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Evaluating A New Movement Tracking App to Engage Kids in Home Exercise Programs – A Protocol for a Mixed Methods Single Case Experimental Design with Alternating Treatments

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ABSTRACT

Introduction

Children with cerebral palsy (CP) are prescribed home exercise programs (HEPs) to increase the frequency of movement practice, yet adherence to HEPs can be low. This paper outlines the protocol for a single case experimental design (SCED) with alternating treatments, using a new home therapy exercise application, Bootle Boot Camp (BBCamp), offered with and without movement tracking feedback. This study will explore the impact of biofeedback on engagement, movement quality, lower limb function and family experiences to help understand how technology supported HEPs should be translated and the added value, if any, of movement tracking technology.

Methods and analysis

In this explanatory sequential mixed methods study using a SCED, sixteen children with cerebral palsy (ages 6-12 years, GMFCS Levels I-II) will set lower limb goals and be prescribed an individualized HEP by their physiotherapist to complete using BBCamp on their home television equipped with a 3D camera-computer system. Children will complete four weekly exercise sessions over six weeks. Children will be randomized to 1 of 16 alternating treatment schedules where BBCamp will provide or withhold feedback during the first four weeks. The version of BBCamp that results in the most therapeutic benefit will be continued for two final weeks. Goals will be re-evaluated, and families interviewed. The primary outcome is adherence (proportion of prescribed exercise repetitions attempted) as a measure of behavioural engagement. Secondary outcomes are affective and cognitive engagement (smiley face ratings), exercise fidelity, lower limb function, goal achievement, and participant experiences. SCED data will be analyzed using visual and statistical methods. Quantitative and qualitative data will be integrated using joint displays.

Ethics and dissemination

Ethical approval was obtained from the Research Ethics Boards at Bloorview Research Institute and the University of Toronto. Results will be distributed through peer-reviewed journals and scientific conferences.

Trial registration number:

NCT05998239; Pre-results.

Key Words: cerebral palsy; exercise (exercise therapy); home-based rehabilitation; virtual applications; virtual reality; gaming; mixed methods

ARTICLE SUMMARY

Strengths and limitations of this study

- This study uses a family- and user-centred approach by supporting accessible opportunities for home-based exercise program completion and assessment delivery while collaborating with knowledge holders to optimize feasibility of study implementation.
- The single case alternating treatments design of this study provides an alternative to group-based research to establish intervention effectiveness within diverse and heterogenous populations (e.g., children with CP), and allows comparison of two interventions without the need for a baseline period or removal of an intervention that may result in a reversal of therapeutic benefits.
- There is the potential that exposure to one intervention may impact children's engagement with the other intervention. Methodological approaches (e.g., the "best alone" phase and randomization) will be used to mitigate this potential limitation.
- While several measures used in this study have established psychometric rigor, some have not been assessed virtually and/or within the home environment or via an interactive computer play technology before. Video demonstrations and instructions of measures will be provided to increase children's understanding of assessment procedures with video recordings of measures reviewed to ensure appropriate completion. Use of repeated measures and mixed methods will further enable increased confidence and depth of understanding of data.

INTRODUCTION

Cerebral palsy (CP) comprises the largest diagnostic group treated within pediatric rehabilitation with a prevalence of 1.6 per 1000 live births worldwide.[1,2] Home exercise programs (HEPs) are widely prescribed to children with CP to improve motor and functional performance.[3,4] For some children, limited access to therapy services, long wait lists and resource constraints result in HEPs accounting for the majority of therapeutic services received.[3,4] Children must receive a high dose of practice combined with goal-directed training, and demonstrate exercise fidelity (i.e. perform the exercises as prescribed) to obtain benefits from an exercise program.[1,5,6] The key to achieving this is promoting children's engagement. Engagement in rehabilitation can be described as a multifaceted state of motivational commitment to the treatment process and encompasses affective (emotional participation), behavioural (active involvement with the treatment plan) and cognitive (conviction that the intervention will be successful in eliciting change) components.[7] Engagement in traditional, non-interactive HEPs can be difficult to promote as manifested by low adherence rates (34-67%), limiting potential effectiveness.[4,8] Self-efficacy (i.e., belief in one's ability to learn or perform a skill at a particular level) is a strong predictor of motivation and exercise adherence.[9]

Interactive computer play (ICP) technologies, computer games or virtual reality technologies that allow users to interact with virtual environments, can motivate children to engage in movement practice while offering "active ingredients" that may facilitate program efficacy, including opportunities for problem-solving, individualization, feedback, and social equalization.[10] These features may also promote the acquisition and retention of motor skills (i.e., motor learning).[11] Movement tracking technologies are now available that can support a greater level of individualization and biofeedback (e.g., information collected about motor performance and communicated back to the user)[6] in ICP-based exercise programs. By facilitating enhanced mastery of skills and confidence, this targeted and individualized feedback may improve motivation and adherence. While movement-tracking is becoming more ubiquitous, it often requires additional sensors and set-up which can be a barrier to translation. Understanding how movement tracking feedback within an exercise application (app) impacts engagement, exercise fidelity, and lower limb outcomes in children with CP will help guide design and translation of technologies to support families with HEPs.

Aims, Objectives and Hypotheses:

The use of a home-based therapy exercise app, Bootle Boot Camp (BBCamp), will be investigated in children with CP, ages 6-12 years, Gross Motor Function Classification System (GMFCS) Levels I-II.[12] This mixed methods study aims to determine the impact of movement tracking feedback on engagement outcomes, primarily behavioural engagement (i.e., adherence), exercise fidelity, participant experiences, and the overall training impact of BBCamp on lower limb clinical outcomes by integrating quantitative and qualitative data.

Specific quantitative objectives are to:

1. Compare participants' levels of engagement with BBCamp with and without movement tracking feedback.
2. Evaluate quality of exercise performance (i.e., exercise fidelity) when participants use BBCamp with and without feedback.

3. Estimate the lower limb motor skills treatment response associated with 6-weeks of overall BBCamp training in the home.

Specific qualitative objective is to:

4. Explore children's, caregivers,' and physiotherapists' (PTs) experiences with BBCamp when used with and without feedback.

Hypotheses:

1. Adherence (proportion of exercise repetitions attempted relative to the number prescribed, as a measure of behavioural engagement) will be greater when BBCamp is played with movement tracking feedback. Affective engagement (study-specific Smileyometer rating scale[13,14] and survey) will be greater with movement tracking feedback in children with high self-efficacy who may enjoy individualized feedback to help refine movement skills. Social play may result in higher ratings independent of app version. Cognitive engagement (study-specific Smileyometer rating scale and survey) will be higher with feedback as children may perceive feedback to contribute more to therapy goals.
2. Exercise fidelity will be higher with movement tracking feedback as feedback will reinforce optimal movement performance.
3. At least 70% of participants will meet or exceed the minimum clinically important difference or minimal detectable change for the Five Time Sit Stand Test (FTSST),[15,16] Canadian Occupational Performance Measure (COPM),[17–20] and modified Timed Up and Go (mTUG).[21–23] Participants will improve by at least 15% (postulated to be clinically meaningful) on the One Leg Stance Test (OLST),[21,24] Pediatric Reach Test (PRT)[21,25] and 30 Second Sit to Stand test (30STS)[26–28] from initial assessment to re-assessment.

METHODS

Patient and Public Involvement in Creation of the Protocol

We engaged in informal interviews and collaborative sessions with key knowledge holders – a PT, child with CP and their caregiver - to gain insight on the feasibility of our research protocol. This participatory approach to research was guided by the Ontario Brain Institute's framework for community member participation in research,[29] and the family engagement in research resource developed as part of the Family Engagement in Research certificate program (CanChild).[30] Knowledge holders provided feedback on the following research components:

- Relevance of research, priority of research questions and outcomes (e.g., identified the importance of treatment response and engagement, followed by exercise fidelity. Knowledge holders recommended monitoring of children's mood and pain).
- Feasibility of study plan (e.g., confirmed 4 exercise sessions per week would be manageable for families if exercises sessions were limited to 30 minutes).
- Advisement of recruitment strategy (e.g., recommended study recruitment pathways through families and clinicians to ensure equitable access).
- Advice on recruitment and study materials vocabulary (e.g., revised research flyers and training resources, recommended use of lay language).

Trial Design

This study is a semi-randomized, non-blinded, single-case experimental design (SCED) with alternating treatments, and employs a mixed methods explanatory sequential approach.[31–33] The design comprises quantitative data collection and initial analysis first (weeks 1 to 6), followed by a qualitative component (weeks 7 to 8) to provide a more robust understanding of quantitative results (Figure 1, Table 1).[32] Integration was introduced at the study design level by including an overall mixed methods objective, at the methods level using quantitative data to help *build* the qualitative interview guide,[34] and within the analysis where quantitative and qualitative data will be *merged* using joint displays.[35] Mixed methods integration will be guided by pragmatism which supports use of different research methods to produce practical solutions.[36] A visual model depicting the study's mixed methods, as recommended by Ivankova et al.[32] is shown in Figure 1.

Insert **Figure 1**. Visual model depicting the study's mixed methods explanatory sequential design.

Single-case methodology involves the intensive study of one or several participants serving as their own controls, where an intervention is experimentally controlled and the target behaviour is measured repeatedly.[37] In an alternating treatments design (ATD), two interventions are compared by rapidly alternating the interventions, with each change of condition representing a demonstration of effect on a target behaviour.[38] Five or more alternations are recommended.[38,39] In this 6-week study (the minimum time needed to elicit a measurable treatment effect),[40] the comparison will consist of home-based BBCamp exercise sessions offered with movement tracking feedback, alternating with BBCamp sessions offered without feedback for 4 weeks. A "best alone" period will follow, where the BBCamp version producing the most therapeutic data pattern (see 'Best Alone' Phase below) will be solely offered for 2 weeks to limit threats to internal validity.[41,42] Participants will be able to distinguish between the two treatment conditions, a requirement for ATDs,[42] through the presence or absence of virtual Coach Botley who will provide or withhold feedback. Adherence, the primary outcome in this study, is considered a reversible behaviour likely to revert to baseline levels when the intervention is removed, with no learning expected.[38]

Randomization and blinding procedure

A randomization schedule which considers a limit of two maximum consecutive administrations of the same condition (e.g., BBCamp play with or without feedback) will be conducted using R open source software (RcmdrPlugin.SCDA package) via the 'quantity' function, such that all possible permutations are calculated.[43] This restriction is established to minimize possible order effects and threats to internal validity.[38,41] Sixteen treatment schedules with random alternation of feedback will be randomly selected (e.g., to provide one treatment schedule per participant) using the 'selectdesign' function (e.g., B-B-C-B-C-C-B-C-C-B-C-B-C-B-C-B) where B = BBCamp with movement tracking feedback and C = BBCamp without feedback.[43] Participants will be randomized to a treatment schedule using the app software. The study design with the treatment schedule, as exemplified for a single participant, is shown in Table 1.

Table 1. Study design, treatment, and measurement schedule where B = Bootle Boot Camp (BBCamp) with movement feedback and C = the app without movement tracking feedback, as exemplified for a single participant.

	Pre-Comparison	Comparison Phase																Best Alone Phase								Follow-Up	
Week	Week 0	Week 1				Week 2				Week 3				Week 4				Week 5				Week 6				Week 7	Week 8
Session		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24		
Condition		B*	B	C	B	C	C	B	C	C	B	C	B	C	B	C	B	B	B	B	B	B	B	B	B		
Phase	QUANTITATIVE																									QUALITATIVE	
Demographics	x																										
PEDI-CAT	x																										
Revised PACES	x																										
CSAPPA	x																										
Objective 1: Behavioural, Affective, Cognitive Engagement																											
Adherence*		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Smileyometer*		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
BB Camp Acceptability Survey																	x										
Objective 2: Fidelity of Movement Practice																											
Exercise fidelity*		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Objective 3: Estimate Treatment Response																											
COPM	x																									x	
FTSST*		xxx																				xxx					
mTUG*			xxx																				xxx				
OLST*				xxx																				xxx			
PRT*				x																				x			
30STS*					xxx																				xxx		
Objective 4: Child, Caregiver and Therapist Experiences and Perspectives																											
Interview																										x	x
SUS + BBCamp Usability Survey	x																										
MARS (one per app version)																	xx										
BBCamp Questions*		x	x	x	x	x	x	x	x	X	x	x	x	x	x	x	x	x	x	x	x		x	x	x		

Outcome measures denoted with * are assessments that will take place as part of BBCamp exercise sessions. PEDI-CAT, Pediatric Evaluation of Disability Inventory Computer Adaptive Test (speedy version); PACES, Physical Activity Enjoyment Scale; CSAPPA, Children's Self

Perceptions of Adequacy in and Predilection for Physical Activity Scale; COPM, Canadian Occupational Performance Measure; FTSST, Five Time Sit to Stand Test; mTUG, modified Timed Up and Go Test; OLST, One Leg Stance Test; PRT, Pediatric Reach Test; 30STS, 30 Second Sit to Stand Test; SUS, System Usability Scale; MARS, Mobile App Rating Scale.

Participants and Eligibility Criteria

PT-child-caregiver triads will be recruited. All must be able and willing to participate. Registered PTs with a minimum of one-year pediatric clinical experience, working at Holland Bloorview (Toronto, ON) or private clinics within Ontario and whose caseloads consist of clients with CP will be eligible. Specific child participant inclusion/exclusion criteria are shown in Table 2.

Table 2. Child participant inclusion and exclusion criteria.

INCLUSION CRITERIA	EXLCUSION CRITERIA
• Diagnosis of CP classified as GMFCS Level I or II (able to independently ambulate on level surfaces without assistive devices).[12] • Ages 6-12 years. • At least one goal related to the lower limb. • Able and willing to complete 4 weekly Bootle Boot Camp sessions for 6 weeks. • On an "off block" from physiotherapy services (not receiving physiotherapy services more than once every two months but still connected to a physiotherapist in the community). • Normal or corrected to normal vision and hearing. • Children and their caregivers can speak and understand the English language. • Has requisite space, internet services and technology (e.g., television, laptop, tablet) to use the app, complete electronic surveys, and participate in interviews via phone or video conference	• Has received a botulinum neurotoxin type A (BoNTA) injection in the previous 12 weeks or has undergone an orthopedic surgery in the previous six months. • Is scheduled to undergo serial casting, BoNTA injection, orthopedic surgery, or other significant medical intervention during the 6-week Bootle Boot Camp training period. • Photosensitivity or unstable epilepsy triggered by video games, screen activities or television light. • Visual or auditory deficits that would interfere with gameplay. • Respiratory, cardiovascular, or other medical conditions that might limit safe participation. • Actively engaging in a home exercise program or training program targeting progressive muscle strengthening or balance training of the lower limbs as prescribed by a health care provider or researcher. Children that are engaging in home exercise for maintenance or stretching purposes will not be excluded. • Has an intensive medical or therapeutic schedule in which cumulative services are scheduled on more than 3 days per week. • Any scheduled event (e.g., family trip) that would likely prevent the participant from completing four weekly exercise sessions during the 6-week training period.

Sample Size

A small number of participants is adequate to make reliable conclusions in SCEDs, with power derived from the number of repeated measures.[44] Previous SCED research suggests a sample size of n=5 is sufficient.[45] However, more participants (e.g., 9 to 17) are needed to reach thematic saturation when analysing qualitative data.[46] Age and gender are also believed to potentially impact BBCamp play experiences. To allow us to explore the diverse experiences of children with CP, ages 6-12 years, using mixed methods, we aim to have 12 participants across 4 strata with 3 participants per stratum (boys and girls, ages 6-8 and 9-12 years). To account for 20% attrition within each stratum, we aim to recruit 16 participants (4 per stratum).

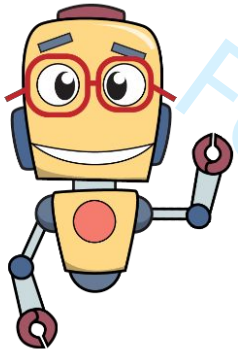
Recruitment

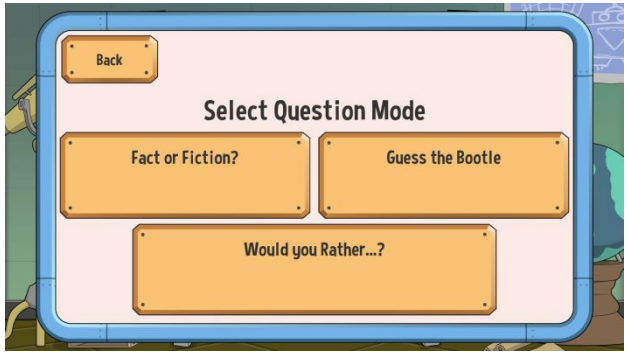
The PT and family research flyers will be distributed in person and virtually through local communication channels. Interested clinicians will be given full study information and asked to identify suitable clients, provide their families with research flyers, and direct families to contact the research team if interested. Families who self-refer will be asked to discuss the study with their child's PT and gain permission for the research team to contact the PT. To limit external variables (e.g., therapy sessions with PTs) from impacting study results, children who are in an active physiotherapy treatment block will not be eligible. Enrollment will be limited to one client per PT to maximize the breadth of PT input collected. Purposive sampling may be used to obtain an equal sample size within each age/gender stratum. Families and PTs will be contacted by MP to confirm interest, eligibility, and gain consent/assent.

Intervention

BBCamp is a therapy exercise app that is played on a television equipped with a 3D motion tracking camera, the Orbbec Persee+ (https://orbbec3d.com).[47] BBCamp promotes physical activity and movement quality through a selection of lower limb exercises targeting range of motion, strengthening, balance, and cardiorespiratory fitness. Exercises and movement quality criteria were developed by lead author/student investigator/physiotherapist, MP, and co-investigator/physiotherapist, FVW, who have over 30 years of combined PT exercise intervention experience. Criteria were additionally reviewed by a group of 5 community and private practice PTs. BBCamp leads children through their HEPs as prescribed by their PT. BBCamp was created with consideration of the key characteristics of biofeedback,[6] and can be played with or without this feedback. It was also designed to offer the "active ingredients" of ICP (Table 3). A video outlining BBCamp can be found at the following link: https://www.youtube.com/watch?v=od4xeEfwPCA.

Table 3. "Active ingredients" of Bootle Boot Camp.

"Active Ingredient"	Implementation into Bootle Boot Camp
1. INDIVIDUALIZATION 	• Allows clinicians to individualize treatment plans by offering a wide selection of standing and seated lower limb exercises in the areas of range of motion/strengthening, balance, and cardiorespiratory fitness. • Treatment parameters can be customized to the child's ability level and needs (e.g., number of repetitions, sets, duration for timed-exercises). • Clinicians can identify whether exercises should be performed unsupported or supported (e.g., holding on to the back of a chair) with video demonstrations for both unsupported and supported versions available to guide movement performance in addition to exercise instructions. • Children can customize the game play environment by selecting a robot (i.e., Helper Bot) to exercise with. The child's chosen name also appears on the main menu screen of the game.
2. OPPORTUNITIES FOR PRACTICE 	• Clinicians can specify the relevant dose and frequency of practice. • Children are encouraged to perform exercise sessions four times per week in alignment with the American College of Sports Medicine (ACSM) and the National Strength and Conditioning Association (NSCA) guidelines for people with CP that recommend strength/resistance training at a frequency of 2-4 times per week.[48,49] • A child is given 3 extra repetition attempts above what has been prescribed by their clinician to try and complete repetitions with good quality. For timed exercises such as stretches, clinicians can prescribe up to 60s for each set of the exercise. A child then has 3 attempts over a 2-minute period to hold the pose or perform the movement for the prescribed amount of time before the next exercise is loaded. Setting these repetition and timed-exercise caps will ensure a child does not spend too long on any one exercise to minimize frustration and fatigue. Clinicians are made aware of built in caps prior to program prescription through an introductory Bootle Boot Camp video that they will watch as part of study onboarding.

3. SOCIAL PLAY EQUALIZATION  	• Children can complete exercise sessions in one-player or two-player mode, allowing for social interaction and barrier free inclusion during gameplay. In multiplayer mode, both players complete the same exercise plan which is tailored to the child who has been prescribed the HEP. This may help to sustain motivation and engagement.
4. MOTIVATION  	• Choice and rewards help to support motivation within the game. • Participants are given a choice to play 1 of 3 game modes: Guess the Bootle, Fact or Fiction, or Would You Rather? • Throughout the game, children are rewarded for optimal movement performance and exercise session completion with Bootle Bucks, the game's form of currency. Bootle Bucks can be spent in the Bootle Bootique where children can choose from a wide array of accessories for their Helper Bot (e.g., pets, gear), different background displays and music to exercise to. • Children are further rewarded with in-game badges and streaks for completion of the prescribed exercise sessions each week and across weeks. Examples of badges include: the Bootle Bump Badge for completion of all four exercise sessions during training week 1 and the Bootle Bonanza Badge for completion of sessions during training week 6. Examples of streaks include the Double Trouble Streak for completion of 8 exercise sessions in 2 weeks and the Bootle Boot Camp Champion for completion of 24 exercise sessions across 6 weeks. • On movement feedback days, children are awarded star-ratings after every exercise based on the quality of their movement performance (exercise fidelity) (i.e., <50% of reps completed with appropriate fidelity = 1 star; 50-75% of reps completed with appropriate fidelity = 2 stars; >75% of reps completed with appropriate fidelity = 3 stars).

	• Children are rewarded for exercise session completion with an animated 'You're Done' song and Bootle celebration.
5. PROBLEM SOLVING 	• Opportunities for problem-solving are provided through visual and audio cues, where children are encouraged to consider their movement performance and whether their body is in optimal alignment (e.g. are your feet far enough apart?).
6. FEEDBACK 	• The game tracks important metrics including the type and frequency of games played, game scores, duration of active and total play time, and number of total repetitions (with and without appropriate fidelity). The game has the capacity to provide biofeedback through the tracking of joint positions. The child's head, trunk and joint positions are tracked and compared against predefined movement acceptability criteria programmed into the software for each exercise, such that each repetition is classified as acceptable (meets criteria, performed with appropriate fidelity) or not acceptable. The game can be played with or without movement tracking feedback. Children are made aware of which version of the app they are playing by the presence or absence of virtual Coach Botley. • **Key Biofeedback Characteristics[6]:** • ***Method of Presentation:*** Game feedback is immersive and multimodal. Feedback is delivered through visual, audio and reward mechanisms within the game environment. Visual and audio feedback exists in the form of markers (e.g., trunk lean, movement speed indicators), and prescriptive prompts (e.g., take a bigger step back).

- ***Movement Variable:*** Feedback is based on movement execution (e.g., completion of sit-to-stand, lunge), with joint angle (e.g., hip flexion, knee flexion) used to determine successful or unsuccessful movement execution using predefined movement acceptability criteria.
- ***Focus of attention:*** The system tracks participants' body movements and performance and offers customized *knowledge of performance* feedback (i.e., related to the quality of movement performance) (e.g., visual lean indicator showing an estimate of the level of truncal lean observed) and *knowledge of results feedback* (i.e., related to the overall outcome of task completion) (e.g., repetition counter that increases when an exercise repetition is performed with appropriate fidelity and does not increase when it is not performed with appropriate fidelity).
- ***Timing of Feedback:*** Feedback is provided concurrently during a repetition attempt (e.g., lean and speed indicators showing child's approximate degree of trunk lean and movement speed) and terminally (e.g., if repetition is deemed acceptable, repetition counter increases). Feedback is also offered in summary form where a child can review the movement quality markers they did well and those that can be improved upon for each exercise after session completion.
- ***Frequency of feedback:*** Feedback frequency is faded based on the child's performance to promote mastery and prevent dependence. During initial task practice, feedback is consistent if <50% of repetitions are completed with appropriate fidelity. When 50-75% of repetitions are completed correctly, feedback begins to fade and is provided at the end of every other repetition for the next exercise session with feedback. When >75% of repetitions are completed with appropriate fidelity, feedback is offered in summary form.
- ***Autonomy over feedback:*** A self-selected, detailed summary of the child's exercise performance is available at the end of exercise sessions on feedback days. The summary screen shows movement indicators done well and those that could be improved upon, current and average star ratings for the selected exercise, and a graph showing star ratings awarded across sessions (as recommended by knowledge holders).

Device and Program Set Up

PTs will receive BBCamp training as follows: watch a BBCamp introductory video, access a web version of the app, and review a PT manual to onboard their client to the HEP.

PTs will schedule an in-person session with their client that will be observed by MP, in person or virtually, who will document any usability issues using an observational checklist and provide technical support/answer questions as needed. The PT will establish lower limb functional goals with their client and will devise a BBCamp training program for their client to complete at home (without supervision from the PT) for four days per week, as is recommended for children with CP.[48,49] The training program will consist of individualized, lower limb exercises provided in the BBCamp app, with treatment parameters provided by the PT that are appropriate to the client and their goals (e.g., repetitions, sets). The PT will instruct the child on how to perform each exercise by reading aloud exercise instructions, showing the child video demonstrations using BBCamp, and having the client trial one set of each exercise. The PT will provide education on smiley face scales used throughout the intervention to rate engagement (as guided by the PT manual). The PT will have no further supervisory role (e.g., will not monitor the child's weekly sessions) as per usual standard of care for off-block therapy periods. MP will contact children by telephone to rate their goals using the COPM. A BBCamp kit (i.e., Persee+ system, BBCamp User Guide and 3m measuring tape to support correct performance of the modified Timed Up and Go test) will be provided to families. MP and/or co-investigator/software engineer, AK, will virtually attend the child's first exercise session to help with system set up and provide technical support.

Procedures

Comparison Phase (weeks 1-4)

Children will complete their prescribed HEP for 4 weeks using BBCamp, with movement feedback offered or withheld by the app (as determined within the child's randomization schedule and programmed into BBCamp by AK). The first four sessions (week 1) will begin with clinical assessments listed in Table 1 (in order of assessment delivery). Integrating administration of gross motor measures within the child's daily routine (e.g., within their HEP) will help children gain knowledge about their performance while minimizing disruption to the child.[50] The Persee+ will video record exercise performance and testing sessions and will track the number of exercise repetitions attempted and the number completed with appropriate fidelity. Families will be sent weekly e-mail reminders by MP encouraging completion of exercise sessions. At the end of the fourth week, children will complete a short survey and caregivers will rate each app version using the Research Electronic Data Capture (REDCap)[51,52] tools hosted at Holland Bloorview Kids Rehabilitation Hospital.

'Best Alone' Phase (weeks 5-6)

The visual data associated with each participant's adherence during the 4-week comparison phase will be analysed to determine which condition resulted in the highest behavioural engagement. The 'optimal' intervention will be selected using one of four decision rules (listed in order of consideration of decision).[53] Option 'a' will consist of calculating the percentage of non overlapping data (PND) with greater than 90% between data paths indicative of the superior intervention.[45] Option 'b' will be selecting the intervention with the highest mean proportion of prescribed exercise repetitions attempted. Option 'c' will represent the child's choice of

preferred system. Option 'd' will be random selection via coin toss. The 'optimal' intervention will be offered for 2 additional weeks. In week 6, clinical assessments will be re-tested. If there are any outstanding assessments (i.e., child does not complete all exercise sessions during week 6), families will be contacted by MP and asked to log into the system to complete testing. No game play will be available during this time.

Follow Up (weeks 7-8)
Families will return BBCamp kits, goals will be re-evaluated, and families will take part in semi-structured interviews. Figure 2 outlines the full study procedure.

Insert **Figure 2:** Study procedure flow diagram

Clinical Tests and Measures
Demographic Questionnaires and Baseline Measures
Measures will be administered via REDCap to be completed independently by older children (i.e., 9-12 years) or with caregiver support for younger children (i.e., 6-8 years), unless otherwise specified. Demographic data will be collected from all participants pre-intervention, including age, sex, and self-reported gender. Children will report their enjoyment, frequency, and motivation for playing video games. Caregivers will report their relationship to the child, ethnicity, household income, education, employment and marital status, residence, and comfort with technology. PTs will report clinical experience, practice setting, populations worked with, use of video games, exercise prescription methods, and client's diagnosis and GMFCS level.

Pediatric Evaluation Disability Inventory Computer Adaptive Test (PEDI-CAT) Speedy Version
Children's level of function will be assessed using the PEDI-CAT,[54] as completed by the child's caregiver via a secure online link. The PEDI-CAT is a reliable and valid measure of daily performance when used with children with CP and measures functional skills in the domains of daily activities, mobility, social/cognition and responsibility.[54] There are two versions: the content balanced and speedy version.[54] The speedy version will be used to obtain precise score estimates from 5-15 items per domain.[54] The PEDI-CAT will help provide baseline information about the child's function which may be explored during post-intervention interviews to understand its impact on BBCamp experiences. The responsibility domain provides information at the participation level of the International Classification of Functioning, Disability and Health for children and youth (ICF-CY),[55] by assessing a child's involvement in life tasks.[56]

Revised Physical Activity Enjoyment Scale (Revised PACES)
Children's pre-intervention enjoyment of physical activity will be assessed using the revised Physical Activity Enjoyment Scale (PACES).[57] The revised PACES measures positive affect associated with physical activity through 16 statements that begin with the stem: "When I am physically active…."[57] The PACES has been previously used with children and youth with CP.[58,59] Items are measured on a 5-point Likert-type, with the score computed by calculating the average of the 16 items.[57] The measure will provide baseline information about the child's physical activity enjoyment which may be explored during interviews to understand impact on BBCamp experiences (ICF-CY activity and participation domains).

Children's Self Perceptions of Adequacy in and Predilection for Physical Activity Scale (CSAPPA)

Children's physical activity self efficacy will be assessed pre-intervention using the Children's Self Perceptions of Adequacy in and Predilection for Physical Activity Scale (CSAPPA).[60–63] This 19-item, validated measure can be used to assess self-perception of adequacy and ability to perform exercises, and desire to join physical activities across 3 subscales in children aged 9-16 years,[61,62] and in those with CP. [62,63] Self-efficacy scores range from 19-76, with ≥60 indicative of high self-efficacy.[62] CSAPPA self-efficacy data may be explored during interviews to understand impact on BBCamp experiences.

Behavioural, Affective, and Cognitive Engagement Outcomes (Objective 1)

Adherence (Behavioural Engagement) (Primary Outcome)

Exercise repetition attempts will be tracked and recorded each session by the Persee+. Children will have three extra repetition attempts above what is prescribed by the clinician to try and perform movements with appropriate form (see 'opportunities for practice' in Table 3). Adherence will be expressed as a proportion (i.e., number of repetitions attempted divided by number prescribed) (see Supplementary File 1 for exercise scoring examples).

Smileyometer Ratings (Affective and Cognitive Engagement)

Affective and cognitive engagement will be measured within BBCamp after every session using study-specific Smileyometer 5-point rating scales.[13,14] "Did you have fun today?" and "did today's session help your body?" will be used as the questions to measure affective and cognitive engagement, respectively. To optimize response scale understanding for each question, children will be guided by their PT to first select activities they have the most fun and least fun doing, and activities they perceive to be most helpful and least helpful for their body during their in-person session. These activities will appear as pictorial scale anchors, as is done with the Personalized Enjoyment Questionnaire.[64]

Bootle Boot Camp Acceptability Survey

Children will be sent a study-specific survey at the end of the four-week comparison period to assess the perceived therapeutic effectiveness of each version. The survey consists of rating scales, open responses, and selecting app version questions (e.g., select the version that helped your body the most).

Fidelity of Movement Practice (Objective 2)

Exercise Fidelity

Exercise repetitions will be recorded by the Persee+, compared to predefined movement criteria programmed into the system and counted as 'acceptable' (meets criteria; performed with fidelity) or 'not acceptable.' Exercise fidelity will be measured in both treatment conditions (i.e. with feedback and without feedback), but feedback on exercise quality will only be presented to children in the feedback version. For timed exercises (e.g., stretches), the child will have up to three trials to achieve their highest level of performance, as is done with the Challenge – a measure of advanced gross motor skills for children with CP.[65] The child's best performance (i.e., longest time achieving movement criteria) will then be used to measure fidelity. Exercise fidelity will be expressed as a proportion (i.e., number of acceptable repetitions divided by

number prescribed or best time divided by time prescribed) (Supplementary File 1).

Treatment Response (Objective 3)

Lower limb treatment response will be assessed using a battery of clinical tests: the FTSST,[15,16] the mTUG,[21–23] the OLST,[21,24] the PRT,[21,25] the 30STS,[26–28] and through goal achievement using the COPM[17–20] pre- and post-intervention (Table 4). Clinical tests will be administered during training weeks 1 and 6 and will appear as warmup activities within BBCamp.

Table 4. Battery of clinical tests and measures used to evaluate treatment response.

Clinical Assessment	Outcome	Administration	Scoring	Measurement Properties (Psychometrics)	Research Relevance
The Five Time Sit to Stand Test (FTSST)[15,16]	Functional lower limb muscle strength	- Measures the time (seconds) needed to complete five sit-to-stand cycles as fast as possible from a chair without armrests.[15]	- Rate (repetitions/second) - Mean rate (repetitions/second) of three trials is calculated.[15]	**Validity:** - Convergent validity supported by significant correlation with one-repetition maximum of the loaded sit-to-stand test, isometric muscle strength, scores of Gross Motor Function measure and gait function (*rho* = 0.40–0.78) in children with cerebral palsy (CP).[15] **Reliability:** - High intra-session reliability in children with CP (intraclass correlation coefficient (ICC) = 0.95).[15] - High test-retest reliability in children with CP (ICC=0.99).[15] **Standard Error of Measurement (SEM):** - SEM = 0.02 in children with CP.[15] **Minimal Detectable Difference (MDD):** - MDD = 0.06 repetitions/second in children with CP.[15]	- Previous studies have explored remote performance of the FTSST, concluding that it may be a useful instrument to conduct regular in-home assessments.[46]
Modified Timed Up and Go (mTUG)[21–23]	Functional mobility and balance	- Measures the time (seconds) needed to rise from a chair, walk 3 meters, turn, walk back to the chair, and sit down. - In the modified version, instructions are repeated,	- Time (seconds) - Mean time (seconds) of three trials is calculated.[22]	**Validity:** - Moderate to strong inverse correlations with GMFM, 10 seconds sit to stand test, Berg Balance Scale (*rho* = -0.88) and walking speed (*rho* = -0.93) in children with CP.[21]	- Has the potential to differentiate performance between children at different GMFCS levels and different subtypes of CP.[21]

		and concrete tasks are used (e.g., children asked to touch a target) as compared to the more abstract instructions in the TUG that have been shown to limit performance in children with CP.[22]		**Reliability:** - High test-retest reliability (ICC = 0.99) of the TUG in children with CP. [21] - High within-session reliability in young people with CP (ICC = 0.99).[22] - High inter-rater reliability (time) (ICC = 0.99) of the TUG in children with typical development (TD).[21] **Standard Error of Measurement:** - SEM = 1.00 (second) in children with CP.[21] **Minimal Clinically Important Difference (MCID):** - MCID GMFCS I (medium effect size; 0.5) = 1.1.[23] - MCID GMFCS I (large effect size; 0.8) = 1.7.[23] - MCID GMFCS II (medium effect size; 0.5) = 0.7.[23] - MCID GMFCS II (large effect size; 0.8) = 1.2.[23]	- Track record of use in studies involving children with CP and virtual reality therapies.[66]
One Leg Stance Test (OLST)[21,24]	Static standing balance and stability	- Measures the time a child can maintain their balance on one leg (on each leg) with their eyes open and hands on their hips. - The time (seconds) is measured between when the foot lifts off the ground to when the child unfolds their arms, moves weight bearing to the	- Time (seconds) - Longest/best time (seconds) of three trials is calculated for each leg.	**Validity:** - Significant correlation between the OLST and Pediatric Balance Scale in TD children aged 7-8 years.[24] - Moderate to very strong correlations with one legged hopping (*rho* = 0.75) and balance beam walking (*rho* = 0.74) in children with TD.[21] **Reliability:** - High intra-rater reliability (ICC = 0.99) in children with CP and TD.[21]	- Requires minimal equipment making it ideal to test in the home environment.[24] - Maintaining balance on one leg for 45 seconds is considered good balance.[24]

		other side or exceeds 45 seconds.[24]		- High inter-rater reliability (ICC =0.99) in children with CP and TD.[21] **Standard Error of Measurement:** - SEM = 10.16 (seconds) in TD children.[21] - SEM = 8.71 (seconds) in children with hearing impairment.[21]	
Pediatric Reach Test (PRT)[21,25]	Dynamic balance	- Measures the distance (cm) that a child can reach forward and sideways from a standing and seated position without losing their balance across six positions:[40] 1. Reaching forward in sitting 2. Reaching to the right in sitting 3. Reaching to the left in sitting 4. Reaching forward in standing 5. Reaching to the right in standing 6. Reaching to the left in standing	- Total distance (centimeters) - The difference between starting and end positions of the third metacarpal during each task is measured and summed to produce a final score/total sum (centimeters).[51]	**Validity:** - Moderately to strongly related to step length (*rho* = -0.67 to -0.72) in children with traumatic brain injury (TBI).[21] **Reliability:** - Intra-rater reliability in children with CP (ICC=0.54-0.88).[21] - Inter-rater reliability in children with CP (ICC=0.50-0.93).[21] - Test-retest reliability in children with CP (ICC = 0.54-0.88).[51] - Inter-tester reliability in children with CP (ICC = 0.50-0.93).[51] **Standard Error of Measurement:** - SEM = 0.97 (forward)(cm), 0.72 (lateral, preferred arm) (cm) and 0.80 (lateral, nonpreferred arm) (cm) in children with TBI.[21]	- Based on the Functional Reach Test (defined as maximum distance one can reach forward beyond arm's length while maintaining a fixed base of support in standing)[21] that was developed for use in adult populations and was determined to be a reasonable approximation of a force platform measure of the foot centre of pressure excursion (gold standard).[51]
30 Second Sit to Stand Test (30STS)[26–28]	Functional lower limb muscle strength	- Child is asked to stand up from a chair without using their arms and return to a seated position over a thirty second period.	- Number of full stands achieved. - Mean number of repetitions across three trials is calculated.[26]	**Reliability:** - Good test-retest reliability (ICC = 0.84) in older adults with dementia.[26] - Excellent intra-session reliability (ICC > 0.9) in adults with knee osteoarthrtitis.[27]	- May be more suitable to evaluate exercise capacity and tolerance (as compared to the shorter version sit to stand tests).[28]

		- Measures the number of full-stands that a participant can achieve in this time interval.[26]		**Standard Error of Measurement:** - SEM = 1.26 in older adults with dementia.[26] **Minimal Detectable Change:** - $MDC_{individual}$ = 2.5 stands in adults with knee osteoarthritis.[27] - MDC_{group} = 0.3-0.4 stands in adults with knee osteoarthritis.[27] - MDC = 3.49 in older adults with dementia.[26] **Minimum Clinically Important Difference:** - MCID = ≥ 2 repetitions in older adults with chronic obstructive pulmonary disease.[28]	
Canadian Occupational Performance Measure (COPM)[17–20]	Goal achievement	- Measure used to assess client outcomes in occupational performance in the areas of self-care, productivity, and leisure. - User rates level of importance, performance and satisfaction on each activity using a 10-point rating scale.[17]	- Performance and satisfaction score (rated from 0 to 10) - Higher ratings indicate greater importance, better performance and greater satisfaction.[18]	**Validity:** - Good construct validity when parents used as proxies for young children with CP.[19] - Significantly correlated to the Satisfaction with Performance Scaled questionnaire, Reintegration to Normal Living Index and Perceived Problems List.[20] **Reliability:** - Acceptable internal consistency reliability for performance (mean alpha 0.73) and satisfaction (mean alpha 0.82) when parents used as proxies for young children with CP.[19]	- Extensively used in pediatric rehabilitation for goal-setting and as an outcome measure.[18] - Used in rehabilitation research as individualized, client-focused goals align with the activities and participation domains of the ICF framework.[17]

				Minimal Clinically Important Difference: - A change of at least 2 points from initial assessment to reassessment is considered a clinically meaningful change.[20]	

Child, Caregiver and Physiotherapist Experiences and Perspectives (Objective 4)

BBCamp Questions (Mood, Energy, Pain)

Children will be asked to rate their mood, energy level, and pain pre/post exercise sessions. Mood will be assessed using Pick-A-Mood,[67] a cartoon-based pictorial self-report scale where users select one of eight different characters to represent their mood states.[67] Energy level will be measured using a study-specific battery rating scale ranging from 0 (no energy) to 10 (lots of energy). Pain will be measured using the Wong-Bakers Faces Pain Scale,[68] consisting of six gender-neutral faces ranging from no pain (0) to the most pain possible (10).[68] These data may be further explored in interviews to understand their impact on engagement outcomes.

Mobile App Rating Scale (MARS)

Caregivers' perceived value and usability of BBCamp will be evaluated using the MARS,[69] a scale assessing app quality via 5 subscales: engagement, functionality, aesthetics, information quality, and subjective quality.[69] Caregivers will complete one MARS per app version following the 4-week comparison period.

Semi Structured Interviews with Families

Children and caregivers will take part in semi-structured interviews (together or separate based on child preference) within 2-weeks of training completion to better understand their experiences with using BBCamp. Individual and dyad interviews have been used in previous studies exploring children's engagement with ICP technologies.[70] The engagement framework described by King et al.[7] and implemented by James et al.[71] was used to create the preliminary interview guide (Supplementary File 2). Quantitative survey results will be used to further build the qualitative interview guide.[34]

System Usability Scale (SUS) and BBCamp Usability Survey

Following their in-person session with the child, PTs will receive two surveys via REDCap. The SUS[72,73] is a standard 10-item questionnaire that measures usability of digital health applications, with items measured on a 5-point Likert scale.[72,73] Total scores range from 0 to 100, with a score of >68 representing above average usability and >80 representing high usability.[72,73] The BBCamp Usability Survey will supplement SUS data with open-ended questions targeting satisfaction with app features for exercise prescription.

Data and quality management

BBCamp systems will be monitored regularly by AK to ensure that data are being recorded, transferred, encrypted, and stored. Action will be taken to troubleshoot any issues that arise if complete data are not received.

ANALYSIS

Based on the Single-Case Reporting Guidelines in Behavioural Interventions (SCRIBE)[74] recommendations, a combined visual and statistical approach will be used to analyze SCED data using Microsoft Excel and R open source software. There is no agreed upon criteria to guide this type of statistical analysis.[75]

Behavioural, Affective and Cognitive Engagement (Objective 1)

Visual Analysis: To determine whether a functional relationship exists between adherence (behavioural engagement) and app version, and between Smileyometer ratings (affective/cognitive engagement) and app version, engagement across exercise sessions will be plotted and line graphs will be analysed using visual inspection for level, trend, variability, and overlap, based on the standards published in the What Works Clearinghouse (WWC) Single-Case Designs Technical Documentation.[76]

Statistical Analysis: Mean adherence and Smileyometer scores during each condition will be calculated to compare the mean difference scores between app versions. A Single Case Randomization Test (SCRT) will be conducted to determine if difference scores are statistically significant.[38,43] A celeration line and probability table may be used to further confirm statistical significance, with significance determined if all data points of one treatment condition are above the celeration line for the other treatment condition.[45,75] Use of a celeration line fits with a one-tailed test of significance ($p < 0.05$) for behaviour change.[45,77] Further exploratory analyses may be performed to supplement primary findings.

Data from the BBCamp Acceptability Survey will be presented descriptively, with inferential statistics used to compare numerical rating responses related to affective/cognitive engagement for each app version. The non-parametric Wilcoxon signed rank test will be used to conduct this comparison. (Note: data will be checked for normality prior to analyses and if normal, the parametric counterparts to the statistical tests identified (e.g., paired t-test) will be used. In this and all other inferential analyses, power calculations will be completed in the event of no difference conclusions.

Exercise Fidelity (Objective 2)

Descriptive statistics will be used to summarize exercise fidelity across conditions, with the Wilcoxon signed rank test used to determine if differences are statistically significant.

Treatment Response (Objective 3)

Changes in FTSST, mTUG, OLST, PRT, and 30STS scores from week 1 to 6 and COPM scores from initial to reassessment will be compared to minimum detectable change and/or minimum clinically important difference values where available (Table 4). The Wilcoxon signed rank test will be used to determine if changes are significant.

Children's, Caregivers', and Physiotherapists' Experiences (Objective 4)

Reflective thematic analysis[78] will be used to learn about families' experiences with BBCamp. Audio recordings of semi-structured interviews will be transcribed and analysed inductively by two independent coders using NVivo 12.0 software.[79] A codebook will be created with regular team meetings held to discuss coding decisions, resolve coding conflicts, and develop preliminary and final themes. Study rigor will also be maintained through maintenance of reflexive notes. Caregivers' perspectives will be further reflected through descriptive presentation of MARS scores. To understand PTs' perspectives on app usability for exercise prescription, SUS and BBCamp Usability Survey data will be summarized descriptively.

Understand Engagement Outcomes Using Mixed Methods Data Integration

Quantitative engagement data and qualitative textual data will be integrated and interpreted using joint displays[35,80] to facilitate generation of new inferences and meta-inferences.[35,80] Meta-inferences will be classified as confirmed (findings from data sources agree), discordant (findings conflict) or expanded (findings expand understanding).[34,80]

ETHICS AND DISSEMINATION

The adverse events (AE) that seem most likely to occur are repetitive strain injuries resulting from repetitive motions, increased pace or poor body mechanics.[81] Since exercises and treatment parameters will be prescribed by PTs to meet the children's ability levels and goals, it is unlikely that app usage will result in an increased risk compared to traditional HEPs. The aims of this app are to promote physical activity, improve strength and movement quality which all help to reduce the risk of injury. AEs will be tracked within weekly emails, with any reported AEs prompting contact with the family by EB or FVW. The nature and severity of the AE will be documented on AE forms. These forms will be reviewed by an external safety monitoring committee (i.e., PT, pediatrician, and researcher) that will make recommendations for next steps for the study intervention. Protocol amendment procedures, reporting of adverse events and maintaining potential and enrolled participant confidentiality will be followed in accordance with Research Ethics Boards at Bloorview Research Institute and the University of Toronto. The Standard Protocol Items: Recommendations for Interventional Trials guidelines,[82] SCRIBE,[74] and the Good Reporting of a Mixed Methods Study (GRAMMS)[83] guided design and reporting. Results will be distributed through peer-reviewed journals and conferences, with knowledge holders informing the dissemination plan.

DISCUSSION

This paper outlines the research protocol for a SCED involving a new home therapy exercise app, BBCamp, with alternating treatments consisting of BBCamp offered with and without movement tracking feedback. Learning how biofeedback impacts engagement will help guide future implementation of BBCamp and similar apps. If movement tracking does not measurably increase engagement and/or exercise fidelity, it may be appropriate to release the app without movement tracking on commonplace mobile devices (e.g., tablets, phones, laptops) making it more accessible and cost effective for families. However, if movement tracking is important to ensure appropriate exercise performance and maintenance of engagement, then the advantages of using BBCamp with the specialized technology that supports movement tracking likely outweighs the implementation barriers (e.g., US$379.99 cost for Persee+).[47] This research will provide important insight on how/if gamification of HEPs can support children and families in engaging in home movement practice. It will further clarify the need for biofeedback in ICP technologies to facilitate positive children's rehabilitation experiences and clinical outcomes.

AUTHOR CONTRIBUTIONS

MP reviewed relevant literature, helped develop BBC, outlined the research design and protocol, selected outcome measures, sought ethical approval, and drafted the manuscript. EB and FVW contributed to BBCamp development, guided research design and outcome measure selection, revised the manuscript, and provided supervision. AK helped with BBCamp development and research design implementation. SM contributed to the mixed methods research component and DF contributed to the eligibility criteria and knowledge holder involvement processes.

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COMPETING INTERESTS
Holland Bloorview is supporting the creation of a company called Pearl Interactives to commercialize products like BBCamp so that they can be made widely available to those who can benefit from them. EB and AK are shareholders in Pearl Interactives and may financially benefit from this interest if Pearl Interactives commercializes BBCamp in the future and is successful in marketing it. The terms of this arrangement have been reviewed and approved by Holland Bloorview Kids Rehabilitation Hospital and the University of Toronto in accordance with its policy on objectivity in research and will continue to be actively monitored to mitigate and manage any conflicts of interest. The remaining authors declare that the research was conducted in the absence of any potential conflicts of interest.

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SUPPLEMENTARY FILES
S1 - Adherence, exercise fidelity and star ratings as exemplified across four exercise sessions for a sample participant
S2 – Interview guide

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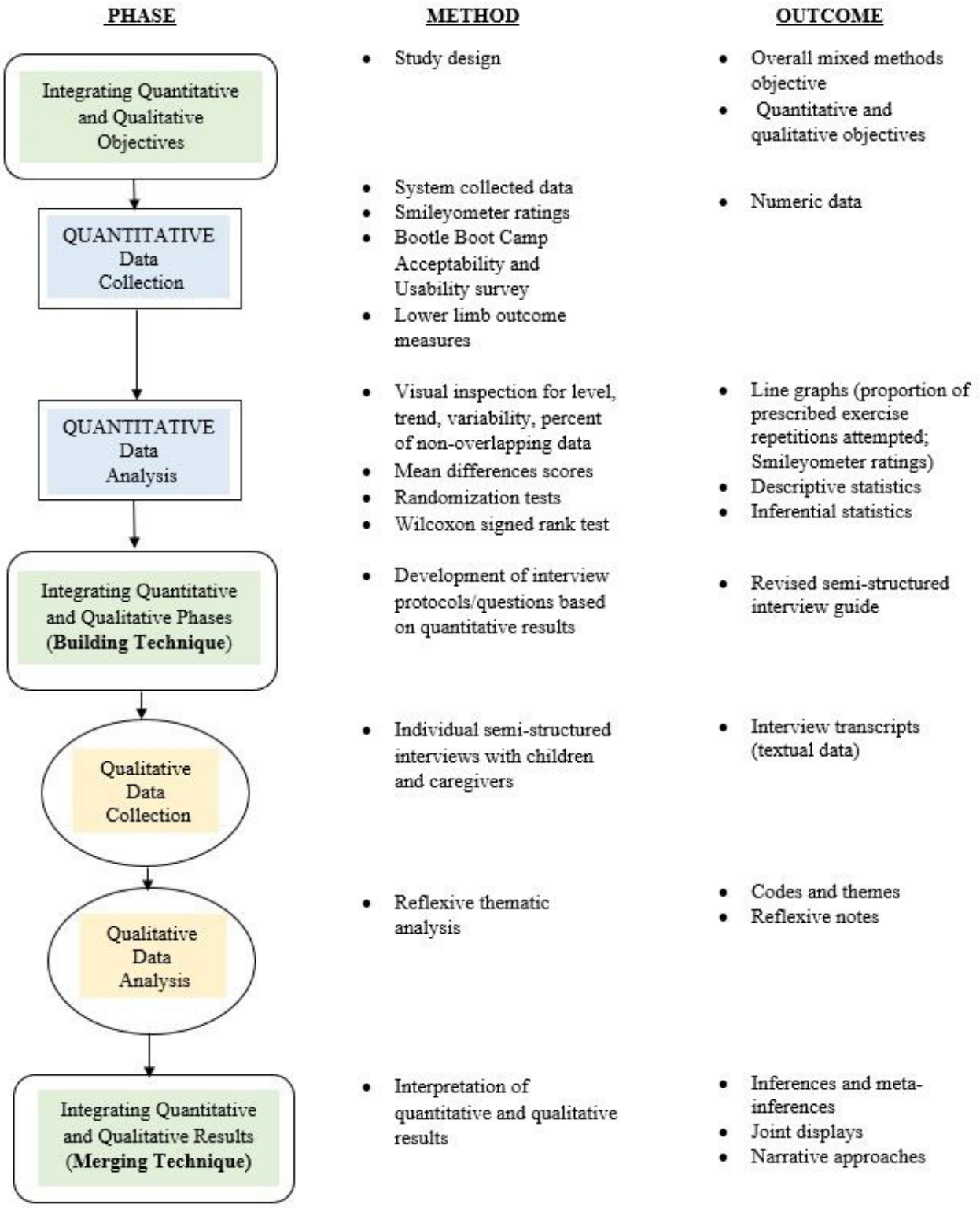

Figure 1. Visual model depicting the study's mixed methods explanatory sequential design.

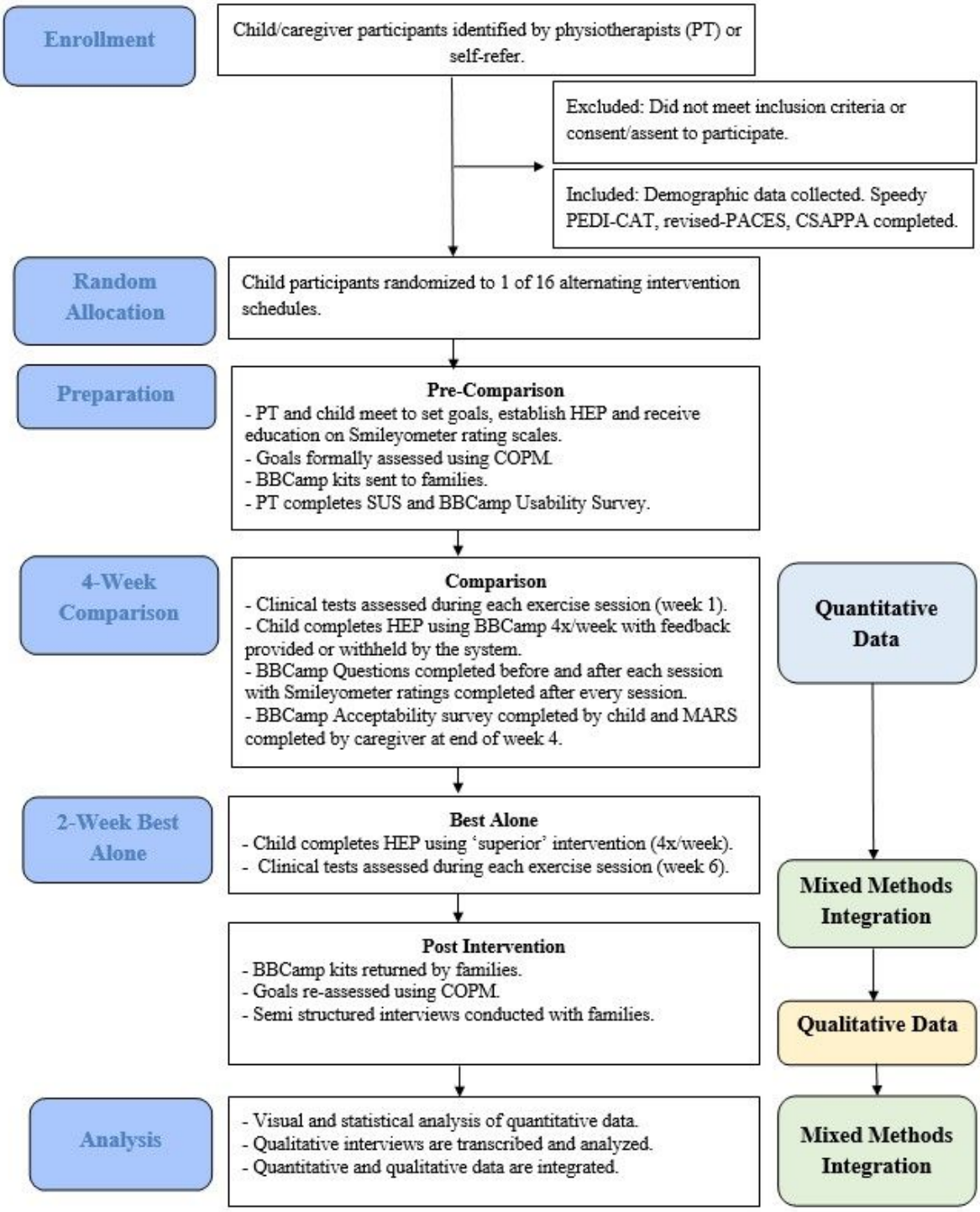

Figure 2. Trial procedure flow diagram.

PEDI-CAT, Pediatric Evaluation of Disability Inventory Computer Adaptive Test; PACES, Physical Activity Enjoyment Scale; CSAPPA, Children's Self Perceptions of Adequacy and Predilection for Physical Activity Scale; HEP, home exercise program; COPM, Canadian Occupational Performance Measure; BBCamp, Bootle Boot Camp; SUS, System Usability Scale; MARS, Mobile App Rating Scale.

Supplementary File 1. Adherence, exercise fidelity and star ratings as exemplified across four exercise sessions for a sample participant.

Prescribed Home Exercise Program			
Exercises	Repetitions	Sets	Time (seconds)
1. Sit to stand	10	2	N/A
2. Marching	N/A	1	30
3. Calf stretch	N/A	2	30

Day 1 Exercise Session

Exercises	Repetitions or Timed Attempts	Repetitions or Time Prescribed (Per Set)	Proportion Attempted (Adherence)	Acceptable Repetitions or Best Time	Repetitions or Time Prescribed (Per Set)	Acceptable Proportion (Exercise Fidelity)	Star Rating* (Per Set)	Average Star Rating (Across Sets)
1.Sit to stand (set 1)	10	10	10/10 = 1.0	8	10	8/10 = 0.8	3	3 (8+9=17/20 =0.85)
2. Sit to stand (set 2)	10	10	10/10 = 1.0	9	10	9/10 = 0.9	3	
3.Marching	25s + 5s	30s	30/30s = 1.0	25	30	25/30 = 0.83	3	3
4.Calf stretch (set 1)	10s + 10s + 10s	30s	30/30 = 1.0	10	30	10/30 = 0.33	1	1 (10+10=20/60 =0.33)
5.Calf stretch (set 2)	10s + 10s + 10s	30s	30/30 = 1.0	10	30	10/30 = 0.33	1	
Mean Proportion of Prescribed Attempts			**1.0**	**Mean Proportion of Acceptable Attempts**		**0.64**		

*Star ratings are awarded based on exercise fidelity with 1 star awarded with <50% of repetitions are completed with appropriate fidelity, 2 stars when 50-75% of repetitions are completed with appropriate fidelity and 3 stars when >75% of repetitions are completed with appropriate fidelity.

Day 2 Exercise Session

Exercises	Repetition or Timed Attempts	Repetitions or Time Prescribed (Per Set)	Proportion Attempted (Adherence)	Acceptable Repetitions or Best Time	Repetitions or Time Prescribed (Per Set)	Acceptable Proportion (Exercise Fidelity)	Star Rating (Per Set)	Average Star Rating (Across All Sets)
1.Sit to stand (set 1)	12	10	12/10 = 1.2	8	10	8/10 = 0.8	3	3 (8+9=17/20 =0.85)
2. Sit to stand (set 2)	13	10	13/10 = 1.3	9	10	9/10 = 0.9	3	
3.Marching	15s + 10s + 5s	30s	30/30 = 1.0	15	30	15/30 = 0.5	1	1
4.Calf stretch (set 1)	10s + 5s + 12s	27	27/30 = 0.9	10	30	10/30 =0.33	1	1 (10+18=28/60 =0.47
5.Calf stretch (set 2)	18s + 12s	30s	30/30 = 1.0	18	30	18/30 = 0.60	2	
Mean Proportion of Prescribed Attempts			**1.08**	**Mean Proportion of Acceptable Attempts**		**0.63**		

Day 3 Exercise Session

Exercises	Repetition or Timed Attempts	Repetitions or Time Prescribed (Per Set)	Proportion Attempted (Adherence)	Acceptable Repetitions or Best Time	Repetitions or Time Prescribed (Per Set)	Acceptable Proportion (Exercise Fidelity)	Star Rating (Per Set)	Average Star Rating (Across All Sets)
1.Sit to stand (set 1)	7	10	7/10 = 0.7	5	10	5/10 = 0.5	1	1 (5+1=5/20 =0.25)
2. Sit to stand (set 2)	1	10	1/10 = 0.1	1	10	1/10 = 0.1	1	
2.Marching	5s + 5s	30s	10/30 = 0.33	5	30	5/30 = 0.17	1	1

3.Calf stretch (set 1)	29s + 1s	30s	30/30 = 1.0	29	30	29/30 =0.97	3	2 (29+6=35/60 =0.58
4.Calf stretch (set 2)	3s + 2s + 6s	30s	11/30 = 0.37	6	30	6/30 = 0.20	1	
Mean Proportion of Prescribed Attempts			**0.68**	**Mean Proportion of Acceptable Attempts**		**0.42**		

Day 4 Exercise Session

Exercises	Repetition or Timed Attempts	Repetitions or Time Prescribed (Per Set)	Proportion Attempted (Adherence)	Acceptable Repetitions or Best Time	Repetitions or Time Prescribed (Per Set)	Acceptable Proportion (Exercise Fidelity)	Star Rating (Per Set)	Average Star Rating (Across All Sets)
1.Sit to stand (set 1)	13	10	13/10 = 1.3	9	10	9/10 = 0.9	3	2 (9+4=13/20 =0.65)
2. Sit to stand (set 2)	5	10	5/10 = 0.5	4	10	4/10 = 0.4	1	
2.Marching	24s + 4s + 2s	30s	30/30 = 1.0	24	30	24/30 =0.80	3	3
3.Calf stretch (set 1)	10s + 10s + 10s	30s	30/30 = 1.0	10	30	10/30 =0.33	1	2 (10+28=38/60 =0.63)
4.Calf stretch (set 2)	28s	30s	28/30 = 0.93	28	30	28/30 =0.93	3	
Mean Proportion of Prescribed Attempts			**0.95**	**Mean Proportion of Acceptable Attempts**		**0.67**		

Supplementary File 2: Child and Caregiver Interview Guide

Note: Child- and caregiver-specific versions of the interview guide that are tailored to each participant and that use similar questions as those shown below will be used, where applicable. In the version presented, the child will be asked questions first, with caregivers given the opportunity to add comments following their child's responses (unless otherwise specified).

Part 1: Bootle Boot Camp Play Experience

1. Tell me about the **home exercise programs** that you usually do outside of this program.
2. Tell me about your **experiences using Bootle Boot Camp** to complete your home exercise program.
3. How does using Bootle Boot Camp **compare** to the usual way you do exercises or therapy at home?

Part 2: Engagement Framework

1. What **hopes** did you have for using Bootle Boot Camp?

CAREGIVER: What **hopes** did you have for your child using Bootle Boot Camp?

CAREGIVER: Did you feel playing Bootle Boot Camp would be **valuable** for your child? Why or why not?

2. How did you **feel** about playing Bootle Boot Camp? Why did you feel this way?
3. Did you **like getting feedback** on the way you performed your exercises? Why or why not?

CAREGIVER: How do you think the movement feedback from Coach Botley impacted your **child's feelings** and **experiences** playing Bootle Boot Camp?

CAREGIVER: What did you **like** and **not like** about the movement feedback given to your child by Coach Botley? Why is that?

4. Would you have liked to get **feedback** on your exercise performance **in a different way**?
5. Did your **level of excitement**/wanting to play Bootle Boot Camp change over the 6 weeks? If so, how did it change?

CAREGIVER: Did you notice any changes to your child's **level of engagement** during the study period? If so, can you explain these changes?

6. How did you feel about your ability to **exercise** and **be active** using **Bootle Boot Camp**?
7. Did the feedback **affect your confidence with exercising**? If yes, how so?

CAREGIVER: Did you feel **confident** in your ability to support your child's home use of Bootle Boot Camp? Why or why not?

CAREGIVER: Were four exercise sessions manageable for you and your child's schedule? Why or why not?

8. Did you **expect to see changes** in yourself or your body after using Bootle Boot Camp? Why or why not?

CAREGIVER: Did you **expect to see changes** in your child or your child's body after using Bootle Boot Camp?

CAREGIVER: Did you think that Bootle Boot Camp would be **useful for your child to achieve their goals**? Why or why not?

9. Did you **see any changes** in yourself or your body after using the app for 6 weeks? What were those changes, if any?

CAREGIVER: Did you **see any changes** in your child or your child's body after using the app for 6 weeks? What were those changes, if any?

10. Do you think the exercise feedback **changed your exercise performance**?

CAREGIVER: Did Botley's movement feedback impact your **child's exercise performance**? If so, how?

11. Do you feel Coach Botley was **needed** to help you perform the exercises to the best of your abilities? Why or why not?
12. How did the **feedback from Botley compare to the feedback your physiotherapist might give you** during a regular therapy session?
13. How did you **feel not being able to contact your physiotherapist** while using Bootle Boot Camp?

CAREGIVER: Which version of the app did you **prefer**? Why?

Part 3: Survey Results

1. In the survey, you indicated that the [Feedback/No feedback/Both] version was the **most fun to play**. Can you tell me more about why you chose this?
2. In the survey, you reported that [Feedback/No Feedback/Both] version made you feel the **most confident** that you could do the exercises well. Can you tell me more about why you chose this?
3. In the survey, you indicated that the [Feedback/No feedback/Both] version **helped your body the most**. Can you tell me more about why you chose this?
4. In the survey, you stated that [Feedback/No Feedback/Both] version **helped you try and reach your goals** the most. Can you tell me more about why you chose this?

CAREGIVER**:** Based on the rating scales, you gave the Bootle Boot Camp app without feedback an X **star rating** and the version with movement feedback an X **star rating.** Tell me more about why you gave each version of the app these ratings?

Part 4: Future Use

1. What changes should be made to the Bootle Boot Camp app to make it better for kids to use in the future?
2. What information would you want Bootle Boot Camp to track? What information would you want to be able to see, have your parents see, your physiotherapist?

CAREGIVER: What **information or training** do you think would have been beneficial for you to have to support your child's use of Bootle Boot Camp within the home? How would you like to receive this information or training (e.g., in person training session with physiotherapist, training session with game developers or technical support team, instructions manual, etc.)

CAREGIVER: What **supports** do you think are necessary for Bootle Boot Camp to be used in the home?

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	29
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 28

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	1
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	29
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	4
Objectives	#7	Specific objectives or hypotheses	4-5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will	9

		perform the interventions (eg, surgeons, psychotherapists)	
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	18
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	18-19, 25
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	10
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6

Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	16
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7, 16-25
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	17
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	25
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	25-27
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A

Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	27
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	27
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	27
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	27

Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	28
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	27
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

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Evaluating the Impact of Movement Tracking Feedback on Children with Cerebral Palsy's Engagement with Home Exercise Programs Using a New Therapy App – A Protocol for a Mixed Methods Single Case Experimental Design with Alternating Treatments

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Evaluating the Impact of Movement Tracking Feedback on Children with Cerebral Palsy's Engagement with Home Exercise Programs Using a New Therapy App – A Protocol for a Mixed Methods Single Case Experimental Design with Alternating Treatments

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ABSTRACT

Introduction

Children with cerebral palsy (CP) are prescribed home exercise programs (HEPs) to increase the frequency of movement practice, yet adherence to HEPs can be low. This paper outlines the protocol for a single case experimental design (SCED) with alternating treatments, using a new home therapy exercise application, Bootle Boot Camp (BBCamp), offered with and without movement tracking feedback. This study will explore the impact of feedback on engagement, movement quality, lower limb function and family experiences to help understand how technology supported HEPs should be translated and the added value, if any, of movement tracking technology.

Methods and analysis

In this explanatory sequential mixed methods study using a SCED, sixteen children with cerebral palsy (ages 6-12 years, GMFCS Levels I-II) will set lower limb goals and be prescribed an individualized HEP by their physiotherapist to complete using BBCamp on their home television equipped with a 3D camera-computer system. Children will complete four weekly exercise sessions over six weeks. Children will be randomized to 1 of 16 alternating treatment schedules where BBCamp will provide or withhold feedback during the first four weeks. The version of BBCamp that results in the most therapeutic benefit will be continued for two final weeks. Goals will be re-evaluated, and families interviewed. The primary outcome is adherence (proportion of prescribed exercise repetitions attempted) as a measure of behavioural engagement. Secondary outcomes are affective and cognitive engagement (smiley face ratings), exercise fidelity, lower limb function, goal achievement, and participant experiences. SCED data will be analyzed using visual and statistical methods. Quantitative and qualitative data will be integrated using joint displays.

Ethics and dissemination

Ethical approval was obtained from the Research Ethics Boards at Bloorview Research Institute and the University of Toronto. Results will be distributed through peer-reviewed journals and scientific conferences.

Trial registration number:

NCT05998239; Pre-results.

Key Words: cerebral palsy; exercise (exercise therapy); home-based rehabilitation; virtual applications; virtual reality; gaming; mixed methods

ARTICLE SUMMARY

Strengths and limitations of this study

- This study uses a family-centred approach by supporting accessible opportunities for home movement practice and assessment delivery while collaborating with knowledge holders to optimize feasibility of study implementation.
- The single case alternating treatments design of this study provides an alternative to group-based research to establish intervention effectiveness within a diverse and heterogenous population (e.g., children with CP), and allows comparison of two interventions without the need for a baseline period or removal of an intervention that may result in a reversal of therapeutic benefits.
- Methodological approaches (e.g., the "best alone" phase and randomization) will be used to mitigate the potential that exposure to one intervention may impact children's engagement with the other.
- Instructions and video demonstrations of outcome measures that have not been previously assessed virtually and/or within the home environment will be provided to increase children's understanding of assessment procedures, with assessment video recordings reviewed to ensure appropriate completion.

INTRODUCTION

Cerebral palsy (CP) comprises the largest diagnostic group treated within pediatric rehabilitation with a prevalence of 1.6 per 1000 live births worldwide.(1,2) Home exercise programs (HEPs) are widely prescribed to children with CP to improve motor and functional performance.(3,4) For some children, limited access to therapy services, long wait lists and resource constraints result in HEPs accounting for the majority of therapeutic services received.(3,4) Children must receive a high dose of practice combined with goal-directed training, and demonstrate exercise fidelity (i.e. perform the exercises as prescribed) to obtain benefits from an exercise program.(1,5,6) The key to achieving this repetitive and salient movement practice is promoting children's engagement. Engagement in rehabilitation can be described as a multifaceted state of motivational commitment to the treatment process and encompasses affective (emotional participation), behavioural (active involvement with the treatment plan) and cognitive (conviction that the intervention will be successful in eliciting change) components.(7) Engagement in traditional, non-interactive HEPs can be difficult to promote as manifested by low adherence rates (34-67%), limiting potential effectiveness.(4,8) Self-efficacy (i.e., belief in one's ability to learn or perform a skill at a particular level) is a strong predictor of motivation and exercise adherence.(9)

Interactive computer play (ICP) technologies, computer games or virtual reality technologies that allow users to interact with virtual environments, can motivate children to engage in movement practice.(10) ICP systems offer "active ingredients" that may facilitate program efficacy, including opportunities for problem-solving, individualization, social equalization and feedback.(10) These features may also promote the acquisition and retention of motor skills (i.e., motor learning).(11) ICP systems have been successfully used to support home movement practice in children with CP including commercial entertainment systems (e.g., Nintendo Wii,(12) Sony EyeToy(13)) and systems designed specifically for therapeutic purposes (e.g., Timocco,(14) Move It to Improve It (Mitii),(15,16) PedBotHome(17)). While commercial entertainment systems often incorporate motivational game elements such as variability, reward systems, competition and goal setting, they may be too difficult for children with CP who are not the target user.(18) Rehabilitation-specific systems, while offering an appropriate level of challenge, often lack these engaging gamification elements.(18)

Extrinsic feedback (i.e., information collected by an external source and communicated back to the user)(6,19) that is individualized and targeted may improve motivation and adherence by facilitating enhanced mastery of skills and confidence within the context of ICP-based exercise programs. Mainstream movement tracking technologies such as the Microsoft Kinect sensor(20) and the Orbbec Persee(20) can support a greater level of customized feedback. However, the addition of motion tracking sensors is associated with an added expense and additional set up requirements, both of which can introduce barriers to uptake and translation. Understanding how/if movement tracking feedback within a novel therapy exercise application (app), Bootle Boot Camp (BBCamp), impacts engagement, exercise fidelity, and lower limb outcomes in children with CP will help guide design and translation of these technologies to best support families with HEP completion.

Aims, Objectives and Hypotheses:

The use of a home-based therapy exercise app, BBCamp, offered with and without movement tracking feedback, will be investigated in children with CP, ages 6-12 years, Gross Motor Function Classification System (GMFCS) Levels I-II.(21) The overall mixed methods objective of this research protocol is to determine the impact of movement tracking feedback on engagement outcomes, primarily behavioural engagement (i.e., adherence), exercise fidelity, participant experiences, and the overall training impact of BBCamp on lower limb clinical outcomes by integrating quantitative and qualitative data.

Specific quantitative objectives are to:

1. Compare participants' levels of engagement with BBCamp with and without movement tracking feedback.
2. Evaluate quality of exercise performance (i.e., exercise fidelity) when participants use BBCamp with and without movement tracking feedback.
3. Estimate the lower limb motor skills treatment response associated with 6-weeks of overall BBCamp training in the home.

Specific qualitative objective is to:

4. Explore children's, caregivers,' and physiotherapists' (PTs) experiences with BBCamp when used with and without movement tracking feedback.

Hypotheses:

1. Adherence (proportion of exercise repetitions attempted relative to the number prescribed, as a measure of behavioural engagement) will be greater when BBCamp is played with movement tracking feedback. Affective engagement (study-specific Smileyometer rating scale(22,23) and survey) will be greater with movement tracking feedback in children with high self-efficacy who may enjoy individualized feedback to help refine movement skills. Social play may result in higher ratings independent of app version. Cognitive engagement (study-specific Smileyometer rating scale and survey) will be higher with feedback as children may perceive feedback to contribute more to therapy goals.
2. Exercise fidelity will be higher with movement tracking feedback as feedback will reinforce optimal movement performance.
3. At least 70% of participants will meet or exceed the minimum clinically important difference or minimal detectable change for the Five Time Sit Stand Test (FTSST),(24,25) Canadian Occupational Performance Measure (COPM),(26–29) and modified Timed Up and Go (mTUG).(30–32) Participants will improve by at least 15% (postulated to be clinically meaningful) on the One Leg Stance Test (OLST),(30,33,34) Pediatric Reach Test (PRT)(30,35) and 30 Second Sit to Stand test (30STS)(36–38) from initial assessment to re-assessment.

METHODS

Patient and Public Involvement in Creation of the Protocol

We engaged in informal interviews and collaborative sessions with key knowledge holders – a PT, child with CP and their caregiver - to gain insight on the feasibility of our research protocol.

The participatory components of our research project were guided by the Ontario Brain Institute's framework for community member participation in research,(39) and the family engagement in research resource developed as part of the Family Engagement in Research certificate program (CanChild).(40) Knowledge holders provided feedback on the following research components:

- Relevance of research, priority of research questions and outcomes (e.g., identified the importance of treatment response and engagement, followed by exercise fidelity). Knowledge holders recommended monitoring of children's mood and pain.
- Feasibility of study plan (e.g., confirmed 4 exercise sessions per week would be manageable for families if exercises sessions were limited to 30 minutes).
- Advisement of recruitment strategy (e.g., recommended study recruitment pathways through families and clinicians to ensure equitable access).
- Advice on recruitment and study materials vocabulary (e.g., revised research flyers and training resources, recommended use of lay language).

Trial Design

This study is a semi-randomized, non-blinded, single-case experimental design (SCED) with alternating treatments, and employs a mixed methods explanatory sequential approach.(41–43) The design comprises quantitative data collection and initial analysis first (weeks 1 to 6), followed by a qualitative component (weeks 7 to 8) to provide a more robust understanding of quantitative results (Figure 1, Supplementary Material 1).(42) Integration was introduced at the study design level by including an overall mixed methods objective, at the methods level using quantitative data to help *build* the qualitative interview guide,(44) and within the analysis where quantitative and qualitative data will be *merged* using joint displays.(45) Mixed methods integration will be guided by pragmatism which supports use of different research methods to produce practical solutions.(46) A visual model depicting the study's mixed methods, as recommended by Ivankova et al.(42) is shown in Figure 1.

Insert **Figure 1**. Visual model depicting the study's mixed methods explanatory sequential design.

Single-case methodology involves the intensive study of one or several participants serving as their own controls, where an intervention is experimentally controlled and the target behaviour is measured repeatedly.(47) In an alternating treatments design (ATD), two interventions are compared by rapidly alternating the interventions, with each change of condition representing a demonstration of effect on a target behaviour.(41,48) Five or more alternations are recommended.(48,49) In this 6-week study (the minimum time needed to elicit a measurable treatment effect),(13) the comparison will consist of home-based BBCamp exercise sessions offered with movement tracking feedback, alternating with BBCamp sessions offered without feedback for 4 weeks. Since multitreatment interference may occur during the comparison condition in the form of rapid alternation effects, a "best alone" condition will follow.(50) In this "best alone" period, the BBCamp version producing the most therapeutic data pattern (see 'Best Alone' Phase below) will be solely offered for 2 weeks to limit this threat to internal validity (e.g., if data remain similar during this period, multitreatment interference is unlikely to have occurred).(50) Participants will be able to distinguish between the two treatment conditions,

a requirement for ATDs,(51) through the presence or absence of virtual Coach Botley who will provide or withhold feedback. Adherence, the primary outcome in this study, is considered a reversible behaviour likely to revert to baseline levels when the intervention is removed, with no learning expected.(48)

Randomization and blinding procedure

A randomization schedule which considers a limit of two maximum consecutive administrations of the same condition (e.g., BBCamp play with or without feedback) will be conducted using R open source software (RcmdrPlugin.SCDA package) via the 'quantity' function, such that all possible permutations are calculated.(52) This restriction is established to minimize possible order effects and threats to internal validity.(48,50) Sixteen treatment schedules with random alternation of feedback will be randomly selected (e.g., to provide one treatment schedule per participant) using the 'selectdesign' function (e.g., B-B-C-B-C-C-B-C-C-B-C-B-C-B-C-B) where B = BBCamp with movement tracking feedback and C = BBCamp without feedback.(52) Participants will be randomized to a treatment schedule using the app software. The study design with the treatment schedule, as exemplified for a single participant, is shown in Supplementary Material 1.

Participants and Eligibility Criteria

PT-child-caregiver triads will be recruited from January to June 2024. All must be able and willing to participate. Registered PTs with a minimum of one-year pediatric clinical experience, working at Holland Bloorview (Toronto, ON) or private clinics within Ontario and whose caseloads consist of clients with CP will be eligible. Specific child participant inclusion/exclusion criteria are shown in Table 1.

Table 1. Child participant inclusion and exclusion criteria.

INCLUSION CRITERIA	EXLCUSION CRITERIA
• Diagnosis of CP classified as GMFCS Level I or II (able to independently ambulate on level surfaces without assistive devices).(21) • Ages 6-12 years. • At least one goal related to the lower limb. • Able and willing to complete 4 weekly Bootle Boot Camp sessions for 6 weeks. • On an "off block" from physiotherapy services (not receiving physiotherapy services more than once every two months but still connected to a physiotherapist in the community). • Normal or corrected to normal vision and hearing. • Children and their caregivers can speak and understand the English language. • Has requisite space, internet services and technology (e.g., television, laptop, tablet) to use the app, complete electronic surveys, and participate in interviews via phone or video conference	• Has received a botulinum neurotoxin type A (BoNTA) injection in the previous 12 weeks or has undergone an orthopedic surgery in the previous six months. • Is scheduled to undergo serial casting, BoNTA injection, orthopedic surgery, or other significant medical intervention during the 6-week Bootle Boot Camp training period. • Photosensitivity or unstable epilepsy triggered by video games, screen activities or television light. • Visual or auditory deficits that would interfere with gameplay. • Respiratory, cardiovascular, or other medical conditions that might limit safe participation. • Actively engaging in a home exercise program or training program targeting progressive muscle strengthening or balance training of the lower limbs as prescribed by a health care provider or researcher. Children that are engaging in home exercise for maintenance or stretching purposes will not be excluded. • Has an intensive medical or therapeutic schedule in which cumulative services are scheduled on more than 3 days per week. • Any scheduled event (e.g., family trip) that would likely prevent the participant from completing four weekly exercise sessions during the 6-week training period.

Sample Size

A small number of participants, typically 1 to 3, is adequate to make reliable conclusions in SCEDs, with power derived from the number of repeated measures.(53) Previous single-case ATD research involving children with CP suggests a sample size of up to 6 participants is sufficient.(47) However, more participants (e.g., 9 to 17) are needed to reach thematic saturation when analysing qualitative data.(54) Age and gender are also believed to potentially impact BBCamp play experiences. Age has been shown to influence time spent playing virtual reality games, with increasing age associated with reduced game play.(55) A gender difference has also been well established, with boys spending significantly more time engaging in physical activity

as compared to girls and being more physically active while exergaming.(56,57) To allow us to explore the diverse experiences of children with CP, ages 6-12 years, using mixed methods, we aim to have 12 participants across 4 strata with 3 participants per stratum (boys and girls, ages 6-8 and 9-12 years). To account for 20% attrition within each stratum, we aim to recruit 16 participants (4 per stratum).

Recruitment

The PT and family research flyers will be distributed in person and virtually through local communication channels. Interested clinicians will be given full study information and asked to identify suitable clients, provide their families with research flyers, and direct families to contact the research team if interested. Families who self-refer will be asked to discuss the study with their child's PT and gain permission for the research team to contact the PT. To limit external variables (e.g., therapy sessions with PTs) from impacting study results, children who are in an active physiotherapy treatment block will not be eligible. Enrollment will be limited to one client per PT to maximize the breadth of PT input collected. Purposive sampling may be used to obtain an equal sample size within each age/gender stratum. Families and PTs will be contacted by MP to confirm interest, eligibility, and gain consent/assent.

Intervention

BBCamp is a therapy exercise app developed by an interdisciplinary team (i.e., physiotherapists, engineers, game designers, digital artists, researchers, family partners) at Holland Bloorview Kids Rehabilitation Hospital. It is played on a television equipped with a 3D motion tracking camera, the Orbbec Persee+ (https://orbbec3d.com).(58) BBCamp promotes physical activity and movement quality through a selection of lower limb exercises targeting range of motion, strengthening, balance, and cardiorespiratory fitness. Exercises and movement quality criteria were developed by lead author/student investigator/physiotherapist, MP, and co-investigator/physiotherapist, FVW, who have over 30 years of combined PT exercise intervention experience. Movement quality criteria were additionally reviewed by a group of 5 community and private practice PTs. BBCamp leads children through their HEPs as prescribed by their PT. BBCamp was created with consideration of the key characteristics of feedback,(6) and can be played with or without this feedback. It was also designed to offer the "active ingredients" of ICP(10) (Table 2). A video outlining BBCamp can be found at the following link: https://www.youtube.com/watch?v=od4xeEfwPCA.

Table 2. "Active ingredients" of Bootle Boot Camp.

"Active Ingredient"	Implementation into Bootle Boot Camp
INDIVIDUALIZATION	- Allows clinicians to individualize treatment plans by offering a wide range of standing and seated of range of motion/strengthening, balance, and cardiorespiratory fitness lower limb exercises. - Treatment parameters can be customized to the child's abilities/needs (e.g., number of repetitions, sets) - Clinicians can identify whether exercises should be performed unsupported or supported (e.g., holding on to the back of a chair) with video demonstrations for both versions available in addition to exercise instructions. - Children can customize the game play environment by selecting a robot (i.e., Helper Bot) to exercise with. The child's chosen name also appears on the main menu screen of the game.
OPPORTUNITIES FOR PRACTICE	- Clinicians can specify the relevant dose and frequency of practice. - Children are encouraged to perform exercise sessions four times per week in alignment with the American College of Sports Medicine (ACSM) and the National Strength and Conditioning Association (NSCA) guidelines for people with CP that recommend strength/resistance training 2-4 times per week.(59,60) - A child is given 3 extra repetition attempts above what has been prescribed by their physiotherapist to try and complete repetitions with good quality. For timed exercises (e.g., stretches), clinicians can prescribe up to 60s for each exercise set. A child then has 3 attempts over a 2-minute period to hold the pose or perform the movement for the prescribed amount of time before the next exercise is loaded. These repetition/time caps will ensure a child does not spend too long on any exercise to minimize frustration/fatigue. Physiotherapists are made aware of built in caps prior to plan prescription through an introductory Bootle Boot Camp video that they will watch during onboarding.
SOCIAL PLAY EQUALIZATION	- Children can complete exercise sessions in one-player or two-player mode, allowing for social interaction and barrier free inclusion during gameplay that may sustain engagement. In multiplayer mode, both players complete the same plan which is tailored to the child who has been prescribed the home exercise program.
MOTIVATION	- Choice and rewards help to support motivation within the game. - Players are given a choice to play 1 of 3 games: Guess the Bootle, Fact or Fiction, or Would You Rather? - Children are rewarded for optimal movement performance and exercise session completion with Bootle Bucks, the game's form of currency. Bootle Bucks can be spent in the Bootle Bootique where children can choose from different accessories (e.g., pets, gear) for their Helper Bot, different backgrounds and music. - Children are rewarded with in-game badges and streaks for completion of the prescribed exercise sessions each week and across weeks. Examples of badges and streaks include: the Bootle Bump Badge (4 sessions completed during training week 1) and the Double Trouble Streak (8 sessions completed across 2 weeks). - On movement feedback days, children are awarded star-ratings after every exercise based on movement quality (i.e., exercise fidelity). For repetition-based exercises, stars are awarded as follows: <50% of reps completed with appropriate fidelity = 1 star; 50-75% of reps completed with appropriate fidelity = 2 stars; >75% of reps completed with appropriate fidelity = 3 stars. For timed exercises (e.g., stretches), stars are awarded based on the best/longest

	time (of up to 3 trials) achieving movement criteria as follows: achieved for <50% of prescribed time = 1 star, achieved for 50-75% of prescribed time = 2 stars, achieved for >75% of prescribed time = 3 stars). - Post exercise session completion, players are rewarded with a 'You're Done' song and Bootle celebration.
PROBLEM SOLVING	- Opportunities for problem-solving are provided through visual and audio cues. Children are encouraged to consider their movement performance and their body alignment (e.g., are your feet far enough apart?).
FEEDBACK	- The game tracks the type and frequency of games played, game scores, duration of active and total play time, and number of exercise repetitions (with and without exercise fidelity). - The child's head, trunk and joint positions are tracked and compared to predefined movement acceptability criteria programmed into the software for each exercise. Each repetition is classified as acceptable (meets criteria, performed with exercise fidelity) or not acceptable. The game can be played with or without movement feedback. Children are made aware of the app version played by the presence or absence of virtual coach Botley. **- Key Feedback Characteristics**(6)**:** **1) Method of Presentation:** immersive/multimodal (visual, audio and reward). Visual/audio feedback is offered through indicators (e.g., movement speed), and prescriptive prompts (e.g., take a bigger step back). **2) Movement Variable*:*** based on movement execution (e.g., completion of sit-to-stand) with joint angle (e.g., hip flexion, knee extension) used to determine movement success using predefined movement acceptability criteria. **3) Focus of Attention*:*** the system tracks participants' body movements and performance and offers customized *knowledge of performance* feedback (i.e., related to the quality of movement performance) (e.g., visual speed indicator) and *knowledge of results feedback* (i.e., related to the outcome of task completion) (e.g., repetition counter that increases when a repetition is performed with exercise fidelity). **4) Timing of Feedback:** concurrent during a repetition attempt (e.g., visual indicator showing approximate degree of truncal lean), terminal (e.g., repetition counter increases if movement is performed with exercise fidelity), and in summary form (e.g., checklist of movement quality markers done well and those that can be improved upon for each exercise; graph showing star ratings for each exercise across exercise sessions). **5) Frequency of Feedback:** faded based on the child's performance t(o promote mastery and prevent dependence). During initial task practice, feedback is consistent if <50% of repetitions are completed with appropriate fidelity. When 50-75% of repetitions are completed appropriately, feedback fades and is provided at the end of every other repetition for the next exercise session with movement tracking feedback. When >75% of repetitions are completed with appropriate fidelity, feedback is offered in summary form. **6) Autonomy over Feedback:** a self-selected, detailed summary of the child's exercise performance is available at the end of every exercise session on feedback days. The summary screen shows movement criteria that were done well and those that could be improved upon, current and average star ratings for the selected exercise, and a graph showing exercise star ratings across sessions (as recommended by knowledge holders).

Device and Program Set Up

PTs will receive BBCamp training as follows: watch a BBCamp introductory video, access a web version of the app, and review a PT manual to onboard their client to the HEP.

PTs will schedule an in-person session with their client that will be observed by MP, in person or virtually, who will document any usability issues using an observational checklist and provide technical support/answer questions as needed. The PT will establish lower limb functional goals with their client and will devise a BBCamp training program for their client to complete at home (without supervision from the PT) for four days per week, as is recommended for children with CP.(59,60) The training program will consist of individualized, lower limb exercises selected from those available in the BBCamp app, with treatment parameters provided by the PT that are appropriate to the client and their goals (e.g., repetitions, sets). The PT will instruct the child on how to perform each exercise by reading aloud exercise instructions, showing the child video demonstrations using BBCamp, and having the client trial one set of each exercise. The PT will provide education on smiley face scales used throughout the intervention to rate engagement (as guided by the PT manual). The PT will have no further supervisory role (e.g., will not monitor the child's weekly sessions) as per usual standard of care for off-block therapy periods. MP will contact children by telephone to rate their goals using the COPM. A BBCamp kit (i.e., Orbbec Persee+ system with the child's individualized exercise plan uploaded, BBCamp User Guide and 3m measuring tape to support correct performance of the modified Timed Up and Go test) will be provided to families. MP and/or co-investigator/software engineer, AK, will virtually attend the child's first exercise session to help with system set up and provide technical support.

Procedures

Comparison Phase (weeks 1-4)

Children will complete their prescribed HEP for 4 weeks using BBCamp, with movement feedback offered or withheld by the app (as determined within the child's randomization schedule and programmed into BBCamp by AK). The first four sessions (week 1) will begin with clinical assessments listed in Supplementary Material 1 (in order of assessment delivery). The Persee+ will video record exercise performance and testing sessions and will track the number of exercise repetitions attempted and the number completed with appropriate fidelity. If exercise sessions are missed during week 1 (and the corresponding clinical assessments), these assessments will be tested during the first session of week 2. Video recordings of clinical assessments will be reviewed at the end of week 1 and if technical issues are noted (e.g., child not captured fully on video recording) or procedural issues observed (e.g., incorrect assessment completion), assessments will be repeated during the first session of week 2 with a member of the research team present virtually. Integrating administration of gross motor measures within the child's daily routine (e.g., within their HEP) will help children gain knowledge about their performance while minimizing disruption to the child.(61) Families will be sent weekly e-mail reminders by MP encouraging completion of exercise sessions. At the end of the fourth week, children will complete a short survey and caregivers will rate each app version using the Research Electronic Data Capture (REDCap)(62,63) tools hosted at Holland Bloorview Kids Rehabilitation Hospital.

'Best Alone' Phase (weeks 5-6)

The visual data associated with each participant's behavioural engagement (i.e., adherence) during the 4-week comparison phase will be analysed to determine which condition (i.e., BBCamp with or without movement tracking feedback) resulted in the highest behavioural engagement. The 'optimal' intervention will be selected using one of four decision rules (listed in order of consideration of decision).(64) Option 'a' will consist of calculating the percentage of non overlapping data (PND) between conditions.(50,65) The PND compares data points from one intervention to the data points of the other intervention and can range from 0 to 100%.(65) A PND greater than 90% between data paths is indicative of a highly effective treatment(65) and will be used to determine the superior intervention. If this is not satisfied, option 'b' will be selecting the intervention with the highest mean proportion of prescribed exercise repetitions attempted. Option 'c' will represent the child's choice of preferred system. Option 'd' will represent the caregiver's choice of preferred system. The 'optimal' intervention will be offered for 2 additional weeks. In week 6, clinical assessments will be re-tested. If there are any outstanding assessments (i.e., child does not complete all exercise sessions during week 6) or problems with assessment performance or recordings, families will be contacted by MP and asked to log into the system to complete testing or repeat testing with a member of the research team present virtually (as needed). No game play will be available during this time.

Follow Up (weeks 7-8)
Families will return BBCamp kits, goals will be re-evaluated, and families will take part in semi-structured interviews. Figure 2 outlines the full study procedure.

Insert **Figure 2:** Study procedure flow diagram

Clinical Tests and Measures
Demographic Questionnaires and Baseline Measures
Measures will be administered via REDCap to be completed by children with caregiver support as needed, unless otherwise specified. Caregivers will be instructed to review questionnaire instructions with children before allowing them to complete questionnaires independently, with caregivers providing support if/when asked by the child. Post questionnaire completion, children will be asked follow-up questions on REDCap to identify how much caregiver support was needed and who provided support. Demographic data will be collected from all participants pre-intervention, including age, sex, and self-reported gender. Children will report their enjoyment, frequency, and motivation for playing video games. Caregivers will report their relationship to the child, ethnicity, household income, education, employment and marital status, residence, and comfort with technology. PTs will report clinical experience, practice setting, populations worked with, use of video games, exercise prescription methods, and client's diagnosis and GMFCS level.

Pediatric Evaluation Disability Inventory Computer Adaptive Test (PEDI-CAT) Speedy Version
Children's level of function will be assessed using the PEDI-CAT,(66) as completed by the child's caregiver via a secure online link. The PEDI-CAT is a reliable and valid measure of daily performance when used with children with CP and measures functional skills in the domains of daily activities, mobility, social/cognition and responsibility.(66) There are two versions: the content balanced and speedy version.(66) The speedy version will be used to obtain precise score

estimates from 5-15 items per domain.(66) The PEDI-CAT will help provide baseline information about the child's function which may be explored during post-intervention interviews to understand its impact on BBCamp experiences. The responsibility domain provides information at the participation level of the International Classification of Functioning, Disability and Health for children and youth (ICF-CY),(67) by assessing a child's involvement in life tasks.(66)

Revised Physical Activity Enjoyment Scale (Revised PACES)

Children's pre-intervention enjoyment of physical activity will be assessed using the revised Physical Activity Enjoyment Scale (PACES).(68) The revised PACES measures positive affect associated with physical activity through 16 statements that begin with the stem: "When I am physically active…."(68) The PACES has been previously used with children and youth with CP.(69,70) Items are measured on a 5-point Likert-type scale, with the score computed by calculating the average of the 16 items.(68) The measure will provide baseline information about the child's physical activity enjoyment which may be explored during interviews to understand impact on BBCamp experiences (ICF-CY activity and participation domains).

Children's Self Perceptions of Adequacy in and Predilection for Physical Activity Scale (CSAPPA)

Children's physical activity self efficacy will be assessed pre-intervention using the Children's Self Perceptions of Adequacy in and Predilection for Physical Activity Scale (CSAPPA).(71–74) This 19-item, validated measure can be used to assess self-perception of adequacy and ability to perform exercises, and desire to join physical activities across 3 subscales in children aged 9-16 years,(72,73) and in those with CP. (73,74) Self-efficacy scores range from 19-76, with ≥60 indicative of high self-efficacy.(73) CSAPPA self-efficacy data may be explored during interviews to understand impact on BBCamp experiences.

Behavioural, Affective, and Cognitive Engagement Outcomes (Objective 1)

Adherence (Behavioural Engagement) (Primary Outcome)

Exercise repetition attempts will be tracked and recorded each session by the Persee+. Children will have three extra repetition attempts above what is prescribed by the clinician to try and perform movements with appropriate form (see 'opportunities for practice' in Table 2). For timed exercises (e.g., stretches), children will have up to three attempts over a 2-minute period to perform the exercise as prescribed. Adherence will be expressed as a proportion (i.e., number of repetitions attempted divided by number prescribed or duration of timed attempts divided by time prescribed) (see Supplementary Material 2 for exercise scoring examples).

Smileyometer Ratings (Affective and Cognitive Engagement)

Affective and cognitive engagement will be measured within BBCamp after every session using study-specific Smileyometer 5-point rating scales.(22,23) "Did you have fun today?" and "did today's session help your body?" will be used as the questions to measure affective and cognitive engagement, respectively. To optimize response scale understanding for each question, children will be guided by their PT to first select activities they have the most fun and least fun doing, and activities they perceive to be most helpful and least helpful for their body during their in-person

session. These activities will appear as pictorial scale anchors, as is done with the Personalized Enjoyment Questionnaire.(75)

Bootle Boot Camp Acceptability Survey
Children will be sent a study-specific survey at the end of the four-week comparison period to assess the perceived therapeutic effectiveness of each version. The survey consists of rating scales, open responses, and selecting app version questions (e.g., select the version that helped your body the most).

Fidelity of Movement Practice (Objective 2)
Exercise Fidelity
Exercise repetitions will be recorded by the Persee+, compared to predefined movement quality criteria programmed into the system and counted as 'acceptable' (meets criteria; performed with fidelity) or 'not acceptable.' Exercise fidelity will be measured in both treatment conditions (i.e. with feedback and without feedback), but feedback on exercise quality will only be presented to children in the feedback version. For timed exercises (e.g., stretches), the child will have three trials to achieve their highest level of performance, as is done with the Challenge – a measure of advanced gross motor skills for children with CP.(76) The child's best performance (i.e., longest time achieving movement criteria) will then be used to measure fidelity (see 'motivation' in Table 2). Exercise fidelity will be expressed as a proportion (i.e., number of acceptable repetitions divided by number prescribed or best time divided by time prescribed) (Supplementary Material 2).

Treatment Response (Objective 3)
Lower limb treatment response will be assessed using a battery of clinical tests: the FTSST,(24,25) the mTUG,(30–32) the OLST,(30,33,34) the PRT,(30,35) the 30STS,(36–38) and through goal achievement using the COPM(26–29) pre- and post-intervention (Table 3). Clinical tests will be administered during training weeks 1 and 6 and will appear as warmup activities within BBCamp.

Table 3. Battery of clinical tests and measures used to evaluate treatment response.

Measure and Outcome	Administration and Scoring	Measurement Properties (Psychometrics)	Research Relevance
Measure: Five Time Sit to Stand Test (FTSST)(24,25) **Outcome:** functional lower limb muscle strength.	- Measures the time (seconds) needed to complete five sit-to-stand cycles as fast as possible from a chair without armrests.(24) - Rate (repetitions/second) is determined. - Best/highest rate (repetitions/second) of three trials will be used.	**Validity:** convergent validity supported by significant correlation with one-repetition maximum of the loaded sit-to-stand test, isometric muscle strength, scores of Gross Motor Function measure and gait function (*rho* = 0.40–0.78) in children with cerebral palsy (CP).(24) **Reliability:** high intra-session reliability in children with CP (intraclass correlation coefficient (ICC) = 0.95)(24); high test-retest reliability in children with CP (ICC=0.99).(24) **Standard Error of Measurement (SEM):** 0.02 in children with CP. (24) **Minimal Detectable Difference (MDD):** 0.06 repetitions/second in children with CP.(24)	- Previous studies have explored remote FTSST assessment and suggest that it may be useful for conducting regular in-home testing. (25)
Measure: Modified Timed Up and Go (mTUG)(30–32) **Outcome:** functional mobility and balance	- Measures the time (seconds) needed to rise from a chair, walk 3 meters, turn, walk back to the chair, and sit down.(31) - In the modified version, instructions are repeated, and concrete tasks are used (e.g., children asked to touch a target) as compared to the more abstract instructions in the TUG that have been shown to limit performance in children with CP.(31) - Best/shortest time of three trials will be used.	**Validity:** moderate to strong inverse correlations with GMFM, 10 seconds sit to stand test, Berg Balance Scale (*rho* = -0.88) and walking speed (*rho* = -0.93) in children with CP.(30) **Reliability:** high test-retest reliability of the TUG in children with CP (ICC = 0.99)(30); high within-session reliability in young people with CP (ICC = 0.99)(31); high inter-rater reliability (time) of the TUG in children with typical development (TD) (ICC = 0.99).(30) **SEM:** 1.00 (second) in children with CP.(30) **Minimum Clinically Important Difference (MCID):** MCID GMFCS I (medium effect size; 0.5) = 1.1(32); MCID GMFCS I (large effect size; 0.8) = 1.7(32); MCID GMFCS II (medium effect size; 0.5) = 0.7(32); MCID GMFCS II (large effect size; 0.8) = 1.2.(32)	- Can differentiate performance between children at different GMFCS levels and different subtypes of CP.(30) - Track record of use in studies involving children with CP and virtual reality therapies.(12)
Measure: One Leg Stance Test (OLST)(30,33,34) **Outcome:**	- Measures the time (seconds) a child can maintain their balance on one leg (for each leg) with their eyes open and hands on their hips.(34) The time is stopped when the child lifts their hands off their	**Validity:** significant correlation between the OLST and Pediatric Balance Scale in TD children aged 7-8 years (33); moderate to very strong correlations with one legged hopping (*rho* = 0.75) and balance beam walking (*rho* = 0.74) in children with TD.(30)	- Requires minimal equipment making it ideal to test in the home.(33) - Maintaining balance on one leg

static standing balance, stability, and functional mobility	hips or touches the floor with the opposite foot.(34) - Best/longest time of three trials (for each leg) will be used.(34)	**Reliability:** high intra-rater reliability in children with CP and TD (ICC = 0.99)(30); high inter-rater reliability in children with CP and TD (ICC = 0.99).(30) **SEM:** 10.16 (seconds) in TD children(30); 8.71 (seconds) in children with hearing impairment.(30)	for 45 seconds is considered good balance.(33,34)
Measure: Pediatric Reach Test (PRT)(30,35) **Outcome:** dynamic balance	- Measures the total distance (centimeters) that a child can reach forward and sideways (to the right and left) from a seated and standing position without losing their balance across six positions(35). - The difference between starting and end shoulder joint positions for each task will be measured and summed to produce a final score.	**Validity:** moderately to strongly related to step length (*rho* = -0.67 to -0.72) in children with traumatic brain injury (TBI).(30) **Reliability:** intra-rater reliability in children with CP (ICC = 0.54-0.88)(30); inter-rater reliability in children with CP (ICC = 0.50-0.93)(30); test-retest reliability in children with CP (ICC = 0.54-0.88)(35); inter-tester reliability in children with CP (ICC = 0.50-0.93).(35) **SEM:** 0.97 (forward)(cm), 0.72 (lateral, preferred arm) (cm) and 0.90 (lateral, nonpreferred arm) (cm) in children with TBI.(30)	- Based on the Functional Reach Test (30), a reasonable approximation of a force platform measure of the foot centre of pressure excursion (gold standard).(35)
Measure 30 Second Sit to Stand Test (30STS)(36–38) **Outcome:** functional lower limb muscle strength	- Measures the number of full-stands that a participant can achieve from a chair without using their arms over a thirty second period. (36) - Best/highest number of stands achieved across three trials will be used.	**Reliability:** good test-retest reliability in older adults with dementia (ICC = 0.84)(36); excellent intra-session reliability in adults with knee osteoarthritis (ICC > 0.9).(37)bar **SEM:** 1.26 in older adults with dementia.(36) **Minimal Detectable Change (MDC):** $MDC_{individual}$ = 2.5 stands in adults with knee osteoarthritis(37); MDC_{group} = 0.3-0.4 stands in adults with knee osteoarthritis(37); MDC = 3.49 in older adults with dementia.(36) **MCID:** ≥ 2 stands in older adults with pulmonary disease.(38)	- May be more suitable to evaluate exercise capacity and tolerance (as compared to the shorter version sit to stand tests).(38)
Measure: Canadian Occupational Performance Measure (COPM)(26–29) **Outcome:** goal achievement	- Measure used to assess client outcomes in the areas of self-care, productivity, and leisure. - User rates level of importance, performance and satisfaction on each activity using a 10-point scale(26), with higher ratings indicative of greater importance, better performance and greater satisfaction.(27)	**Validity:** good construct validity when parents used as proxies for young children with CP.(28) Significantly correlated to the Satisfaction with Performance Scaled questionnaire, Reintegration to Normal Living Index and Perceived Problems List.(29) **Reliability:** acceptable internal consistency reliability for performance (mean alpha 0.73) and satisfaction (mean alpha 0.82) when parents used as proxies for young children with CP.(28) **MCID:** change of at least 2 points from initial assessment to reassessment is considered clinically meaningful.(29)	- Used in pediatric rehabilitation for goal-setting.(27) - Individualized, client-focused goals align with the activities and participation domains of the ICF framework.(26)

Child, Caregiver and Physiotherapist Experiences and Perspectives (Objective 4)

BBCamp Questions (Mood, Energy, Pain)

Children will be asked to rate their mood, energy level, and pain pre/post exercise sessions. Mood will be assessed using Pick-A-Mood,(77) a cartoon-based pictorial self-report scale where users select one of eight different characters to represent their mood states.(77) Energy level will be measured using a study-specific battery rating scale ranging from 0 (no energy) to 10 (lots of energy). Pain will be measured using the Wong-Bakers Faces Pain Scale,(78) consisting of six gender-neutral faces ranging from no pain (0) to the most pain possible (10).(78) These data may be further explored in interviews to understand their impact on engagement outcomes.

Mobile App Rating Scale (MARS)

Caregivers' perceived value and usability of BBCamp will be evaluated using the MARS,(79) a scale assessing app quality via 5 subscales: engagement, functionality, aesthetics, information quality, and subjective quality.(79) Caregivers will complete one MARS per app version following the 4-week comparison period.

Semi Structured Interviews with Families

Within two weeks of training completion, children and caregivers will take part in semi-structured interviews (in person or virtually through Zoom based on family preference and feasibility) to better understand their experiences with using BBCamp. Children will be given the choice of whether they wish to be interviewed in the presence or absence of their caregiver (preference to be determined during telephone call between MP and the family). A combination of individual and dyad interviews has been used in previous studies exploring children's engagement with ICP technologies,(80) with caregivers' scaffolding of stories helping to evoke important memories for younger children and adding a richness to the information collected.(81,82) The engagement framework described by King et al.(7) and implemented by James et al.(80) was used to create the preliminary interview guide (Supplementary Material 3). Quantitative survey results will be used to further build the qualitative interview guide.(44) Each interview will take approximately 60 to 90 minutes and will be audio recorded.

System Usability Scale (SUS) and BBCamp Usability Survey

Following their in-person session with the child, PTs will receive two surveys via REDCap. The SUS(83,84) is a standard 10-item questionnaire that measures usability of digital health applications, with items measured on a 5-point Likert scale.(83,84) Total scores range from 0 to 100, with a score of >68 representing above average usability and >80 representing high usability.(83,84) The BBCamp Usability Survey will supplement SUS data with open-ended questions targeting satisfaction with app features for exercise prescription.

Data and quality management

BBCamp systems will be monitored regularly by AK to ensure that data are being recorded, transferred, encrypted, and stored. Action will be taken to troubleshoot any issues that arise if complete data are not received.

ANALYSIS

Based on the Single-Case Reporting Guidelines in Behavioural Interventions (SCRIBE)(85) recommendations, a combined visual and statistical approach will be used to analyze SCED data using Microsoft Excel and R open source software. There is no agreed upon criteria to guide this type of statistical analysis.(86)

Behavioural, Affective and Cognitive Engagement (Objective 1)

Visual Analysis: To determine whether a functional relationship exists between adherence (behavioural engagement) and app version, and between Smileyometer ratings (affective/cognitive engagement) and app version, engagement across exercise sessions will be plotted and line graphs will be analysed using visual inspection for level, trend, variability, and overlap, based on the standards published in the What Works Clearinghouse (WWC) Single-Case Designs Technical Documentation.(87)

Statistical Analysis: Mean adherence and Smileyometer scores during each condition will be calculated to compare the mean difference scores between app versions. A Single Case Randomization Test (SCRT) will be conducted to determine if difference scores are statistically significant.(48,52) A celeration line and probability table may be used to further confirm statistical significance, with significance determined if all data points of one treatment condition are above the celeration line for the other treatment condition.(65,86) Use of a celeration line fits with a one-tailed test of significance ($p < 0.05$) for behaviour change.(65,88) Further exploratory analyses may be performed to supplement primary findings.

Data from the BBCamp Acceptability Survey will be presented descriptively, with inferential statistics used to compare numerical rating responses related to affective/cognitive engagement for each app version. The non-parametric Wilcoxon signed rank test will be used to conduct this comparison. (Note: data will be checked for normality prior to analyses and if normal, the parametric counterparts to the statistical tests identified (e.g., paired t-test) will be used. In this and all other inferential analyses, power calculations will be completed in the event of no difference conclusions.

Exercise Fidelity (Objective 2)

Descriptive statistics will be used to summarize exercise fidelity across conditions, with the Wilcoxon signed rank test used to determine if differences are statistically significant.

Treatment Response (Objective 3)

Changes in FTSST, mTUG, OLST, PRT, and 30STS scores from week 1 to 6 and COPM scores from initial to reassessment will be compared to minimum detectable change and/or minimum clinically important difference values where available (Table 3). The Wilcoxon signed rank test will be used to determine if changes are significant.

Children's, Caregivers', and Physiotherapists' Experiences (Objective 4)

Reflective thematic analysis(89) will be used to learn about families' experiences with BBCamp. Audio recordings of semi-structured interviews will be transcribed verbatim and analysed inductively by two independent coders using NVivo 12.0 software.(90) A codebook will be created with regular team meetings held to discuss coding decisions, resolve coding conflicts,

and develop preliminary and final themes. Study rigor will also be maintained through maintenance of reflexive notes. Caregivers' perspectives will be further reflected through descriptive presentation of MARS scores. To understand PTs' perspectives on app usability for exercise prescription, SUS and BBCamp Usability Survey data will be summarized descriptively.

Understand Engagement Outcomes Using Mixed Methods Data Integration

Quantitative engagement data and qualitative textual data will be integrated and interpreted using joint displays(45,91) to facilitate generation of new inferences and meta-inferences.(45,91) Meta-inferences will be classified as confirmed (findings from data sources agree), discordant (findings conflict) or expanded (findings expand understanding).(44,91) Inferences and meta-inferences will be used to help understand the impact of movement tracking feedback on children's engagement outcomes to help elucidate the need for and value of motion tracking technologies within home therapy exercise apps, as well as potential facilitators and barriers to their use. This will help guide future design, implementation, and translation of home-based therapy technologies.

ETHICS AND DISSEMINATION

The adverse events (AE) that seem most likely to occur are repetitive strain injuries resulting from repetitive motions, increased pace or poor body mechanics.(92) Since exercises and treatment parameters will be prescribed by PTs to meet the children's ability levels and goals, it is unlikely that app usage will result in an increased risk compared to traditional HEPs. The aims of this app are to promote physical activity, improve strength and movement quality which all help to reduce the risk of injury. AEs will be tracked within weekly emails, with any reported AEs prompting contact with the family by EB or FVW. The nature and severity of the AE will be documented on AE forms. These forms will be reviewed by an external safety monitoring committee (i.e., PT, pediatrician, and researcher) that will make recommendations for next steps for the study intervention. Protocol amendment procedures, reporting of adverse events and maintaining potential and enrolled participant confidentiality will be followed in accordance with Research Ethics Boards at Bloorview Research Institute and the University of Toronto. The Standard Protocol Items: Recommendations for Interventional Trials guidelines,(93) SCRIBE,(85) and the Good Reporting of a Mixed Methods Study (GRAMMS)(94) guided design and will guide reporting. Results will be distributed through peer-reviewed journals and conferences, with knowledge holders helping to inform the dissemination plan.

DISCUSSION

This paper outlines the research protocol for a SCED involving a new home therapy exercise app, BBCamp, with alternating treatments consisting of BBCamp offered with and without movement tracking feedback. Learning how movement tracking feedback impacts engagement will help guide future implementation of BBCamp and similar apps. If movement tracking does not measurably increase engagement and/or exercise fidelity, it may be appropriate to release the app without movement tracking on commonplace mobile devices (e.g., tablets, phones, laptops) making it more accessible and cost effective for families. However, if movement tracking is important to ensure appropriate exercise performance and maintenance of engagement, then the advantages of using BBCamp with the specialized technology that supports movement tracking

likely outweighs the implementation barriers (e.g., US$379.99 cost for Persee+).(58) This research will provide important insight on how/if gamification of HEPs can support children and families in engaging in home movement practice. It will further clarify the need for movement tracking feedback in ICP technologies to facilitate positive children's rehabilitation experiences and clinical outcomes.

AUTHOR CONTRIBUTIONS

MP reviewed relevant literature, helped develop BBCamp, outlined the research design and protocol, selected outcome measures, sought ethical approval, and drafted the manuscript. EB and FVW contributed to BBCamp development, guided research design and outcome measure selection, revised the manuscript, and provided supervision. AK helped with BBCamp development and research design implementation. SM contributed to the mixed methods research components and DF contributed to the eligibility criteria and knowledge holder involvement processes.

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COMPETING INTERESTS

Holland Bloorview is supporting the creation of a company called Pearl Interactives to commercialize products like BBCamp so that they can be made widely available to those who can benefit from them. EB and AK are shareholders in Pearl Interactives and may financially benefit from this interest if Pearl Interactives commercializes BBCamp in the future and is successful in marketing it. The terms of this arrangement have been reviewed and approved by Holland Bloorview Kids Rehabilitation Hospital and the University of Toronto in accordance with its policy on objectivity in research and will continue to be actively monitored to mitigate and manage any conflicts of interest. The remaining authors declare that the research was conducted in the absence of any potential conflicts of interest.

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SUPPLEMENTARY MATERIALS

Supplementary Material 1 – Study design, treatment and measurement schedule as exemplified for a single participant.
Supplementary Material 2 - Adherence, exercise fidelity and star ratings as exemplified across four exercise sessions for a sample participant
Supplementary Material 3 – Interview guide

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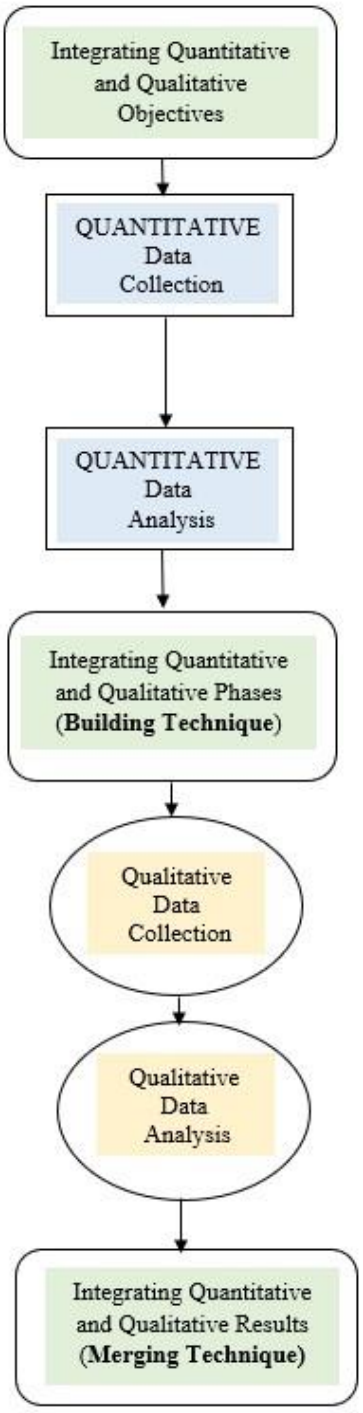
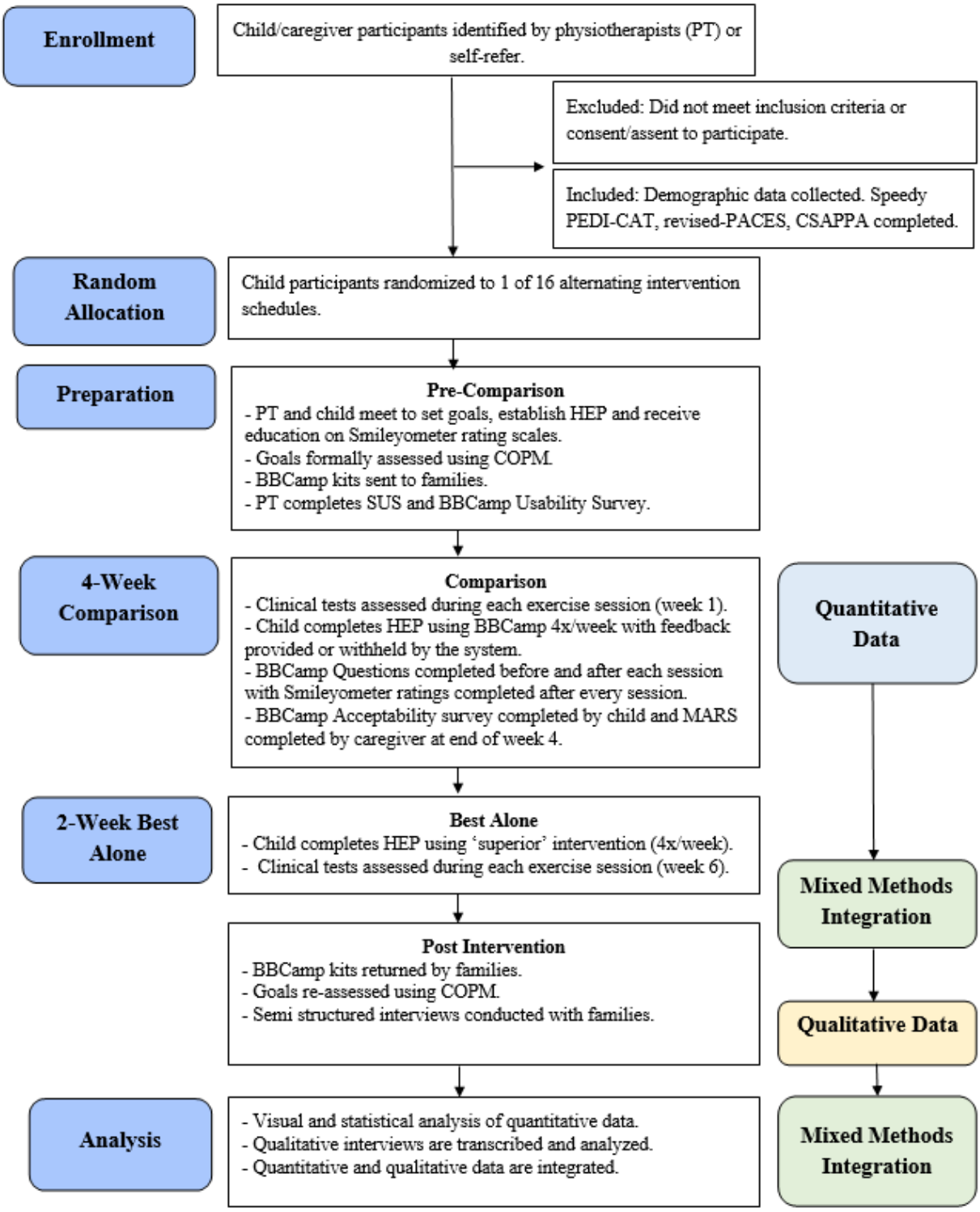


METHOD

- Study design
- System collected data
- Smileyometer ratings
- Bootle Boot Camp Acceptability and Usability survey
- Lower limb outcome measures
- Visual inspection for level, trend, variability, percent of non-overlapping data
- Mean differences scores
- Randomization tests
- Wilcoxon signed rank test
- Development of interview protocols/questions based on quantitative results
- Individual semi-structured interviews with children and caregivers
- Reflexive thematic analysis
- Interpretation of quantitative and qualitative results

OUTCOME

- Overall mixed methods objective
- Quantitative and qualitative objectives
- Numeric data
- Line graphs (proportion of prescribed exercise repetitions attempted; Smileyometer ratings)
- Descriptive statistics
- Inferential statistics
- Revised semi-structured interview guide
- Interview transcripts (textual data)
- Codes and themes
- Reflexive notes
- Inferences and meta-inferences
- Joint displays
- Narrative approaches



Supplementary Material 1 (Table 1). Study design, treatment, and measurement schedule where B = Bootle Boot Camp (BBCamp) with movement tracking feedback and C = the app without movement tracking feedback, as exemplified for a single participant.

Pre-Comparison		**Comparison**																**Best Alone**								**Follow Up**	
Week	0	1				2				3				4				5				6				7	8
Session	-	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	-	-
Condition	-	B	B	C	B	C	C	B	C	C	B	C	B	C	B	C	B	B	B	B	B	B	B	B	B	-	-
Phase		**QUANTITATIVE**																								**QUAL**	
Demographics	x																										
PEDI-CAT	x																										
Revised PACES	x																										
CSAPPA	x																										
Objective 1: Behavioural, Affective, Cognitive Engagement																											
Adherence*		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Smileyometer *		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
BBCamp Acceptability Survey																	x										
Objective 2: Fidelity of Movement Practice																											
Exercise fidelity*		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Objective 3: Estimate Treatment Response																											
COPM	x																									x	
FTSST*		xxx				x^																xxx				x^	
mTUG*			xxx			x^																	xxx			x^	
OLST*				xxx		x^																		xxx		x^	
PRT*				x		x^																		x		x^	
30STS*					xxx	x^																			xxx	x^	
Objective 4: Child, Caregiver and Therapist Experiences and Perspectives																											
Interview																										x	x
SUS and BBCamp Usability Survey	x																										
MARS (1 per app version)																	xx										
BBCamp Questions*		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		

* denotes measures that will take place as part of BBCamp exercise sessions.
^ denotes measures that will be tested in the following week if exercise session(s) are missed or re-tested if technical or procedural issues are identified on video recordings (as needed).
QUAL: qualitative. PEDI-CAT: Pediatric Evaluation of Disability Inventory Computer Adaptive Test (speedy version). PACES: Physical Activity Enjoyment Scale. CSAPPA: Children's Self Perceptions of Adequacy in and Predilection for Physical Activity Scale. COPM: Canadian Occupational Performance Measure. FTSST: Five Time Sit to Stand Test. mTUG: modified Timed Up and Go Test. OLST: One Leg Stance Test. PRT: Pediatric Reach Test. 30STS: 30 Second Sit to Stand Test. SUS: System Usability Scale. MARS: Mobile App Rating Scale.

Supplementary Material 2. Adherence, exercise fidelity and star ratings as exemplified across four exercise sessions for a sample participant.

Prescribed Home Exercise Program			
Exercises	Repetitions	Sets	Time (seconds)
1. Sit to stand	10	2	N/A
2. Marching	N/A	1	30
3. Calf stretch	N/A	2	30

Day 1 Exercise Session

Exercises	Repetitions or Timed Attempts	Repetitions or Time Prescribed (Per Set)	Proportion Attempted (Adherence)	Acceptable Repetitions or Best Time	Repetitions or Time Prescribed (Per Set)	Acceptable Proportion (Exercise Fidelity)	Star Rating* (Per Set)	Average Star Rating (Across Sets)
1.Sit to stand (set 1)	10	10	10/10 = 1.0	8	10	8/10 = 0.8	3	3 (8+9=17/20 =0.85)
2. Sit to stand (set 2)	10	10	10/10 = 1.0	9	10	9/10 = 0.9	3	
3.Marching	25s + 5s	30s	30/30s = 1.0	25	30	25/30 = 0.83	3	3
4.Calf stretch (set 1)	10s + 10s + 10s	30s	30/30 = 1.0	10	30	10/30 = 0.33	1	1 (10+10=20/60 =0.33)
5.Calf stretch (set 2)	10s + 10s + 10s	30s	30/30 = 1.0	10	30	10/30 = 0.33	1	
Mean Proportion of Prescribed Attempts			**1.0**	**Mean Proportion of Acceptable Attempts**		**0.64**		

*Star ratings are awarded based on exercise fidelity with 1 star awarded with <50% of repetitions are completed with appropriate fidelity, 2 stars when 50-75% of repetitions are completed with appropriate fidelity and 3 stars when >75% of repetitions are completed with appropriate fidelity.

Day 2 Exercise Session

Exercises	Repetition or Timed Attempts	Repetitions or Time Prescribed (Per Set)	Proportion Attempted (Adherence)	Acceptable Repetitions or Best Time	Repetitions or Time Prescribed (Per Set)	Acceptable Proportion (Exercise Fidelity)	Star Rating (Per Set)	Average Star Rating (Across All Sets)
1.Sit to stand (set 1)	12	10	12/10 = 1.2	8	10	8/10 = 0.8	3	3 (8+9=17/20 =0.85)
2. Sit to stand (set 2)	13	10	13/10 = 1.3	9	10	9/10 = 0.9	3	
3.Marching	15s + 10s + 5s	30s	30/30 = 1.0	15	30	15/30 = 0.5	1	1
4.Calf stretch (set 1)	10s + 5s + 12s	27	27/30 = 0.9	10	30	10/30 =0.33	1	1 (10+18=28/60 =0.47
5.Calf stretch (set 2)	18s + 12s	30s	30/30 = 1.0	18	30	18/30 = 0.60	2	
Mean Proportion of Prescribed Attempts			**1.08**	**Mean Proportion of Acceptable Attempts**		**0.63**		

Day 3 Exercise Session

Exercises	Repetition or Timed Attempts	Repetitions or Time Prescribed (Per Set)	Proportion Attempted (Adherence)	Acceptable Repetitions or Best Time	Repetitions or Time Prescribed (Per Set)	Acceptable Proportion (Exercise Fidelity)	Star Rating (Per Set)	Average Star Rating (Across All Sets)
1.Sit to stand (set 1)	7	10	7/10 = 0.7	5	10	5/10 = 0.5	1	1 (5+1=5/20 =0.25)
2. Sit to stand (set 2)	1	10	1/10 = 0.1	1	10	1/10 = 0.1	1	
2.Marching	5s + 5s	30s	10/30 = 0.33	5	30	5/30 = 0.17	1	1

3.Calf stretch (set 1)	29s + 1s	30s	30/30 = 1.0	29	30	29/30 =0.97	3	2 (29+6=35/60 =0.58
4.Calf stretch (set 2)	3s + 2s + 6s	30s	11/30 = 0.37	6	30	6/30 = 0.20	1	
Mean Proportion of Prescribed Attempts			**0.68**	**Mean Proportion of Acceptable Attempts**		**0.42**		

Day 4 Exercise Session

Exercises	Repetition or Timed Attempts	Repetitions or Time Prescribed (Per Set)	Proportion Attempted (Adherence)	Acceptable Repetitions or Best Time	Repetitions or Time Prescribed (Per Set)	Acceptable Proportion (Exercise Fidelity)	Star Rating (Per Set)	Average Star Rating (Across All Sets)
1.Sit to stand (set 1)	13	10	13/10 = 1.3	9	10	9/10 = 0.9	3	2 (9+4=13/20 =0.65)
2. Sit to stand (set 2)	5	10	5/10 = 0.5	4	10	4/10 = 0.4	1	
2.Marching	24s + 4s + 2s	30s	30/30 = 1.0	24	30	24/30 =0.80	3	3
3.Calf stretch (set 1)	10s + 10s + 10s	30s	30/30 = 1.0	10	30	10/30 =0.33	1	2 (10+28=38/60 =0.63)
4.Calf stretch (set 2)	28s	30s	28/30 = 0.93	28	30	28/30 =0.93	3	
Mean Proportion of Prescribed Attempts			**0.95**	**Mean Proportion of Acceptable Attempts**		**0.67**		

Supplementary Material 3: Child and Caregiver Interview Guide

Note: Child- and caregiver-specific versions of the interview guide that are tailored to each participant and that use similar questions as those shown below will be used, where applicable. In the version presented, the child will be asked questions first, with caregivers given the opportunity to add comments following their child's responses (unless otherwise specified).

Part 1: Bootle Boot Camp Play Experience

1. Tell me about the **home exercise programs** that you usually do outside of this program.
2. Tell me about your **experiences using Bootle Boot Camp** to complete your home exercise program.
3. How does using Bootle Boot Camp **compare** to the usual way you do exercises or therapy at home?

Part 2: Engagement Framework

1. What **hopes** did you have for using Bootle Boot Camp?

CAREGIVER: What **hopes** did you have for your child using Bootle Boot Camp?

CAREGIVER: Did you feel playing Bootle Boot Camp would be **valuable** for your child? Why or why not?

2. How did you **feel** about playing Bootle Boot Camp? Why did you feel this way?
3. Did you **like getting feedback** on the way you performed your exercises? Why or why not?

CAREGIVER: How do you think the movement feedback from Coach Botley impacted your **child's feelings** and **experiences** playing Bootle Boot Camp?

CAREGIVER: What did you **like** and **not like** about the movement feedback given to your child by Coach Botley? Why is that?

4. Would you have liked to get **feedback** on your exercise performance **in a different way**?
5. Did your **level of excitement**/wanting to play Bootle Boot Camp change over the 6 weeks? If so, how did it change?

CAREGIVER: Did you notice any changes to your child's **level of engagement** during the study period? If so, can you explain these changes?

6. How did you feel about your ability to **exercise** and **be active** using **Bootle Boot Camp**?
7. Did the feedback **affect your confidence with exercising**? If yes, how so?

CAREGIVER: Did you feel **confident** in your ability to support your child's home use of Bootle Boot Camp? Why or why not?

CAREGIVER: Were four exercise sessions manageable for you and your child's schedule? Why or why not?

8. Did you **expect to see changes** in yourself or your body after using Bootle Boot Camp? Why or why not?

CAREGIVER: Did you **expect to see changes** in your child or your child's body after using Bootle Boot Camp?

CAREGIVER: Did you think that Bootle Boot Camp would be **useful for your child to achieve their goals**? Why or why not?

9. Did you **see any changes** in yourself or your body after using the app for 6 weeks? What were those changes, if any?

CAREGIVER: Did you **see any changes** in your child or your child's body after using the app for 6 weeks? What were those changes, if any?

10. Do you think the exercise feedback **changed your exercise performance**?

CAREGIVER: Did Botley's movement feedback impact your **child's exercise performance**? If so, how?

11. Do you feel Coach Botley was **needed** to help you perform the exercises to the best of your abilities? Why or why not?
12. How did the **feedback from Botley compare to the feedback your physiotherapist might give you** during a regular therapy session?
13. How did you **feel not being able to contact your physiotherapist** while using Bootle Boot Camp?

CAREGIVER: Which version of the app did you **prefer**? Why?

Part 3: Survey Results

1. In the survey, you indicated that the [Feedback/No feedback/Both] version was the **most fun to play**. Can you tell me more about why you chose this?
2. In the survey, you reported that [Feedback/No Feedback/Both] version made you feel the **most confident** that you could do the exercises well. Can you tell me more about why you chose this?
3. In the survey, you indicated that the [Feedback/No feedback/Both] version **helped your body the most**. Can you tell me more about why you chose this?
4. In the survey, you stated that [Feedback/No Feedback/Both] version **helped you try and reach your goals** the most. Can you tell me more about why you chose this?

CAREGIVER**:** Based on the rating scales, you gave the Bootle Boot Camp app without feedback an X **star rating** and the version with movement feedback an X **star rating.** Tell me more about why you gave each version of the app these ratings?

Part 4: Future Use

1. What changes should be made to the Bootle Boot Camp app to make it better for kids to use in the future?
2. What information would you want Bootle Boot Camp to track? What information would you want to be able to see, have your parents see, your physiotherapist?

CAREGIVER: What **information or training** do you think would have been beneficial for you to have to support your child's use of Bootle Boot Camp within the home? How would you like to receive this information or training (e.g., in person training session with physiotherapist, training session with game developers or technical support team, instructions manual, etc.)

CAREGIVER: What **supports** do you think are necessary for Bootle Boot Camp to be used in the home?

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet	2

		registered, name of intended registry	
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	29
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 28
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	1
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	29
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial,	N/A

		if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	4
Objectives	#7	Specific objectives or hypotheses	4-5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6

Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	18
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	18-19, 25

Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	10
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to	6

		conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	16
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7, 16-25
Data collection plan:	#18b	Plans to promote participant retention and complete	17

retention		follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	25
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	25-27
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to	27

		where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	27
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	27
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	N/A

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	27
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	28
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any	27

		publication restrictions	
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Uploaded under 'patient consent form' file designation
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A