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Usability of a daily mHealth application designed to address mobility, speech and dexterity in Parkinson's disease

Neurodegenerative Disease Management



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Practice points

- People with Parkinson's disease exhibit deficits in gait, speech and dexterity.
- The usability of a mobile health (mHealth) smartphone application designed to target symptoms of gait, speech and dexterity in Parkinson's disease was investigated.
- Primary outcome measures included adherence, gait characteristics, number of steps per day, sustained phonation, speech prosody and the 9-hole peg test.
- Adherence to the mHealth application was moderate and there was little effect on gait, speech and dexterity.
- Increased adherence to mHealth treatment was not associated with improved outcomes.
- User-friendly mHealth to complement traditional rehabilitation may improve efficacy.

Aim: This study investigated the usability of a mobile health (mHealth) smartphone application to treat gait, speech and dexterity in people with Parkinson's disease. **Methods:** Participants either used an mHealth application (intervention) or maintained their normal routine (control) for 12 weeks and were evaluated at baseline and post-test time points for primary outcome measures of adherence, gait, speech and dexterity. mHealth application adherence was compared with percent change scores on gait, speech and dexterity measures. **Results:** Adherence was moderate and there were no significant group, time or interaction effects for any outcome measures. Correlations between adherence and outcomes were weak and negative. **Conclusion:** These data suggest that usability of this mHealth application was limited as indicated by low adherence. The application alone in its present form was not adequate to treat symptoms of gait, speech or dexterity in people with Parkinson's disease.

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Parkinson's disease (PD) is a neurodegenerative movement disorder that is expected to impact nine million people by the year 2030 [1]. PD is characterized by resting tremor, rigidity, bradykinesia and postural instability [2]. These symptoms commonly affect gait, speech and dexterity. PD is a progressive disorder, so disease severity increases over time and is associated with detrimental effects on daily living [3]. Common pharmacological treatments often do not alleviate all symptoms and other treatment options are needed [4]. For instance, physical therapy may be useful for gait impairments [5], speech therapy for speech decrements [6] and occupational therapy for changes associated with dexterity [7]. However, the cost of additional treatments can be burdensome, and treatment sessions are often intermittent due to limitations in treatment availability [8]. With the increasing prevalence of PD, there is a need to study affordable and accessible treatment options for gait, speech and dexterity impairments.

Impairments in gait are associated with increased fall risk and decreased mobility and indicate worsening disability and disease severity [9,10]. Gait treatments are often administered through physical therapy. One method



of treatment commonly used to address gait deficits in PD is rhythmic auditory cueing, which involves playing an auditory cue with a salient beat to which an individual matches their gait pattern [11]. This treatment can increase gait velocity and stride length during cueing [12,13]; however, improvements are not retained after training is discontinued [14]. In-home gait training that could be used on a continuous basis has the potential to facilitate retention of improvements from rhythmic auditory cueing [15].

In addition to gait impairments, alternative treatments are also needed for speech and dexterity deficits in PD. Speech deficits affect up to 90% of patients with PD and can include reduced vocal loudness and reduced speaking prosody, hindering communication abilities [6]. Speech and language therapists have targeted these symptoms through several rehabilitative approaches. One approach is the Lee Silverman Voice Treatment (LSVT[®]LOUD), which improved vocal loudness, prosody and sustained phonation duration in people with PD, with improvements retained up to 24 months after intensive training concluded [16,17]. The LSVT LOUD treatment has been successfully adapted as a computer program for at-home use in concurrence with in-person therapy to treat speech deficits in PD [18]. However, administration of speech treatment exclusively from a mobile health (mHealth) platform has not been investigated.

Affordable and accessible treatments for deficits in dexterity should also be investigated, as dexterity is important for activities of daily living such as dressing and handwriting [19]. Dexterity-related issues are typically targeted through treatments provided by occupational therapists. Occupational therapy improved handwriting and fine motor skills in people with PD [5,20], and at-home dexterity training resulted in greater improvements on nine-hole peg test (9HPT) performance than traditional dexterity treatments [19].

In the present study, we investigated the usability and effects of an mHealth smartphone application employed over 12 weeks to improve gait, speech and dexterity in people with PD. The application incorporates evidence-based treatments designed for daily use, improving access and affordability of a continuous treatment. Patients must be able to use the technology [21] and adhere to the treatment [22,23] in order to effectively receive benefit. As such, ease of use is an important aspect of successful mHealth treatment, especially in aging populations. Thus, in addition to objective tests measuring the effectiveness of the mHealth application on gait, speech and dexterity, we also examined the effect of adherence on these outcomes and assessed usability of the mHealth application.

Materials & measures

Participants

Participants were recruited through the Movement Disorders Clinic at the university and from the local chapter of the American Parkinson Disease Association. All participants were diagnosed with idiopathic PD, with mildmoderate disease severity, Hoehn & Yahr score 2–3, and met the following inclusion criteria: able to stand independently for at least 30 min, normal peripheral neurological function, no history of vestibular disease, at least 30 years of age, access to an Apple iPhone (Apple, CA, USA), and no evidence of dementia (determined by a score of 24 or greater on the mini mental state examination) [24]. Exclusion criteria included: any serious medical problem other than PD, using neuroleptic or dopamine-blocking drugs, previous abnormal brain scan, history of other neurological deficits such as stroke or muscle disease, or deep brain stimulation. All participants who were taking medication for PD were tested in their self-reported ON state for all assessments. Participants were part of a larger intervention study that included randomization into three groups (mHealth intervention, group exercise intervention and control); in the present study we will compare the mHealth intervention and control groups only. Baseline and post-test assessments were conducted 1 week prior to and directly after the intervention or control period by research staff who were not blinded to group assignment. The study was approved by the Institutional Review Board at the university and written informed consent was obtained from all participants prior to starting the study.

Participant characteristics

Descriptive characteristics included age, gender, years since diagnosis, levodopa-equivalent daily dose and Hoehn and Yahr scores. The Movement Disorders Society Unified Parkinson Disease Rating Scale Part 3 (MDS-UPDRS-III) was used to assess motor function [25] and was administered by a trained research staff member.

Gait measures

Participants performed three trials of walking at a normal, comfortable pace and at a fast pace, which were averaged within each condition. Spatiotemporal gait parameters were measured using a 5-m instrumented, computerized

walkway (GAITRite, CIR Systems, NJ, USA), a well-validated method for measuring gait characteristics [26]. Velocity, cadence (steps/min) and stride length were measured for each condition. Velocity and stride length were normalized to leg length by dividing velocity (cm/s) and stride length (cm) by the participant's average leg length (cm).

We also recorded average steps per day using wearable sensors (wGT3X-BT Activity Monitor, Actigraph, FL, USA) with a three-axis accelerometer measuring at 30 Hz and analyzed at 1 epoch. Participants wore the sensor on their dominant ankle for 7 days prior to and 7 days after the intervention or control period. Oral and written instructions were provided to the participants on use and care of the sensors. Steps per day has been validated as a reliable measure of daily activity levels for people with PD [27]. The number of steps per day was averaged over 7 days. One participant in the intervention group only had 6 days averaged for their post-test assessment due to missing data.

Speech measures

All speech measures were recorded using a head-mounted condenser microphone (ShenZhen Huacam Intelligent Technology Co., Hong Kong, China) and recorded through a digital recorder (Voice Tracer 3500, Philips, Amsterdam, The Netherlands) as 44.1 kHz WAV files. The distance of the microphone to the center of the participant's lips was measured and kept consistent for the baseline and post-test assessments, to ensure vocal intensity could be compared within participants. Frequency and intensity measures from all audio files were processed using Praat software [28]. Frequency for the reading passage was processed with a pitch setting window of 75–300 Hz for male voices and 100–500 Hz for female voices. Custom-written MATLAB (MathWorks, Natick, MA, USA) scripts were used to calculate the outcome measures.

Sustained vowel phonation and reading a passage were used to assess speech parameters. For the sustained vowel phonation participants were asked to take a deep breath and say 'ah' for as long as they could. Maximum duration (s) and mean frequency (Hz) were measured using a custom MATLAB script which determined the onset and offset of the vocal phonation. To ensure vocal intensity did not influence the participants' maximum sustained duration, a paired samples *t*-test was used to compare baseline and post-test vocal intensity; no significant difference was noted (t = -0.759, p = 0.453).

For the passage reading task, participants were asked to read The Rainbow Passage at a comfortable pace [29]. In order to assess speaking prosody, the primary variables of interest were the total time to read (s) and the semitone standard deviations (STSD) of the fundamental frequency from The Rainbow Passage [30]. Semitones of the fundamental frequency were calculated in reference to 1 Hz.

Dexterity measure

The nine-hole peg test (9HPT) has been validated for use in PD and was used to assess dexterity [31]. Participants performed two blocked trials of the 9HPT starting with their dominant hand followed by their nondominant hand.

Feasibility measures

Adherence in the intervention group was checked regularly and participants were contacted via telephone if they had not used the application for two or more consecutive days, for up to three-times during the study. The percent adherence was calculated based on the total number of exercises a participant completed throughout the study.

An exit survey was administered to the intervention group after their post-test assessment to reflect on their experience using the mHealth application. General comments were collected to qualitatively assess the participants experience with the mHealth application.

Intervention

Participants in the intervention group were instructed to independently complete exercises once a day for approximately 90 days (median \pm range: 89 \pm 7 days) using the Beats Medical Parkinsons Treatment App (Beats Medical Ltd, UK) provided to them on their personal smartphone. Exercises were divided into three domains – mobility, speech and dexterity – and took approximately 30 min in total to complete each day. The mobility exercise consisted of a 2-min calibration walk to assess gait cadence, and a 10-min walk where participants matched their footfalls to the beat of a metronome playing at their prescribed cadence. The speech exercises included sustained vowel phonations, reading words and sentences aloud and playing a game involving modulations in volume of sustained

Table 1. Participant characteristics.							
Variable	Control		Intervention				
	Baseline (n = 20)	Post (n = 20)	Baseline (n = 20)	Post (n = 17)			
Gender (% females)	30%	30	40	41			
Age	64.9 (8.4)	-	63.4 (8.6)	63.2 (9.3)			
MDS-UPDRS-III	28.3 (9.7)	31.9 (13.2)	28.3 (8.7)	30.5 (13.0)			
H&Y, median (range)	2 (2, 2)	2 (2, 3)	2 (2, 3)	2 (2, 2)			
Years since dx	6.0 (4.3)	-	6.7 (5.6)	-			
LEDD, mg	937.2 (395.5)	934.7 (442.6)	1087.0 (730.6)	1128.7 (753.5)			
MMSE, median (range)	29 (25, 30)	-	29 (27, 30)	-			

Values are mean (SD) or n, unless otherwise noted

H&Y: Hoehn and Yahr; LEDD: Levodopa-equivalent daily dose; MDS-UPDRS-III: Movement Disorders Society Unified Parkinson Disease Rating Scale Part 3; MMSE: Mini-mental state examination.

phonation. The dexterity exercises included a digitally adapted version of the 9HPT, pinching exercises and writing in circles using a provided stylus.

Statistical analysis

All statistical analyses were conducted in the R statistical computing environment [32]. All outcome measures were assessed for normality by examining the residual outliers using the Median Absolute Deviation method [33]. When appropriate, data were winsorized to the next value within the normal distribution and non-normal distributions are identified in the tables.

Two-way repeated measures ANOVAs were used to determine group, time and interaction effects on the outcome measures. Within subject variation was accounted for in the models. Significance was set at $\alpha = 0.004$ to correct for multiple comparisons.

Pearson correlations were used to determine relationships between outcome measure change scores and adherence to their respective exercises in the mHealth application. Primary outcome measures from each domain were: normalized gait velocity percent change, maximum sustained vowel phonation duration percent change and 9HPT percent change for mobility, speech and dexterity outcomes, respectively.

A qualitative analysis of the exit survey was performed by looking for themes based on repetition of keywords in the participants' comments [34].

Results

Thirty-seven people with PD, 17 intervention and 20 control, completed the study. Participant characteristics are summarized in Table 1. Initially, 23 participants were enrolled in the intervention group and 24 participants were enrolled in the control group. In the intervention group, two participants did not complete a baseline evaluation (one lacked physician clearance to participate and one decided not to participate) and four participants discontinued participation (one due to family situation, one due to unrelated injury, one due to unrelated health concerns and one simply decided not to participate). In the control group, three participants did not complete a baseline evaluation (one due to being unable to contact and two due to family situations) and one participant discontinued participation due to an exclusionary diagnosis.

Adherence to the mHealth application exercises by domain were as follows (mean \pm SD): mobility was 67.4 \pm 26.0%, speech was 66.8 \pm 26.5% and dexterity was 64.6 \pm 25.3%.

There were no significant correlations between outcome percent change scores and adherence for their respective domains: normalized gait velocity percent change and mobility adherence, r(17) = -0.16, p = 0.53; maximum sustained vowel phonation percent change and speech adherence, r(17) = -0.17, p = 0.52; and 9HPT percent change score and dexterity adherence, r(17) = -0.20, p = 0.44.

Outcome measures are summarized in Tables 1 and 2. There were no significant main effects of group for MDS-UPDRS-III scores ($F_{1,35} = 0.01$, p = 0.94, $\eta_p^2 < 0.001$); forward gait normalized velocity ($F_{1,35} = 0.01$, p = 0.94, $\eta_p^2 < 0.001$), cadence ($F_{1,35} = 1.44$, p = 0.24, $\eta_p^2 = 0.04$) or normalized stride length ($F_{1,35} = 0.38$, p = 0.54, $\eta_p^2 = 0.01$); fast gait normalized velocity ($F_{1,35} = 0.00$, p = 0.96, $\eta_p^2 < 0.001$), fast cadence ($F_{1,35} = 1.78$, p = 0.19, $\eta_p^2 = 0.05$) or fast normalized stride length ($F_{1,35} = 0.80$, p = 0.38, $\eta_p^2 = 0.02$); steps per day ($F_{1,35} = 0.00$, p = 0.99, $\eta_p^2 < 0.01$); sustained phonation maximum duration ($F_{1,35} = 0.90$, p = 0.35, $\eta_p^2 = 0.03$) or mean frequency

Table 2. Outcome measures.							
Variable	Control		Intervention				
	Baseline	Post	Baseline	Post			
Mobility							
Forward gait							
– Velocity (cm/s/LL)	1.51 (0.20)	1.57 (0.21)	1.55 (0.27)	1.54 (0.24)			
- Cadence (steps/min)	111.2 (8.7)	111.7 (8.0)	114.7 (8.3)	114.6 (8.3)			
– Stride length (cm/LL)	1.63 (0.18)	1.69 (0.21)	1.62 (0.24)	1.61 (0.22)			
Fast gait							
– Velocity (cm/s/LL)	2.12 (0.29)	2.17 (0.32)	2.20 (0.40)	2.10 (0.39)			
- Cadence (steps/min)	133.1 (10.6)	132.9 (11.3)	139.7 (14.2)	136.6 (14.1)			
– Stride length (cm/LL)	1.91 (0.20)	1.96 (0.19)	1.89 (0.28)	1.84 (0.29)			
Steps/day	8016 (3197)	7529 (3010)	8183 (2803)	7338 (2759)			
Speech							
Sustained phonation							
- Maximum duration (s)	20.09 (7.45)	20.06 (8.06)	22.32 (10.18)	23.84 (13.55)			
– Mean frequency (Hz)	136.4 (42.0)	144.4 (49.2)	156.1 (46.8)	156.9 (50.1)			
Rainbow passage							
– Total duration (s)	123.2 (17.6) [†]	122.2 (19.4) [†]	119.2 (11.0)†	114.8 (10.6)†			
– STSD	2.08 (0.70)	2.22 (0.91)	2.28 (0.54)	2.18 (0.41)			
Dexterity							
9НРТ							
– Dominant (s)	26.68 (4.32) [†]	26.20 (3.61) [†]	24.83 (4.80) [†]	24.41 (5.90) [†]			
– Nondominant (s)	27.37 (4.50) [†]	25.99 (3.28) [†]	25.89 (4.96) [†]	25.99 (4.64)			
Values are mean (SD).							

[†]Non-normal distributions

9HPT: 9-Hole Peg test; LL: Leg length; STSD: Semitone standard deviation.

 $(F_{1,35} = 1.15, p = 0.30, \eta_p{}^2 = 0.03); \text{ Rainbow Passage total time } (F_{1,35} = 1.45, p = 0.24, \eta_p{}^2 = 0.04) \text{ or STSD } (F_{1,35} = 0.15, p = 0.70, \eta_p{}^2 < 0.01); \text{ or 9HPT dominant } (F_{1,35} = 1.54, p = 0.22, \eta_p{}^2 = 0.04) \text{ or nondominant } (F_{1,35} = 0.28, p = 0.60, \eta_p{}^2 = 0.01).$

There were no significant main effects of time for MDS-UPDRS-III scores ($F_{1,35} = 2.64$, p = 0.11, $\eta_p^2 = 0.07$); forward gait normalized velocity ($F_{1,35} = 1.71$, p = 0.20, $\eta_p^2 = 0.05$), cadence ($F_{1,35} = 0.15$, p = 0.70, $\eta_p^2 < 0.01$) or normalized stride length ($F_{1,35} = 2.66$, p = 0.11, $\eta_p^2 = 0.07$); fast gait normalized velocity ($F_{1,35} = 0.16$, p = 0.69, $\eta_p^2 < 0.01$), fast cadence ($F_{1,35} = 1.06$, p = 0.31, $\eta_p^2 = 0.03$) or fast normalized stride length ($F_{1,35} = 0.16$, p = 0.74, $\eta_p^2 < 0.01$); steps per day ($F_{1,35} = 2.73$, p = 0.11, $\eta_p^2 = 0.07$); sustained phonation maximum duration ($F_{1,35} = 0.70$, p = 0.41, $\eta_p^2 = 0.02$) or mean frequency ($F_{1,35} = 1.55$, p = 0.22, $\eta_p^2 = 0.04$); Rainbow Passage total time ($F_{1,35} = 1.78$, p = 0.19, $\eta_p^2 = 0.05$) or STSD ($F_{1,35} = 0.43$, p = 0.52, $\eta_p^2 = 0.01$); or 9HPT dominant ($F_{1,35} = 0.93$, p = 0.34, $\eta_p^2 = 0.03$) or nondominant ($F_{1,35} = 3.50$, p = 0.07, $\eta_p^2 = 0.09$).

There were no significant interaction effects of group and time for MDS-UPDRS-III scores ($F_{1,35} = 0.53$, p = 0.47, $\eta_p^2 = 0.01$); forward gait normalized velocity ($F_{1,35} = 3.03$, p = 0.09, $\eta_p^2 = 0.08$), cadence ($F_{1,35} = 0.23$, p = 0.63, $\eta_p^2 = 0.01$) or normalized stride length ($F_{1,35} = 4.10$, p = 0.05, $\eta_p^2 = 0.10$); fast gait normalized velocity ($F_{1,35} = 3.92$, p = 0.06, $\eta_p^2 = 0.10$), fast cadence ($F_{1,35} = 1.01$, p = 0.32, $\eta_p^2 = 0.03$) or fast normalized stride length ($F_{1,35} = 3.92$, p = 0.06, $\eta_p^2 = 0.10$); fast cadence ($F_{1,35} = 1.01$, p = 0.32, $\eta_p^2 = 0.03$) or fast normalized stride length ($F_{1,35} = 6.60$, p = 0.01, $\eta_p^2 = 0.16$); steps per day ($F_{1,35} = 0.21$, p = 0.65, $\eta_p^2 = 0.01$); sustained phonation maximum duration ($F_{1,35} = 0.91$, p = 0.35, $\eta_p^2 = 0.03$) or mean frequency ($F_{1,35} = 0.92$, p = 0.34, $\eta_p^2 = 0.03$); rainbow passage total time ($F_{1,35} = 0.80$, p = 0.40, $\eta_p^2 = 0.02$) or STSD ($F_{1,35} = 6.24$, p = 0.02, $\eta_p^2 = 0.15$); or 9HPT dominant ($F_{1,35} = 0.00$, p = 0.95, $\eta_p^2 < 0.01$) or nondominant ($F_{1,35} = 3.94$, p = 0.06, $\eta_p^2 = 0.10$).

Qualitatively, based on extracting themes from comments in the exit survey from the 17 participants in the intervention group, seven participants reported perceiving a benefit from one or more exercises in the mHealth application, four participants reported feeling motivated by the mHealth application, and three participants reported the mHealth application was easy to use. Also, four participants reported the mHealth application was repetitive,

nine participants reported that they did not like one or more of the exercises in the mHealth application, and 11 participants reported experiencing technical issues that interfered with their use of the mHealth application.

Discussion

The present study investigated the usability of an mHealth application to address gait, speech and dexterity symptoms in people with PD. While previous studies suggest technology can be used to provide at-home treatment for people with PD and rehabilitation and health organizations endorse incorporating mHealth technologies into treatments to overcome difficulties with treatment access [35], the results of the present study suggest that targeted treatment using an mHealth application alone may not be adequate to measurably or meaningfully improve gait, speech and/or dexterity in people with PD.

Based on prior research using mHealth technology to administer therapy to people with PD, we expected to see improvements in the targeted domains for the mHealth application used in the present study. However, differences in experimental design in the present study compared with previous studies may have contributed to differences in outcomes. Previous research incorporating mHealth technology often involves either therapist consultation or performance feedback for users. In the present study participants only received instruction on how to use the mHealth application without receiving a direct therapist intervention, consultation or performance feedback.

A previous study demonstrated a device administering cued gait training could be successfully implemented in a patient's home to treat gait impairments. However, the administration of the cueing technology supervised by a trained therapist may have contributed to the benefits reported [36]. The supervision and training from a therapist may have contributed to the benefits seen from the cueing technology. Likewise, LSVT[®]LOUD treatment, administered in conjunction with at-home technology can be as effective as treatment alone; however, participants received multiple training sessions with a therapist prior to using the technology [18], which may have contributed to the efficacy of the technology-based treatment. The present study did not show improvements in gait or speech outcomes in the intervention group, suggesting a therapist intervention may still be necessary in order to receive benefit from a treatment that incorporates at-home technology. In a study investigating an at-home dexterity exercise program participants only received feedback once during a 4-week intervention and still yielded positive outcomes [19], suggesting that even limited therapist intervention may be feasible.

Adherence to treatment is important for mHealth interventions. Our participants did not exhibit high adherence rates, unlike a previous study using an mHealth treatment for weight loss [22]. That study noted that participants who received the most benefit from the treatment were those who had the highest number of website logins. The present study's low adherence demonstrates a limitation in the usability of the application, which may have played a role in its lack of effect in treating symptoms of PD.

Qualitatively, participants seemed willing to use an mHealth application and some participants perceived improvements from doing the exercises. However, participants also noted the exercises were repetitive and more than half of the participants did not like one or more of the exercises.

Limitations

The present study had several limitations. Our sample exhibited mild–moderate symptoms of PD, had higher average steps per day than healthy older adults [37], and had lower MDS-UPDRS-III scores than scores typically associated with deficits that affect daily living [3]. Thus, participants did not have as much potential for improvement as people with more severe PD. Compared with the literature, participants in the present sample had higher average steps per day than healthy older adults [37]. Additionally, MDS-UPDRS-III scores also can take up to 2 years to show significant declines, so 3 months was not a long enough timespan to see significant changes in disease severity [9].

The sample size of the present study was small. Examining the usability of the mHealth application was the primary focus and thus the study was not powered to test outcomes or efficacy of the mHealth application. The effect sizes reported should therefore not be used for future sample size calculations.

Another limitation facing research using mHealth applications for rehabilitation is the regulations for therapist– patient interaction, especially when geographic location may prohibit treatment if licensure is not accepted across jurisdictions [36]. In the case of the mHealth application used in this study, support service specialists are typically provided to work with clients via telephone in order to provide feedback on treatment. However, due to the study design and geographic limitations, these support service specialists were not provided to participants in the present study. Our participants only received technical support for the mHealth application from our staff. The lack of counselor feedback and communication, known to provide motivation and assistance to the patient [38], may have hindered the efficacy of the mHealth treatment in our study. Also, usability is an important factor that can impact the efficacy of an mHealth treatment [21], so technological issues experienced by our participants and low adherence may have interfered with their outcomes.

Conclusion

Here we showed that providing an mHealth application without therapist consultation or intervention was not adequate to improve gait, speech or dexterity. The results of this study suggest that usability of an mHealth application and incorporating therapist intervention remain important elements of technology-based treatment.

Future perspective

For future studies, usability of mHealth technology should be enhanced and subjected to continuous quality improvement. In addition, therapist interventions with and without concurrent supplemental mHealth treatments should be investigated to determine the extent to which mHealth treatments may be able to either enhance therapist interventions, while reducing frequency of therapist contact.

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Author contributions

AP Horin: acquisition, analysis and interpretation of data, drafting and revising the work, final approval, agreement to be accountable for all aspects of the work. ME McNeely: substantial contribution to conception and design, acquisition of data, drafting and revising the work, final approval, agreement to be accountable for all aspects of the work. EC Harrison: substantial contribution to conception and design, acquisition of data, drafting and revising the work, final approval, agreement to be accountable for all aspects of the work. PS Myers: substantial contribution to conception and design, acquisition of data, drafting and revising the work, final approval, agreement to be accountable for all aspects of the work. EN Sutter: acquisition of data, drafting and revising the work, final approval, agreement to be accountable for all aspects of the work. KS Rawson: acquisition, analysis and interpretation of data, drafting and revising the work, final approval, agreement to be accountable for all aspects of the work. KS Rawson: acquisition, analysis and interpretation of data, drafting and revising the work, final approval, agreement to be accountable for all aspects of the work. KS Rawson: acquisition, analysis and interpretation of data, drafting and revising the work, final approval, agreement to be accountable for all aspects of the work. KS Rawson: acquisition, analysis and interpretation of data, drafting and revising the work, final approval, agreement to be accountable for all aspects of the work. GM Earhart: substantial contribution to conception and design, analysis and interpretation of the data, drafting and revising the work, final approval and agreement to be accountable for all aspects of the work.

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Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

Data sharing statement

The authors certify that this manuscript reports original clinical trial data. The data will not be made publicly available.

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