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Evaluating the impact of movement tracking feedback on engagement with home exercise programmes of children with cerebral palsy 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 programmes (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, 16 children with CP (aged 6–12 years, Gross Motor Function Classification System levels I–II) will set lower limb goals and be prescribed an individualised HEP by their physiotherapist to complete using BBCamp on their home television equipped with a three-dimensional camera-computer system. Children will complete four weekly exercise sessions over 6 weeks. Children will be randomised to 1 of 16 alternating treatment schedules where BBCamp will provide or withhold feedback during the first 4 weeks. The version of BBCamp that results in the most therapeutic benefit will be continued for 2 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 analysed 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.

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 optimise 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 heterogeneous population (eg, children with cerebral palsy), 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 (eg, the 'best alone' phase and randomisation) 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 paediatric rehabilitation with a prevalence of 1.6 per 1000 live births worldwide.[1 2] Home exercise programmes (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 (ie, perform the exercises as prescribed) to obtain benefits from an exercise programme.[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 (ie, 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 programme efficacy, including opportunities for problem-solving, individualisation, social equalisation and feedback.[10] These features may also promote the acquisition and retention of motor skills (ie, motor learning).[11] ICP systems have been successfully used to support home movement practice in children with CP including commercial entertainment systems (eg, Nintendo Wii,[12] Sony EyeToy[13]) and systems designed specifically for therapeutic purposes (eg, Timocco,[14] Move It to Improve It,[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 (ie, information collected by an external source and communicated back to the user)[6 19] that is individualised and targeted may improve motivation and adherence by facilitating enhanced mastery of skills and confidence within the context of ICP-based exercise programmes. Mainstream movement tracking technologies such as the Microsoft Kinect sensor[20] and the Orbbec Persee[20] can support a greater level of customised 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, aged 6–12 years, classified as 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 (ie, 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 (ie, 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 individualised 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 reassessment.

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 into 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 programme (CanChild).[40] Knowledge holders provided feedback on the following research components:

- Relevance of research, priority of research questions and outcomes (eg, 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 (eg, confirmed four exercise sessions per week would be manageable for families if exercises sessions were limited to 30 minutes).
- Advisement of recruitment strategy (eg, 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 semirandomised, 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 1–6), followed by a qualitative component (weeks 7–8) to provide a more robust understanding of quantitative results (figure 1 and online supplemental 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.

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 the 'Best alone' phase section below) will be solely offered for 2 weeks to limit this threat to internal validity (eg, 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]

Randomisation and blinding procedure

A randomisation schedule which considers a limit of two maximum consecutive administrations of the same condition (eg, 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 minimise possible order effects and threats to internal validity.[48 50] 16 treatment schedules with random alternation of feedback will be randomly selected (eg, to provide one treatment schedule per participant) using the 'selectdesign' function (eg, 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 randomised to a treatment schedule using the app software. The study design with the treatment schedule, as exemplified for a single participant, is shown in online supplemental 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 1-year paediatric clinical experience, working at Holland Bloorview (Toronto, Ontario, Canada) 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.

Sample size

A small number of participants, typically one to three, 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 six participants is sufficient.[47] However, more participants (eg, 9–17) 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

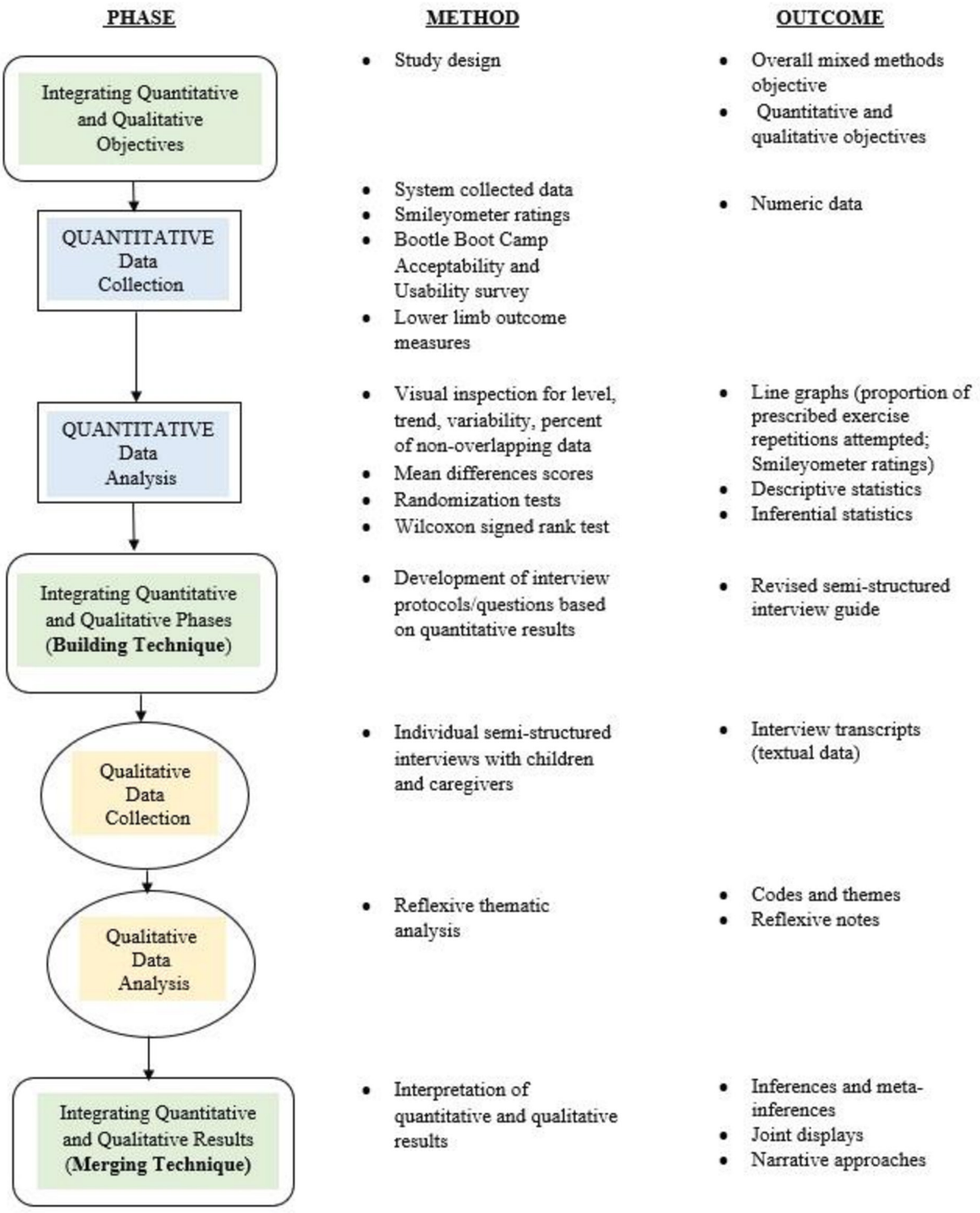

Figure 1 Visual model depicting the study's mixed-methods explanatory sequential design.

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, aged 6–12 years, using mixed methods, we aim to have 12 participants across 4 strata with 3 participants per stratum (boys and girls, aged 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

Table 1 Child participant inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
► Diagnosis of CP classified as GMFCS level I or II (able to independently ambulate on level surfaces without assistive devices)[21] ► Aged 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 2 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 (eg, 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 orthopaedic surgery in the previous 6 months ► Is scheduled to undergo serial casting, BoNTA injection, orthopaedic surgery or other significant medical interventions 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 game play ► Respiratory, cardiovascular or other medical conditions that might limit safe participation ► Actively engaging in a home exercise programme or training programme targeting progressive muscle strengthening or balance training of the lower limbs as prescribed by a healthcare provider or researcher. Children who are engaging in home exercise for maintenance or flexibility 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 (eg, family trip) that would likely prevent the participant from completing four weekly exercise sessions during the 6-week training period

app, application; CP, cerebral palsy; GMFCS, Gross Motor Function Classification System.

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 (eg, therapy sessions with PTs) from impacting study results, children who are in an active physiotherapy treatment block will not be eligible. Enrolment will be limited to one client per PT to maximise 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 (ie, PTs, engineers, game designers, digital artists, researchers, family partners) at Holland Bloorview Kids Rehabilitation Hospital. It is played on a television equipped with a three-dimensional 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/physiotherapist/research trainee, 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 five 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.

Device and programme 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 programme for their client to complete at home (without supervision from the PT) for 4 days per week, as is recommended for children with CP.[59 60] The training programme will consist of individualised, lower limb exercises selected from those available in the BBCamp app, with treatment parameters provided by the PT that are

Table 2 'Active ingredients' of Bootle Boot Camp

'Active ingredient'	Implementation into Bootle Boot Camp
Individualisation	► Allows clinicians to individualise treatment plans by offering a wide range of standing and seated range of motion/strengthening, balance and cardiorespiratory fitness lower limb exercises. ► Treatment parameters can be customised to the child's abilities/needs (eg, number of repetitions, sets). ► Clinicians can identify whether exercises should be performed unsupported or supported (eg, holding on to the back of a chair) with video demonstrations for both versions available in addition to exercise instructions. ► Children can customise the game play environment by selecting a robot (ie, 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 treatment parameters (eg, number of repetitions, sets). ► Children are encouraged to perform exercise sessions four times per week in alignment with the American College of Sports Medicine and the National Strength and Conditioning Association 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 (eg, stretches), clinicians can prescribe up to 60 s 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 minimise 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 equalisation	► Children can complete exercise sessions in one-player or two-player mode, allowing for social interaction and barrier-free inclusion during game play 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 programme.
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 (eg, 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 (ie, 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 (eg, 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 (eg, are your feet far enough apart?).

Continued

Table 2 Continued

'Active ingredient'	Implementation into Bootle Boot Camp
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 completed (with and without exercise fidelity). ► The child's head, trunk and joint positions are tracked and compared with 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 being played by the presence or absence of virtual Coach Botley. 1. Key feedback characteristics[6]:Method of presentation: immersive/multimodal (visual, audio and reward). Visual/audio feedback is offered through indicators (eg, movement speed) and prescriptive prompts (eg, take a bigger step back). 2. Movement variable: based on movement execution (eg, completion of sit-to-stand), with joint angle (eg, 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 customised *knowledge of performance* feedback (ie, related to the quality of movement performance) (eg, visual speed indicator) and *knowledge of results feedback* (ie, related to the outcome of task completion) (eg, repetition counter that increases when a repetition is performed with exercise fidelity). 4. Timing of feedback: concurrent during a repetition attempt (eg, visual indicator showing approximate degree of truncal lean), terminal (eg, repetition counter increases if movement is performed with exercise fidelity) and in summary form (eg, 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 (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 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).

app, application; CP, cerebral palsy.

appropriate to the client and their goals (eg, 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 (eg, 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 (ie, Orbbec Persee+ system with the child's individualised exercise plan uploaded, BBCamp User Guide and 3 m measuring tape to support correct performance of the mTUG) 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 randomisation schedule and programmed into BBCamp by AK). The first four sessions (week 1) will begin with clinical assessments listed in table 3 and online supplemental material 1 (in order of assessment delivery). The Persee+ will video record exercise performance and

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, GMFM scores, and gait function (r=0.40–0.78) in children with CP.[24] **Reliability:** high intrasession reliability in children with CP (ICC=0.95)[24]; high test–retest reliability in children with CP (ICC=0.99).[24] **SE of measurement (SEM):** 0.02 in children with CP.[24] **Minimal detectable difference:** 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 (TUG)[30–32] **Outcome:** functional mobility and balance	► Measures the time (seconds) needed to rise from a chair, walk 3 m, turn, walk back to the chair and sit down.[31] ► In the modified version, instructions are repeated, and concrete tasks are used (eg, children asked to touch a target) as compared with 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 s sit-to-stand test, Berg Balance Scale (r=–0.88) and walking speed (r=–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 TD (ICC=0.99).[30] **SEM:** 1.00 (s) 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:** static standing balance, stability and functional mobility	► 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 hips or touches the floor with the opposite foot.[34] ► Best/longest time of three trials (for each leg) will be used.[34]	**Validity:** significant correlation between the OLST and Pediatric Balance Scale in children with TD aged 7–8 years[33]; moderate to very strong correlations with one-legged hopping (r=0.75) and balance beam walking (r=0.74) in children with TD.[30] **Reliability:** high intrarater 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 (s) in children with TD[30]; 8.71 (s) in children with hearing impairment.[30]	► Requires minimal equipment making it ideal to test in the home.[33] ► Maintaining balance on one leg for 45 s is considered good balance.[33 34]

Continued

Table 3 Continued

Measure and outcome	Administration and scoring	Measurement properties (psychometrics)	Research relevance
Measure: Pediatric Reach Test[30 35] **Outcome:** dynamic balance	► Measures the total distance (centimetres) 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 (r=−0.67 to −0.72) in children with TBI.[30] **Reliability:** intrarater 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]; intertester 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, non-preferred 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[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 30-second period.[37] ► 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 intrasession reliability in adults with knee osteoarthritis (ICC >0.9).[37] **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 with the shorter version sit-to-stand tests).[38]
Measure: Canadian Occupational Performance Measure[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 with 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 paediatric rehabilitation for goal-setting.[27] ► Individualised, client-focused goals align with the activities and participation domains of the ICF framework.[26]

CP, cerebral palsy; GMFCS, Gross Motor Function Classification System; GMFM, Gross Motor Function Measure; ICC, intraclass correlation coefficient; ICF, International Classification of Functioning, Disability and Health; TBI, traumatic brain injury; TD, typical development.

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 (eg, child not captured fully on video recording) or procedural issues observed (eg, 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 (eg, within their HEP) will help children gain knowledge about their performance while minimising disruption to the child.[61] Families will be sent weekly email 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 (ie, adherence) during the 4-week comparison phase will be analysed to determine which condition (ie, 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 retested. If there are any outstanding assessments (ie, 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 semistructured interviews. Figure 2 outlines the full study procedure.

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. After 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 their client's diagnosis and GMFCS level.

Pediatric Evaluation Disability Inventory Computer Adaptive Test (speedy version)

Children's level of function will be assessed using the Pediatric Evaluation Disability Inventory Computer Adaptive Test (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 to 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

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).

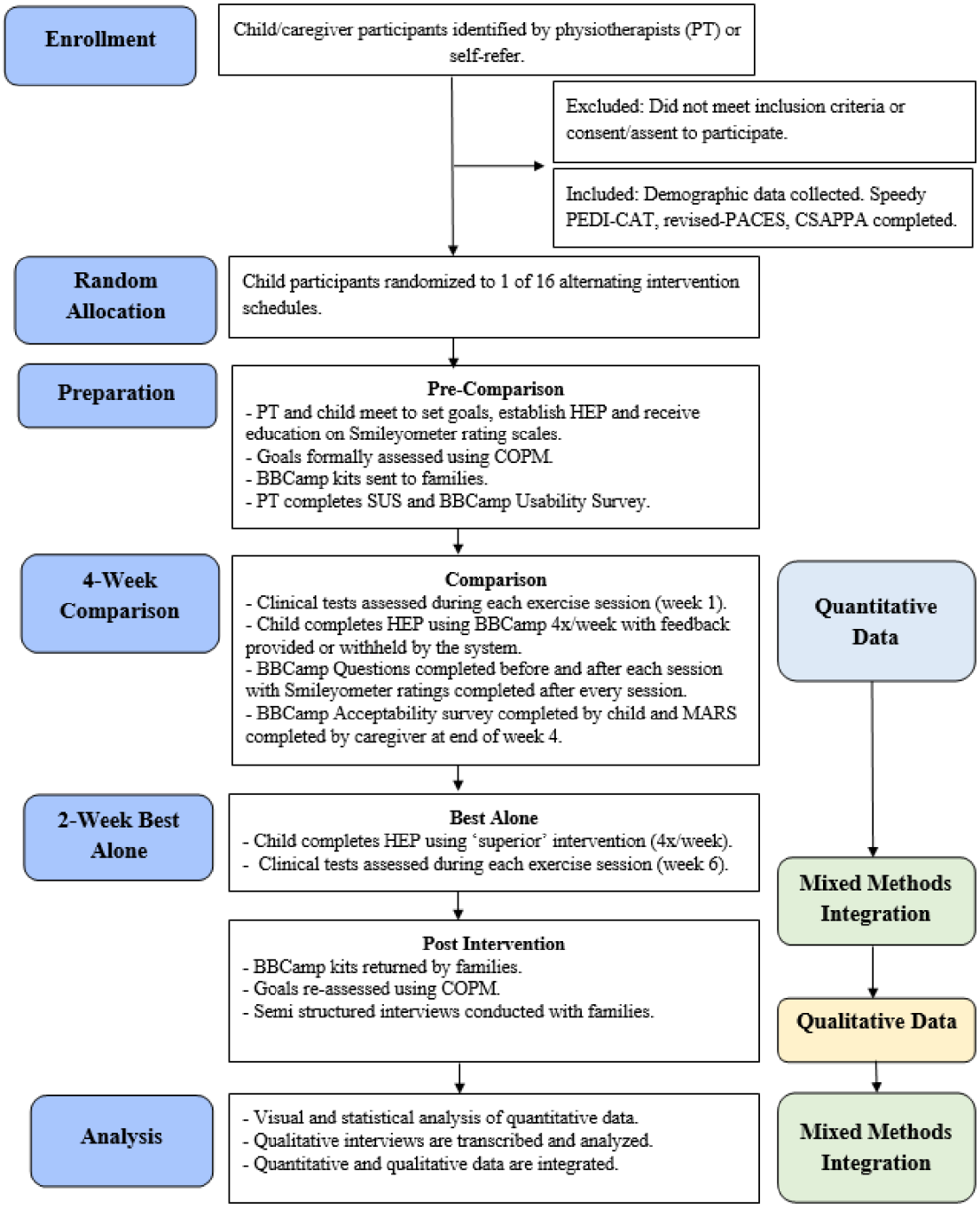

Figure 2 Study procedure flow diagram. BBCamp, Bootle Boot Camp; COPM, Canadian Occupational Performance Measure; CSAPPA, Children's Self Perceptions of Adequacy in and Predilection for Physical Activity Scale; HEP, home exercise programme; MARS, Mobile App Rating Scale; PACES, Physical Activity Enjoyment Scale; PEDI-CAT, Pediatric Evaluation Disability Inventory Computer Adaptive Test; SUS, System Usability Scale.

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

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 three subscales in children aged 9–16 years[72 73] and in those with CP.[73 74] Self-efficacy scores range from 19 to 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 (eg, 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 (ie, number of repetitions attempted divided by number prescribed or duration of timed attempts divided by time prescribed) (see online supplemental 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 optimise 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]

BBCamp Acceptability Survey

Children will be sent a study-specific survey at the end of the 4-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 (eg, 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 with 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 (ie, with feedback and without feedback), but feedback on exercise quality will only be presented to children in the feedback version. For timed exercises (eg, 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 (ie, 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 (ie, number of acceptable repetitions divided by number prescribed or best time divided by time prescribed) (online supplemental 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-intervention and post-intervention (table 3). Clinical tests will be administered during training weeks 1 and 6 and will appear as warm-up activities within BBCamp.

Child, caregiver and PT 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

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

Semistructured interviews with families

Within 2 weeks of training completion, children and caregivers will take part in semistructured 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 (online supplemental material 3). Quantitative survey results will be used to further build the qualitative interview guide.[44] Each interview will take approximately 60–90 min and will be audio-recorded.

System Usability Scale and BBCamp Usability Survey

Following their in-person session with the child, PTs will receive two surveys via REDCap. The System Usability Scale (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 analyse SCED data using Microsoft Excel and R open-source software. There are 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 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 randomisation test 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 conditions.[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 (eg, 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 summarise 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 with 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 PTs' experiences (objective 4)

Reflective thematic analysis[89] will be used to learn about families' experiences with BBCamp. Audio-recordings of semistructured 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 rigour 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 summarised 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 (AEs) 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 with 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 (ie, PT, paediatrician and researcher) that will make recommendations for next steps for the study intervention. Protocol amendment procedures, reporting of AEs 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[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 (eg, 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 specialised technology that supports movement tracking likely outweigh the implementation barriers (eg, US$379.99 cost for Persee+).[58] This research will provide important insight into 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 rehabilitation experiences and clinical outcomes for children with CP.

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Contributors 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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Disclaimer The organisations do not hold influence over study design, data collection, data management, analysis, interpretation of findings, report writing or the decision to submit the manuscript for publication.

Competing interests Holland Bloorview is supporting the creation of a company called Pearl Interactives to commercialise 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 commercialises 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.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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