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Participate CP 2: optimising participation in physically active leisure for children with cerebral palsy – protocol for a phase III randomised controlled trial

Leanne Sakzewski ,[1] Sarah Elizabeth Reedman ,[1] Catherine Elliott,[2,3] Jenny Ziviani ,[4] Iona Novak,[5] Stewart Trost ,[6,7] Annette Majnemer,[8] Tracy Comans,[9] Keiko Shikako,[8] Robert S Ware ,[10] Lynda McNamara,[11] Sian Williams,[2,12] Syed Afroz Keramat,[13] Denise Brookes,[13] Roslyn N Boyd[1]

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For numbered affiliations see end of article.

Correspondence to
Dr Leanne Sakzewski;
l.sakzewski1@uq.edu.au

ABSTRACT

Introduction Children with cerebral palsy (CP) participate less in physical activities and have increased sedentary behaviour compared with typically developing peers. Participate CP is a participation-focused therapy intervention for children with CP with demonstrated efficacy in a phase II randomised controlled trial (RCT) to increase perceived performance of physical activity participation goals. This study will test the effectiveness of Participate CP in a multisite phase III RCT.

Methods and analysis One hundred children with CP, aged 8–14 years, classified Gross Motor Function Classification System levels I–IV will be randomised to either (1) receive Participate CP once/week for 1 hour for 12 weeks, or (2) waitlist control, usual care group. The waitlist group will then receive Participate CP following the 26-week retention time point. Outcomes will be assessed at baseline, 12 weeks and then 26 weeks post baseline. The primary outcomes are (1) self-reported participation goal performance on the Canadian Occupational Performance Measure at 12 weeks and (2) daily time in moderate-to-vigorous physical activity. Secondary outcomes include home and community participation frequency, involvement and environmental supportiveness, contextual barriers to participation, quality of life, intrinsic motivation for physical activities, child perception of an autonomy-supportive climate for physical activities and physical literacy at 12 and 26 weeks post study entry.

Ethics and dissemination The Children's Health Queensland Hospital and Health Service, The University of Queensland and the New Zealand Health and Disability Ethics Committees have approved this study. Findings will be disseminated in peer-reviewed journals and conference presentations.

Trial registration number ACTRN12618000206224.

STRENGTHS AND LIMITATIONS OF THE STUDY

⇒ First phase III randomised controlled trial investigating participation-focused therapy intervention for children with cerebral palsy (CP).
⇒ Participate CP will be powered to detect change on the primary outcomes of participation goal attainment and daily time spent in moderate-to-vigorous physical activity.
⇒ Participate CP will be tested in both metropolitan and regional areas in two countries.
⇒ A comprehensive within trial cost-utility analysis will be conducted to synthesise the costs and benefits of Participate CP compared with usual care.
⇒ One limitation is that usual care will be highly variable and cannot be standardised.

INTRODUCTION

In Australia, 35 000 people are living with cerebral palsy (CP).[1] People with CP have poorer health outcomes, are less physically active and have a 1.2-times to 1.6-times greater risk of chronic health conditions such as diabetes, hypertension and stroke compared with those without a disability.[2 3] From as early as 3 years of age, children with CP participate less in physically active leisure (eg, bicycle riding, team sports) compared with typically developing peers and participation reduces over time.[4–6] Participation in physically active leisure is an important source of habitual physical activity (HPA) for children with CP.[7]

Children with CP not only participate less often in physically active leisure (19% less likely to play sports or ride a bicycle),[5] but they participate with lower intensity,[8] and reduced diversity compared with their typically developing peers.[9] Owing to societal barriers, they are more likely to only have access to informal physical activities (eg, backyard games) than organised community sports (eg, swimming club).[9 10] Over and above their physical

disability, children with CP experience more barriers to inclusion, including pain and fatigue, but also attitudinal and built-environment barriers.[11–14] In a cross-sectional study of children and youth 5–17 years with (n=282) and without (n=294) disabilities, parents of children with disabilities reported that environmental factors (eg, physical access, attitudes of others, adequacy services, availability of equipment) consistently and directly influence involvement in and frequency of participation across home, school and community life.[13] Attitudes and the built-environment are modifiable treatment factors.[15]

Traditionally, therapy interventions for children with CP have targeted impairments (eg, spasticity) and activity limitations (eg, walking) with limited translation to enhanced participation in life roles (eg, mobility in all environments, education and leisure participation). Our systematic review[16] established that traditional interventions focusing on impairments and activity limitations are ineffective in improving participation in sports and other physical activities and overall physical activity levels. This highlighted that therapy models need to additionally consider contextual and environmental barriers in order to enable children to participate in their chosen leisure-time physical activities.[16] Potential barriers and facilitators to participation are individually unique and must be understood and targeted by intervention strategies in order to increase participation in physically active leisure and overall HPA.

We developed Participate CP, a participation-focused therapy, that characterised physical activity as a health behaviour and was underpinned by theories of self-determination and behaviour change.[17] Participate CP is an 8-week, goal-directed, highly individualised and tailored intervention using a selection of behaviour change techniques guided by barriers to physically active leisure participation goals experienced by children and their families. In a phase II randomised controlled trial (RCT) of 37 children with CP, aged 8–12 years, classified in Gross Motor Function Classification System (GMFCS) I–III, children allocated to Participate CP, compared with usual care, had significantly greater gains in perceived performance of individualised participation goals on the Canadian Occupational Performance Measure (COPM, mean difference MD 3.6, 95% CI 2.2 to 5.0; p<0.001) and reduced barriers to participation (MD 26.4, 95% CI 6.1 to 46.7; p=0.01). There were no between group differences on minutes per day spent in moderate-to-vigorous physical activity (MVPA), however for those participants not meeting physical activity guidelines at baseline, time spent in MVPA increased significantly by 6.0 (SD=12.2) min per day. The study, however, was not powered to determine a significant difference between groups for time spent in MVPA. Additionally, we found that 8 weeks of intervention was not long enough to overcome barriers that were particularly related to sourcing equipment or funding to support sporting activities, therefore a longer intervention period may further enhance outcomes.[18]

We now aim to expand our work on Participate CP and conduct a phase III randomised waitlist-controlled trial with 100 children with CP, aged 8–14 years, GMFCS levels I–IV to determine if Participate CP is more effective than usual care to improve performance and satisfaction with individualised physically active leisure goals and daily time spent in MVPA.

METHODS AND ANALYSIS

Aims and hypotheses

This pragmatic, phase III, multisite RCT will be conducted in Queensland, New South Wales and Western Australia, Australia and the North Island in Aotearoa New Zealand with 100 children with CP aged 8–14 years. This single-blind RCT will determine if Participate CP is more effective than usual care to improve performance and satisfaction with individualised physically active leisure participation goals and daily time spent in MVPA. Secondary outcomes will test the differential effects of Participate CP compared with usual care on community participation frequency, involvement and environmental supportiveness, contextual barriers to participation, quality of life, intrinsic motivation for physical activities, child perception of an autonomy-supportive climate for physical activities and physical literacy immediately post intervention and retention at 26 weeks post baseline.

Primary hypothesis

For children with CP aged 8–14 years, Participate CP will be more effective than a waitlist control group (usual care) immediately post intervention and at 26 weeks post baseline in increasing:

1. Performance and satisfaction scores on the COPM by a difference of two points, which is the clinically meaningful important difference,[19] and
2. Daily time spent in MVPA measured by an accelerometer-based motion sensor.

Secondary hypotheses

For children with CP, immediately post intervention and at 26 weeks post baseline, Participate CP will be more effective than a waitlist control group receiving usual care to:

3. Increase participation frequency, involvement and environmental supportiveness scores on the Participation and Environment Measure for Children and Youth (PEM-CY).[20]
4. Reduce motivational and behavioural barriers to participation on the Barriers to Participation in Physical Activities Questionnaire (BPPA-Q).[17]
5. Increase domain scores of the parent-proxy and child-reported CP Quality of Life Questionnaire (CP QOL)[21] and quality of life on the Child Health Utility (CHU9) parent-proxy report.
6. Increase intrinsic types of motivation for physical activities on the Motives for Physical Activities Measure-Revised (MPAM-R).[22]

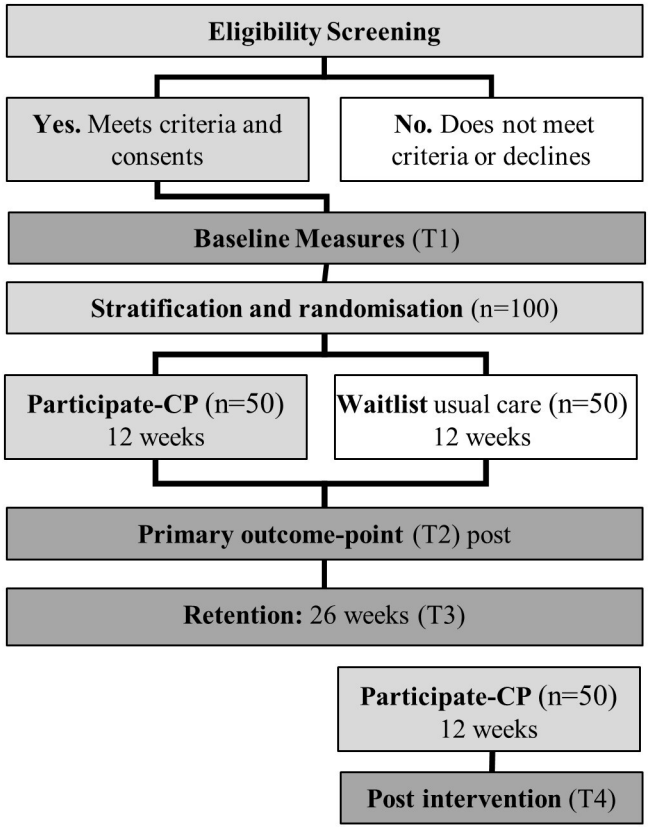

Figure 1 Consolidated Standards of Reporting Trials study flowchart. CP, cerebral palsy.

7. Increase perception of an autonomy-supportive climate for physical activities on the Physical Activity Climate Questionnaire (PACQ).[23]
8. Increase the total mean physical literacy score on the Physical Literacy Assessment for Youth (PLAYfun).[24]
9. Generate value for the health system based on the cost-effectiveness of treatment received.

The measures selected measure the constructs of interest, are age appropriate and have acceptable psychometric properties.

Trial design

This study is a pragmatic, multisite parallel waitlist randomised two-group, pre-test, post-test study (T0–T1 over 12 weeks), inclusive of a 26-week post baseline follow-up. This approach is proposed as RCTs are considered the 'gold standard' for evaluating therapeutic effectiveness.[25] In total, 100 children will be recruited and randomised to receive either Participate CP immediately, or waitlist usual care. The waitlist group will receive Participate CP after the 26-week retention time point as per figure 1. This approach could be considered more ethical than a standard parallel group RCT, as all persons involved are provided with the opportunity to experience the intervention. This study has been designed according to the Standard Protocol Items: Recommendations for Interventional Trials statement,[26] and will be reported according to the Consolidated Standards of Reporting Trials statement[27] and registered on the Australian New Zealand Clinical Trials Registry.

Recruitment

Families with a child meeting eligibility criterion will be invited to join the study through our seven collaborating sites in Australia (Queensland, Western Australia, New South Wales) and New Zealand (Auckland). Children will be recruited across the Brisbane metropolitan area and Cairns in Queensland, Perth metropolitan area in Western Australia, Sydney and the Hunter Valley in New South Wales and in Auckland, New Zealand. Cairns and the Hunter Valley represent two regional sites. We consider it essential to test Participate CP in regional areas as there may be additional and unique barriers to participation compared with metropolitan sites, which may have greater opportunities, resources and/or supports for physically active leisure activities.[28] Recruitment at each site will begin following ethical and governance approvals, and will draw on current databases within each organisation, referrals from clinical services and the Cerebral Palsy Clinical Trials Registers.

Inclusion criteria

Participants must meet the following eligibility criteria prior to randomisation: (1) confirmed diagnosis of CP, (2) aged 8–14 years, (3) classified GMFCS levels I–IV, (4) lives within 150 km radius of trial sites; (5) have at least one parent/caregiver who understands written and verbal English and can speak English (information and consent materials and questionnaires will not be available in languages other than English), (6) the child and their caregiver both have a desire to work on goals around participating more often or being more involved in physical activities. Participants will be excluded if the child has: (1) limited ability to communicate insight into preferred future (needs, wants, desires) in spoken English AND/OR through an interpreter or augmentative/alternative communication (ie, Communication Function Classification System Levels IV–V), (2) significant intellectual disability (<50), (3) uncontrolled epilepsy, (4) severe asthma exacerbated by exercise, not controlled with medication under an asthma management plan, (5) planned orthopaedic surgery 6 months prior to or throughout intervention/follow-up period, (6) was enrolled and previously received the intervention in the phase II study[18] in South-East Queensland (2016–2017).

Random allocation and blinding

A biostatistician not otherwise involved in participant contact, recruitment, assessment or intervention will create one central randomisation schedule using computer-generated random numbers (in random blocks of various sizes), to receive Participate CP immediately or to waitlist usual care in a 1:1 ratio. Participants will be stratified by site and GMFCS (I and II vs III and IV). The biostatistician will upload the randomisation schedule to an electronic database (Research Electronic Data Capture

- REDCap)[29] which will be used by study investigators to allocate participants using the randomisation module. Study staff are not able to access, view or download the schedule at any time. Group allocation will be concealed to the treating therapist, research team, the participant and their family until after all baseline measures (except 7-day accelerometry) are completed. Once randomisation is complete, it will be irrevocable.

It is not possible to blind participants to which group they are allocated to (ie, treatment received) at T2–T3/T4. Therapists will not be aware of allocation until after all baseline assessments have been completed. Children and their caregivers complete questionnaires at home using REDCap and surveys are locked for editing after completion, so there is a reduced chance of therapist influence on these results. It is not possible to blind therapists to the treatment received at T2 and T3 for the main outcome (COPM) as it is an integral part of building rapport within the intervention and it is essential that the therapist who has been aware of the goal-progress to be the person who scores the goal collaboratively. Caregivers are blind to their previous COPM scores. Accelerometry data and physical literacy assessments will be blinded to the person analysing and scoring the data.

Interventions

Participate CP group

Dose

Twelve weekly sessions of 60 min duration for a total dose of 12 hours. The first session will focus on goal setting, and the final session will focus on goal scoring and planning for ongoing participation.

Mode

Individual session with the child and primary caregiver at home or in the community, dependent on the individualised goals of the child and family.

Content and tailoring

We have previously analysed the contents and mechanisms of Participate CP according to the Behaviour Change Technique Taxonomy V.1, Capability, Opportunity, Motivation – Behaviour Model, Behaviour Change Wheel and the Theoretical Domains Framework (TDF).[30] Participate CP employed 32 different behaviour change techniques using six intervention functions, most frequently enablement (defined as increasing means/reducing barriers to increase capability or opportunity). Participate CP targets physical activity behaviour change for children with CP and their families by modulating environmental context and resources, social influences, skills, intentions, knowledge and beliefs about capabilities.[30] Online supplemental material outline the Participate CP weekly programme and intervention strategies.

Mechanism of action

Participate CP is based on self-determination theory and conceptualises physical activity as a human health behaviour.[17] The hypothesised mechanism of action was supported by an analysis of predictors of the magnitude of response to the intervention.[31] We demonstrated that children who were more intrinsically motivated for physical activity at baseline had a greater response, and children who had an additional co-diagnosis of autism spectrum disorder (and were therefore more likely to have extrinsic motivation for physical activity[32]) had a reduced response to Participate CP compared with no diagnosis of Autism Spectrum Disorder (ASD).[31] Furthermore, a greater extent of overcoming barriers to participation during the intervention was associated with an increased response on both performance of physical activity goals and minutes per day MVPA.[31] Participate CP 2 has been optimised in response to these findings, with clinician training emphasising that moving children and families towards more intrinsic types of motivation is ideal, however recognising that it is natural for some children not to self-identify as being physically active and to require extrinsic motivation. In these cases, the clinician may consider careful application of behaviour change techniques involving rewards and incentives (which ordinarily are not recommended as they risk undermining intrinsic motivation).

Intervention providers

Physiotherapists, occupational therapists or accredited exercise physiologists who have completed standardised training to deliver Participate CP.

Location

In the child's home or community setting as relevant to the identified individualised physically active leisure participation goal.

Usual care

Usual care is highly variable and not standardised. It is expected that participants in the waitlist usual care group could receive a range of therapies including physiotherapy, occupational therapy, speech pathology and psychology. Usual care is recorded in a log by caregivers on study exit.

Outcomes

Three measurement time points will be taken: baseline (T1); immediately post intervention *primary endpoint* at 12 weeks (T2); 26 weeks post intervention *retention* (T3). Children allocated to the waitlist group will be offered Participate CP following the 6-month retention time point and will have post intervention (T4) evaluation.

Screening and descriptive measures

All participants will be classified using the:

Gross Motor Function Classification System expanded and revised

The GMFCS will classify the child's ability to carry out self-generated movements related to sitting and walking on a 5-level ordinal scale.[33] The GMFCS has established construct validity, and good inter-rater reliability between therapists.[33]

Manual Abilities Classification System

The Manual Abilities Classification System (MACS) classifies the child's ability to handle objects in daily activities on a 5-level ordinal scale.[34] The MACS has well established construct validity, excellent inter-rater reliability (Intraclass Correlation Coefficient ICC=0.97 between therapists). It is expected that children in the study will be functioning at MACS levels I–III.[34]

Communication Function Classification System

The Communication Function Classification System will classify children's everyday performance of communicating using all methods (eg, speech, gestures, eye gaze, augmentative and alternative communication) on a 5-level ordinal scale.[35 36] There is evidence of content validity, good test–retest reliability, good inter-rater reliability (0.66) between professionals.[35–37]

Primary outcomes at primary endpoint (T2)

Canadian Occupational Performance Measure performance and satisfaction with physically active leisure participation goals

The COPM[19] will be used to measure performance of and satisfaction with individually defined physically active leisure participation goals. Test–retest reliability is high (ICC=0.76–0.89) and the COPM is responsive to change.[38] To ensure that goals reflect the participation construct and not the activity domain of the International Classification of Functioning, Disability and Health, the Family of Participation-Related Constructs will be employed to frame goals in terms of frequency of attendance (eg, attend rock climbing once/week at Walls) and/or involvement (eg, in soccer training and games, increase involvement in offence/defence to 60% from 30%).[39] Two to three COPM goals will be set at baseline and scored at 12 weeks. A further two to three goals will be set at 12 weeks and scored at 26 weeks if the original goal/s have been achieved to the satisfaction of the child and caregiver. New goals can also be set within the intervention period (0–12 weeks) if original goals are achieved to the satisfaction of the child and their caregiver.

Daily time spent in MVPA

An ActiGraph GT3X+ (Pensacola, Florida, USA) will be worn on the least impaired hip during the waking hours for seven consecutive days. For children classified GMFCS level IV, an additional accelerometer will be worn on the less affected wrist. Raw accelerometer data (sampling frequency=30 Hz) will be downloaded and processed into physical activity metrics using a machine-learnt random forest physical activity classification model specifically developed for children with CP.[40] This validated algorithm uses 27 frequency and time domain features extracted from 10 s non-overlapping windows to classify movement behaviour as sedentary (sitting or lying down), standing utilitarian movements (active video game or standing while cleaning a countertop), or walking. In a leave-one-subject-out cross-validation analysis, recognition accuracy for sedentary activities was 96%, 87% for standing utilitarian movements and 94% for comfortable or brisk paced walking. Model predictions will be mapped to traditional physical activity intensity categories as follows: sedentary windows were considered sedentary, standing utilitarian movement windows were considered light intensity physical activity and walking windows were considered MVPA. Children will be provided a standard elastic belt for wearing the device on the waist and a neoprene cover if required for comfort.

Secondary outcomes

Incremental goal attainment

Goal Attainment Scaling (GAS) is an objective method of quantifying goal attainment. Goals are scored on a Likert-type scale from −2 (representing no positive change at all from baseline/regression), −1 (a little less change than expected), 0 (attainment of goal at the expected level), +1 (a little more change than expected), to +2 (attainment of goal at much more than the expected level). Goals will be personally important to the individual (rather than standardised) with the distance between each increment representing a relatively equal amount of effort or improvement to achieve. Each GAS goal will describe a barrier to a primary COPM goal(s) at any level of the International Classification of Functioning, Disability and Health (ICF), or across any area of behaviour and motivation. Goals will be set collaboratively mid-intervention (rather than at the same time as COPM goals in the first session) as some change in goal content is expected due to the iterative nature of the process. As goal-setting forms an integral part of the intervention, the waitlist control group will not set GAS goals until they undertake their own intervention period and GAS scores will be analysed as paired samples (within groups).

Home and community participation frequency, involvement and environmental supportiveness

Participation and Environment Questionnaire (PEM-CY)[20] is a parent-completed questionnaire with good test–retest reliability and internal consistency.[20] Summary scores for participation frequency, involvement and environmental supportiveness in the home and community will be calculated.

Contextual barriers to participation

BPPA-Q[17] is a questionnaire based on the TDF structure and developed by the authors. Questionnaires based on TDF have validity and reliability[41] to detect the presence and quantity of barriers and facilitators to behaviour change and allows categorisation of those barriers and facilitators based on established theories of behaviour change. Similar questionnaires have shown responsiveness to interventions. Questionnaire responses can be used as evidence to support the selection of behaviour change strategies in an intervention, setting of GAS goals and to detect changes following implementation of such strategies.

Quality of life and health resource use

Cerebral Palsy Quality of Life Questionnaire for Children, Child Version and Parent-proxy Version (CP-QOL Child; CP QOL)[21 42 43] will be completed by children over the age of 9 years and their caregiver, respectively. Due to potential discordance between child and parent-reported quality of life,[44] both perspectives will be sought. The CP QOL has good concurrent validity, internal consistency (α 0.80–0.90) and test–retest reliability.[21] The CHU9 instrument a paediatric health-related quality of life measure used in health economic evaluation. The measure consists of nine questions. The CHU9 will be completed by the child's primary caregiver. Resource usage (staff time, equipment, mileage) associated with the programme will be collected alongside the trial. Healthcare usage will be assessed using a resource use questionnaire previously used in CP child studies[45] and linked Australian Medicare claims data that will provide medical services and medication usage.

Intrinsic motivation for physical activities

MPAM-R[22] is a child self-report measure that assesses intrinsic (ie, interest/enjoyment, competence, social) versus extrinsic (appearance, fitness) types of motivation for physical activities undertaken by the child. The MPAM-R has been shown to predict the amount of change in physical activity following an intervention.

Child perception of an autonomy-supportive climate for physical activities

PACQ[23] is filled in by a person (ie, child) with reference to a specific leading individual (ie, their caregiver) in respect of participation in physical activities. The questionnaire contains 15 items that assess the perceived 'climate' created by the caregiver with respect to the child's participation in physical activity. Higher average scores represent a higher level of child-perceived parental autonomy support for physical activity participation.

Physical literacy

The PLAYfun measures 18 fundamental movement skills and fundamental sport skills across five domains.[24] Evaluators will ask a child to perform specific tasks and his/her performance will be rated between 1 and 100 for each skill, based on the four categories (initial, emerging, competent and proficient). A score of 100 represents the best that anyone could ever be at that skill, regardless of age. In this way, the score represents a continuum of process-oriented skill development. The PLAYfun has not yet been validated in children with CP, though it has face validity to apply in the population of ambulant youth GMFCS I–II and five items in children at GMFCS III and IV (PLAYfun adapted).[24] The PLAYfun is videotaped and scored from video in this study. An inter-rater and intra-rater reliability study on the PLAYfun will be embedded within the RCT. Table 1 outlines the assessment schedule and respondent for each measure.

Therapist training and fidelity

Standardised therapist training will be provided to therapists employed to deliver the intervention. The training package will include:

- Intervention manual (based on the pilot intervention study, qualitative interviews and published protocol[17]).
- Presentation of case studies and discussion with master trainer.
- Motivational interviewing training delivered by accredited trainer.

Training sessions will be video recorded and accessible at any time for established or new therapists delivering the intervention.

Fidelity

During the active intervention phase, therapists will have a videoconference meeting once per month facilitated by the study coordinator or representative. Therapists can discuss case studies, clinical reasoning, problems/concerns and calibrate their delivery of the intervention so that consistency is maintained across the trial sites. Therapists will complete a clinical reasoning grid for each child receiving the intervention to support and justify the choice of therapeutic techniques.

In order to report fidelity information alongside the results of the trial, an independent rater who is experienced with the family of Participation-related Constructs will review all COPM goals for consistency with the 'attendance' and/or 'involvement' constructs. All intervention sessions will be videotaped where possible in order to enable a random sample of sessions to be analysed for content and alignment with written information (clinical reasoning grids and progress notes) at the conclusion of the study.

Data monitoring, management and storage

We will collect objective data on HPA, using the ActiGraph accelerometer device which is suitable for use with children. Four subjective measures will be collected from children and are appropriate to be used with children 8 years and older. Three subjective measures will be collected from the child's primary caregiver. Screening measures will be collected from the child's primary caregiver which relate to personal, demographic and health information necessary for the conduct of the trial and data analysis. All data is re-identifiable. Data will be collected via paper forms, online survey platform (REDCap), devices (ActiGraph accelerometer and photo/video/audio recording devices) owned by sites/organisations (not personal devices). Data will be transferred securely in one of the following ways: (1) data collected on paper forms will be converted into an electronic format by the site therapist, forwarded using a secure file transfer service such as CloudStor and stored on the secure Queensland Cerebral Palsy Rehabilitation and Research Centre (QCPRRC) research server or uploaded directly to REDCap. Original paper files will be sent to QCPRRC via registered post or courier after being de-identified at the conclusion of the

Table 1 Schedule of assessments for Participate CP 2 study

Assessment/procedure	Screening	T1 baseline	T2 follow-up: 12 weeks	T3 follow-up: 26 weeks	T4 end waitlist 38 weeks
Informed consent	x	x			
Demographic Q	x	x			
PA readiness Q	x				
GMFCS	x				
MACS	x				
CFCS	x				
Stage of behaviour change Q	x				
HRU Q (P)	x			x**	x††
Outcomes					
COPM (C, P)		x	x	x	x††
Accelerometer-measured PA (C)		x	x	x	x††
PEM-CY(P)		x	x	x	x††
CP QOL child/adolescent self-report (C)		x	x	x	x††
CP QOL parent proxy (P)		x	x	x	x††
CHU9 (P, C)		x	x	x	x††
GAS (P, C)		x**	x**	x	x††
Barriers to participation in PA Q (P)		x	x	x	x††
Motives for PA measure (C)		x	x	x	x††
PA climate Q (P)		x	x	x	x††
PLAYfun (C)		x	x	x	x††

*Immediate group only.
†Waitlist group only.
CFCS, Communication Function Classification System; CHU9, Child Health Utility; COPM, Canadian Occupational Performance Measure; CP QOL, Cerebral Palsy Quality of Life Questionnaire ; FU, follow-up; GAS, Goal Attainment Scale; GMFCS, Gross Motor Function Classification System; HRU, health resource use; MACS, Manual Abilities Classification System; P, parent; PA, physical activity; PEM-CY, Participation and Environment Measure for Children and Youth; PLAYfun, Physical Literacy Assessment for Youth; Q, questionnaire; WL, waitlist.

data collection phase; (2) data collected from devices will be downloaded by the site therapist, forwarded using a secure file transfer service and stored on the secure QCPRRC research server or uploaded directly to REDCap, then deleted. Data recorded on paper will be stored at the trial sites in locked filing cabinets during the data collection phase and within an archive box located in the locked filing cabinets of investigators in the Child Health Research Centre at South Brisbane Australia at the conclusion of the data collection phase. Data will be stored on secure Australian servers using REDCap (database) and the secure QCPRRC research server. Data will not be destroyed.

Statistical methods

Sample size estimation and justification

Based on our systematic review and meta-analysis we expect the intervention will lead to increased time spent in MVPA with an effect size of 0.79.[16] According to our pilot data with an SD of 24.2 min/day, a total sample size of 74 will detect a clinically meaningful difference of 16 min/day between groups, with 80% power at alpha 0.05. Buffering for 25% attrition, we aim to recruit 100 (50 in each group). A sample size of 100 will give >95% power to detect a two-point difference in COPM performance, based on an SD of 2.28.[18]

Statistical methods to be undertaken

Analyses will follow standard principles for RCTs using two-group comparisons on all participants on an intention-to-treat basis. Primary comparison at 12 weeks (T2 post) on COPM performance and satisfaction will be between treatment groups using linear regression with treatment group (Participate CP/waitlist control) included as the main effect and stratification factors as covariables. Effect estimates will be presented as mean difference and 95% CI. Secondary analyses will use similar methods to compare outcomes between groups at 12 weeks for HPA level and sedentary behaviours, participation frequency, involvement and environmental supportiveness (PEM-CY) and self and parent-proxy reported quality of life (CP QOL Child). In cases where interval data cannot be transformed appropriately for regression analyses, non-parametric methods (Mann-Whitney U) will be used for between-treatment comparisons. Recruitment bias will be assessed by comparing socio-demographic and clinical

variables for consenters with non-consenters using t-tests (or Mann-Whitney U tests) for continuous variables and χ^2 tests for categorical variables. Possible differential attrition will be assessed by comparing baseline characteristics of dropouts and continuing participants using t-tests (or Mann-Whitney U tests if appropriate) for continuous variables and χ^2 tests for categorical variables. Sensitivity analyses of all outcomes will be conducted using multiple imputation techniques to investigate the effect of non-ignorable missing data during follow-up. For the PLAYfun, smallest detectable change, SE of measurement and intraclass correlation coefficients will be calculated for inter-rater and intra-rater reliability. Responsiveness will be assessed by comparing change scores (two-group comparison pre–post) to smallest detectable change.

Economic evaluation

A within trial cost-utility[46] analysis will be conducted to synthesise the costs and benefits of the Participate CP intervention. Resource use (staff time, equipment and facility use) associated with the programme will be collected alongside the RCT. Healthcare usage will be collected using a resource use questionnaire previously used in our CP child studies[45] and linked Medicare (Medical Benefits Scheme and Pharmaceutical Benefits Scheme) claims data (Medicare data will not be sought for participants at the New Zealand study site). Utility will be derived from the CHU-9D,[47] a child quality of life measure designed specifically for economic evaluation and which has been validated in an Australian population.[48] Incremental cost-effectiveness ratios will be estimated and where appropriate sensitivity analyses will be undertaken as in previous RCTs by our group.[49]

Participant safety and withdrawal

Risk management and safety

By their nature, sports and active recreation activities may have small-to-moderate risks of injury associated with participation due to hazards present (some of which are integral parts of the activity and cannot be removed). There are also negligible to small risks of psychological harm associated with motivational interviewing/disclosure of personal/sensitive information. A risk assessment will be completed by the therapist in consultation with the child's parent/guardian and any relevant community members (such as coaches), prior to participation in activities considered to be high or extreme risk (eg, contact sports). High risk activities will require a documented risk assessment that is sent to the study coordinator.

Adverse event reporting

Adverse events associated with Participate CP will be screened on a weekly basis by the treating therapist by verbal questioning who will inform the study coordinator and site chief investigator (except major adverse events or those requiring medical treatment, which must be reported as soon as possible and within 24 hours). After reporting to the site chief investigator, local site processes will be followed as necessary.

Handling of withdrawals

Participants can withdraw at any time. Participants who choose to withdraw from the study will not be penalised in any way. If they wish to continue with therapy intervention for their child they will be assisted to source another local therapy option that matches their preferences. Participants are informed of their right to withdraw at any time without consequences at the time of reading participant information forms and signing of consent forms. Data will be analysed on an intention-to-treat basis.

Replacements

Participants that withdraw will not be replaced, as the a priori power calculation accounts for a 20% dropout rate.

Patient and public involvement

Ten parent–child dyads were interviewed at the conclusion of the Participate CP pilot RCT and provided feedback on feasibility and acceptability of the intervention (Reedman S, ParticiPAte CP: a protocol of a randomised waitlist controlled trial of a motivational and behaviour change therapy intervention to increase physical activity through meaningful participation in children with CP). Parents and caregivers reflected that the intervention was highly feasible due to home and community visits during after-school hours, matched their needs well and was perceived to be highly effective. Their feedback was incorporated into the present trial design including: (1) increased emphasis on the social aspect of physical activity participation (encouraging participants to set some goals that involve participating in physical activities with others), and (2) increased length of the intervention to improve ability to address complex barriers. Patients and public were not otherwise involved in the design or conduct of this study. Participants and their families will be informed of progress and outcomes of this study via newsletter and conferences open to consumers.

Ethics and dissemination

Informed consent process

All participants will be less than 16 years of age, therefore, written informed consent will be obtained from the legal guardian.

Ethics and dissemination

The project has received ethics approval from the Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/17/QCHQ/283), The University of Queensland Human Research Ethics Committee (2018000019) and the New Zealand Health and Disability Ethics Committee (2022 FULL 11876). The trial has been registered with the Australian New Zealand Clinical Trial Register. Results of the study will be published/disseminated in the trial registration database, conference abstracts and presentations, peer-reviewed articles in scientific journals, organisation

and institutional newsletters and media releases. In accordance with the Australian National Statement 3.1.65, results will be provided directly to participants in an appropriate and accessible format to them.

DISCUSSION

This paper details the protocol for a phase III waitlist RCT to determine the efficacy of a Participate CP to improve participation in physically active leisure and HPA. We hypothesise that the Participate CP intervention will lead to (1) significantly greater gains perceived performance and satisfaction with individualised physically active leisure participation goals, (2) increased daily time spent in MVPA, (3) increased home and community participation frequency and involvement, (4) increased home and community environmental supportiveness, (5) reduced number of contextual barriers to participation, (6) improved quality of life, (7) greater intrinsic motivation for physical activities, (8) increased child perception of an autonomy-supportive climate for physical activities (9) greater physical literacy immediately post intervention and retention at 26 weeks post baseline and (10) value for money for the health system.

Based on results from our phase II RCT of Participate CP and incorporating consumer feedback, we have extended the intervention time from 8–12 weeks in this current phase III trial. We have additionally added a measure of health literacy and health economic evaluation to understand the cost-effectiveness of Participate CP which will be important to inform implementation more broadly through the Australian National Disability Insurance Scheme. As part of the fidelity framework for this study, we have developed standardised training and resources for interventionists which will provide a framework for later implementation of Participate CP into clinical practice should we find it is effective.

One potential limitation of the study is the lack of blinding of outcome assessors. This was a pragmatic decision as primary outcome, the COPM is an integral component of the intervention and development of rapport between the child, family and interventionist. The second primary outcome, accelerometry data will be downloaded and analysed by ST who will be blinded to group allocation. Another limitation is that usual care will be highly variable and cannot be standardised as there are multiple service providers under pre-agreed funding packages through the Australian National Disability Insurance Scheme. It is possible that aspects of usual care may address participation goals. We will collect information from families on the therapies received by their child during the course of Participate CP so we can report usual care in as much detail as possible.

The study has a number of strengths. The sample size has been calculated for the primary outcomes. The testing of Participate CP both in regional and metropolitan centres will increase the generalisation of findings to different environmental contexts. The inclusion of a health economic evaluation will inform policymakers of the cost, benefits of the intervention. It is recognised that participation and physical activity are of key importance to children with CP and their families,[50] and there is currently a lack of high level studies focused on the effectiveness of interventions that specifically promote leisure participation. This study will address this evidence gap. We plan that results of this RCT will be disseminated widely through peer-reviewed journals and academic conferences, relevant websites and through Facebook and other social media forums for youth with CP and their families.

Author affiliations
[1]Queensland Cerebral Palsy and Rehabilitation Research Centre, Faculty of Medicine, The University of Queensland Child Health Research Centre, South Brisbane, Queensland, Australia
[2]School of Allied Health, Curtin University, Perth, Western Australia, Australia
[3]Telethon Kids Institute, Nedlands, Western Australia, Australia
[4]School of Health and Rehabilitation Science, The University of Queensland - Saint Lucia Campus, Saint Lucia, Queensland, Australia
[5]Faculty of Medicine and Health, The University of Sydney, Sydney, New South Wales, Australia
[6]School of Human Movement and Nutrition Sciences, The University of Queensland, Saint Lucia, Queensland, Australia
[7]Children's Health Queensland Hospital and Health Service, South Brisbane, Queensland, Australia
[8]School of Physical and Occupational Therapy, McGill University, Montreal, Québec, Canada
[9]Centre for Health Services Research, Faculty of Medicine, The University of Queensland, Brisbane, Queensland, Australia
[10]Menzies Health Institute Queensland, Griffith University, Nathan, Queensland, Australia
[11]Physiotherapy Department, Cairns and Hinterland Hospital and Health Service, Cairns, Queensland, Australia
[12]Liggins Institute, The University of Auckland, Auckland, New Zealand
[13]Child Health Research Centre, Faculty of Medicine, The University of Queensland, South Brisbane, Queensland, Australia

Twitter Sarah Elizabeth Reedman @sarah_reedman and Keiko Shikako @KeikoShikako

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ORCID iDs
Leanne Sakzewski http://orcid.org/0000-0001-5395-544X
Sarah Elizabeth Reedman http://orcid.org/0000-0002-3937-5649
Jenny Ziviani http://orcid.org/0000-0002-8185-3405
Stewart Trost http://orcid.org/0000-0001-9587-3944
Robert S Ware http://orcid.org/0000-0002-6129-6736

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