminders, playing music, or sending electronic communications (emails and text messages) or controlling aspects of the clients' environment. Several previous studies have discussed the accessibility benefits of VAT for different populations (such as older adults and people with sensory or physical disabilities) by assisting them with these types of tasks [26-31]. This previous research and our own findings in this sense are not unexpected, given that these are the very functions that VATs are marketed to perform, and are the intended commercial purposes of these devices. Although the accessibility benefits of these functions are undoubtedly useful to individuals requiring SLT, many of whom also have underlying physical disabilities, some of the respondents in our study described further innovative uses for VATs that were of particular interest.

Some of the respondents mentioned explicitly using the devices to target the practice of SLT strategies, with several client groups experiencing diagnoses, such as dysarthria, apraxia, and aphasia. These types of conditions are communication impairments that cause difficulties in producing clear, comprehensible speech. In the first instance, one might question how clients with speech impairments can successfully communicate with VAT, which requires specific trigger words and clear speech to function. However, the respondents explicitly discussed using VATs to support speech practice, particularly as a way to provide biofeedback to the client on their speech clarity. They highlighted the positive impacts of having a device that would provide such a source of feedback on speech production; if the device could understand a client, they were given clarification that they were speaking intelligibly. This echoes the findings of other studies, which have highlighted the successful experiences of users with speech impairment when using commercial VAT devices [27,28,32]. As highlighted by our professional SLT participants, the ability to practice speech at home and obtain real-time, impartial feedback from the devices was found to improve word production accuracy and increase clients' motivation to perform home therapy practice, both of which are SLT outcomes that might regularly be targeted in formal therapy. A study [27] also reported similar findings, discussing that some Alexa users self-reported speech improvements, with a need for distinct pronunciation when using the device actively improving users' speech through continuous practice. Duffy et al [32] also found self-reported speech improvements in approximately 25% of people with Parkinson disease who were using VATs but did not delve into why participants felt this might be happening. This is an exciting and ripe area for future research, which might explore the extent to which speech changes actually occur through device use, how they are maintained, and how speech outcomes being achieved through device use might be measured in SLT practice.

Another significant use case discussed was of AAC users, wherein respondents described how they used a combination of digital AAC devices and VAT with their clients. They discussed how the computerized voice output of the digital AACs was used to access the functionalities of VAT, such as performing day-to-day tasks and environmental controls. They reported very positive impacts on the confidence, accessibility, and independence of their clients and highlighted how the social acceptability and mainstream nature of VATs helped reduce barriers to their use and increased the clients' motivation to use them. As VAT is widely used in society today, therapists can present it as something that everyone is using, not an assistive or *disability device*. This social acceptance surrounding VATs has an inclusive effect and is less isolating for the client, in turn, having a motivating effect. Similar conclusions were drawn in another study [40], which discussed that the popularity of VAT devices added to the feelings of inclusion for people with cognitive and linguistic difficulties. It was also interesting to note how nonverbal users were being supported by therapists to use VAT by combining them with their AAC devices. Although there are a few practice-focused articles in the grey literature [41,42] that discuss this use case and its impact on user independence and motivation, formal research in this space is limited. Future research can further explore the experiences, benefits, and limitations of this integration with AAC users.

Considering the broader perspectives of our sample, 72.1% (166/230) of respondents who had not used VAT in practice were very keen on trying it in the future. This highlights the largely positive outlook and perception of the technology by SaLTs. They perceive multiple benefits of using VAT with their clients, such as increased accessibility, independence, and confidence. Moreover, these respondents also believed that the technology could have an impact on their clients' speech. In total, 52.2% (120/230) of the respondents believed that the technology could help their clients speak louder, although 47.4% (109/230) of the respondents believed that it could help them speak more clearly. Most significantly, 58.7% (135/230) of the respondents stated that the technology could increase their clients' confidence in their speech. These perceptions about the benefits resonate with our findings from the practitioners' experiences. Respondents who had used VAT with their clients reported very similar benefits, as discussed earlier. Furthermore,

these types of benefits have also been discussed in previous literature [27,28,32]. Our findings, backed by previous studies, demonstrate the potential of VAT to support SLT. Future research can explore how the technology can be leveraged to augment traditional SLT by providing users with an opportunity for home practice. However, there is work to be done around how different types of client groups might be best supported in their use as well as the types of activities that might be most beneficial to be conducted with VATs to benefit the service user.

Traditionally, SLT is delivered on an individual basis, face to face usually in clinical settings, but successful outcomes can depend on practice at home [43]. Home practice supports the carryover of skills from clinic to everyday life and contributes to the maintenance of communication improvement. Technology has been found to have the potential to address some of these issues and promote better self-management practices [16,25]. This can be particularly beneficial for clients living alone or in rural areas, where traveling to therapy appointments might be challenging and is perhaps even more important in the current context of the COVID-19 pandemic and lockdowns. VATs have the potential to improve users' self-management practices by supporting the delivery of home-based therapy programs, with the benefit of immediate feedback from the device [44]. Designing such programs that can be facilitated by the qualities of VAT devices is an interesting area for future research. However, we do not suggest that this is a magical solution. Work in this space also needs to consider the role of the technology alongside timely therapist input so that effective long-term and multifaceted support can be provided to the client within such a technology-assisted service delivery model. In addition, researchers and clinicians should be aware of conditions that will see a decline in speech over time or in conditions such as Parkinson disease, where fluctuations might even be seen within the span of days or hours. These types of clients may find VAT interaction challenging and unpredictable and will need support from professionals to ensure their accessibility and reduce frustration.

Barriers to VAT Use in SLT Practice

Although the outlook toward VAT use was largely positive and several potential benefits were identified, the respondents also identified several barriers to adoption and concerns regarding its use. Many respondents described organizational and infrastructure barriers that could affect technology adoption, for example, the cost of devices; supporting infrastructure, such as internet connectivity; limited access to technology; and funding in their organization. Moreover, data collection and protection policies, such as the GDPR, were a concern for some of the participants. Respondents felt that the commercial VATs had unclear data collection and use policies, which would make them difficult to use in client-related contexts. These concerns are not new when it comes to discussing novel technologies and their integration into health care contexts. There has been a wealth of literature exploring the challenges of technology adoption and uptake by health care professionals [45-47]. Respondents discussed concerns about data storage, confidentiality, and privacy, which are always crucial considerations when using technology in health care contexts [32,48]. These are significant concerns to be considered in future work, which would need to explore how commercial VATs (and any new apps or skills to be developed to support clinical care) can be introduced and used in line with user privacy and confidentiality requirements. That said, work is beginning to emerge that is actively exploring the users' perceptions of data and data sharing in relation to commercial devices used for health needs [29]. Transparency, openness, and information about what data are being stored and used and by whom, is enough to alleviate many people's concerns (even if these data are being stored by a large-scale commercial company).

The respondents in our survey who had not used VAT reported multiple reasons for their lack of use. Most respondents (131/181, 72.4%) mentioned a lack of opportunity for use; however, lack of technology awareness and training were other significant reasons that were reported. Most respondents desired basic training about the range of technologies available, their use, potential benefits, and information about applying them in practice. Providing specific application examples in future training may be beneficial, as some respondents wanted information specific to a particular client group, citing examples such as dysarthria, AAC users, and dysfluency. As with any new technology, training before use is essential. Several health care studies have documented this concern [49,50]. Developing structured, co-designed training materials for VAT is essential for practitioner adoption and use. Delivering organization wide technology training may be an optimal solution for this issue. Previous literature has documented the success of delivering technology training with professionals within the space of telehealth [51,52] and virtual reality [53-55]. Future work could focus on developing formal VAT training resources and identifying the best methodologies to deliver this training effectively.

The technological limitations of VAT were another barrier identified by this study. Many respondents discussed how there were existing challenges related to VAT devices' ability to even comprehend attempts produced by users without speech impairments. Failure to detect different accents, unclear speech, low-volume speech, and misinterpreting words were some of the issues respondents felt the technology was *inconsistent* and *temperamental* within its functional ability. In light of this issue, respondents felt that their clients with severe speech impairment would be unable to use VAT effectively, leading to negative impacts on confidence and motivation. There is a risk that such users would feel frustrated because of this issue, demotivating them from using such technology in the future. However, we found that respondents who had actually used the technology found high success rates with a variety of client groups, even clients with severe speech impairments. The respondents found workarounds to the technical limitations of the technology and stated how they managed to use VAT and foster motivation for their clients. This disparity between perceived barriers and actual experiences calls for additional research in this domain. It is possible that developing a community where practitioners can exchange their thoughts and experiences may be beneficial for wider VAT adoption. There are also opportunities for conducting research that would help with anticipating problems as well as developing bespoke skills, integrated apps, or new features for

VATs that may provide solutions. Our findings suggest that different user groups will have different expectations, capabilities, and impacts of using VAT. As such, there is a direction for future research to focus on exploring how individual clients or client groups with different levels of speech impairment are able or unable to use VAT.

Limitations

The study presented in this paper had several limitations that should be discussed. First, it was conducted exclusively with users based in the United Kingdom. Technological preferences, experiences, and outlooks differ across regions and countries, and the survey does not represent the overall global experiences of SaLTs. Future studies are required to understand the generalizability of our results.

Second, the survey was web-based and self-selective, implying that anyone could potentially provide a response. Naturally, the respondents had basic digital skills and were able to successfully navigate and answer the survey. As such, they may be biased toward the use of such technology and have a positive outlook toward its use. Other SaLTs who might not be technologically adept could have different perspectives and a less favorable outlook toward technology use. In addition, we did not explicitly ask the participants if their experiences were with current users of VAT or if they had introduced the technology to their clients. This information would have provided an additional context about use experiences. Clients already using the technology could have developed certain skills and have different perceptions compared with clients that were introduced to the technology for the first time.

Finally, the sample size estimated to obtain 90% confidence with –5% to +5% margin of error was 289. The number of participants who completed our survey was 230, which was somewhat lower than the estimated value. Time and resource constraints meant that we were unable to keep the survey open for longer. Offering respondents a financial benefit to participate in the study might have improved the speed of our uptake; however, this was not within the scope of our resources.

Future Work

Our study highlights several clear directions for future research, which have been described in the discussion section. Our perspective is that the primary directions for future research should first focus on developing a focused understanding of VAT use within specific use case scenarios and understanding the best ways to collect and report upon potential clinical benefits that might be seen in these use cases. Second, work is required to develop VAT education and training to increase future uptake and adoption. Further work must be done to identify the optimal route to deliver this education and training to raise awareness of the potential benefits and confidence in use.

Conclusions

VAT has been used by a number of UK-based SaLTs in clinical practice. Wider adoption of the technology is limited by the lack of professional opportunities, training, and understanding. Although other studies have explored the interaction between technology and several client groups, our study presents opportunities and challenges from the perspective of the practitioners. The data show increased engagement, empowerment, and the possibility of achieving therapeutic outcomes in clients with communication impairment. The disparate responses suggest that this area is ripe for the development of research exploring the role of VATs in evidence-based clinical practice, starting with a clear definition of its use potentials and benefits and the development of plans for outcome measurement when using VAT devices to support therapy aims.

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Conflicts of Interest

None declared.

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Abbreviations

AAC: augmentative and alternative communication
GDPR: General Data Protection Regulation
NHS: National Health Service
RCSLT: Royal College of Speech and Language Therapists
SaLT: speech and language therapist
SLT: speech and language therapy
VAT: voice-assisted technology

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