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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 cerebral palsy

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ABSTRACT

Introduction Children with cerebral palsy (CP) participate in leisure-time physical activities (PA) less often, with less intensity and reduced diversity than their typically developing peers. Participation in leisure-time physical activities may be an important source of habitual physical activity (HPA) for children with CP, who as a group have lower levels of HPA and increased sedentary time compared with their typically developing peers. The proposed study aims to compare the efficacy of a participation focused therapy (ParticiPAte CP) to usual care in a pragmatic, randomised waitlist controlled trial.

Methods and analysis Thirty-six children with CP (18 in each group), classified as Gross Motor Function Classification System levels I to III, aged between 8 and 12 years will be recruited across South East Queensland, Australia. Children will be randomised to receive either ParticiPAte CP or waitlist usual care using concealed allocation. ParticiPAte CP is an individually tailored, goal-directed intervention model of pragmatic participation-focused therapy using a toolbox of evidence-based strategies in the treatment of children with CP. This will include goal-setting; identification of barriers and facilitators to participation goals, strategy formation and planning and communication guided by principles of Self-Determination Theory using strategies of Motivational Interviewing. The intervention comprises 8 weekly sessions of 1 hour duration conducted by a physiotherapist in the child's home or community.

Trial registration number ACTRN12615001064594.

Strengths and limitations of this study

- To our knowledge, this is the first pragmatic randomised controlled trial to evaluate the effect of a participation-focused physiotherapy intervention on physical activity participation in children with cerebral palsy in an adequately powered study.
- The study is designed to detect whether improvement in child perceived leisure time physical activity participation goal performance and satisfaction will translate into increased levels of habitual physical activity as measured by triaxial accelerometry.
- Inclusion of instruments measuring process-related outcomes including child motivational orientation for physical activity, behavioural barriers to physical activity participation and parental autonomy-supportiveness will enable examination of the hypothesised mechanism of action.
- Individualised intervention parameters may introduce challenges in replication of the study.
- Exclusion of an objective activity capacity measure limits the ability to examine the effect of increased activity capacity on physical activity goal attainment.

INTRODUCTION

Cerebral palsy (CP) is an umbrella term for a group of disorders of the development of movement and posture attributed to non-progressive disturbances to the developing brain in the perinatal period.[1] Motor impairments may be accompanied by secondary musculoskeletal complications and disturbances of sensation, cognition, perception or behaviour.[1] Children with CP experience limitations in their performance of day-to-day activities and restrictions to their participation in home, school and community life.

The WHO's International Classification of Functioning, Disability and Health: Child and Youth Version (ICF-CY) defines participation as 'involvement in a life situation' (p. 9).[2] This definition has, however, been criticised

as conceptually unclear, with overlap of the term with other constructs within the ICF-CY (such as activity and environment).[3–8] Key distinctions between participation and other related constructs have been proposed. Participation refers to 'performance at the societal level' (p. 23) as opposed to the individual, and is associated with the fulfilment of social roles.[3] Participation is described as a relational concept that is dependent on context, and may be influenced by characteristics of the environment predominantly over characteristics of the individual.[3]

Children with CP participate in leisure-time physical activities (PA) less often,[9] with less intensity[10] and with reduced diversity than their typically developing peers.[11] Children and youth with CP and physical disabilities also participate in more informal compared with formal (organised and structured) PA.[11 12] A longitudinal study in young children with CP aged 2–6 years found that activity limitations could predict reduced participation in leisure-time PA.[13] An integrative review of the relationship between motor functioning and leisure participation for young children with a physical disability also concluded that suboptimal motor functioning impacts frequency and diversity of participation in PA.[14] Children with physical disabilities, however, preferred to participate in PA over other types of activity irrespective of their level of motor functioning.[14] This evidence suggests that in the presence of support that enables participation in the activity of choice, the individual preferences of a child and other psychosocial aspects may be equally important determinants to the extent of participation.[15]

Compared with their typically developing peers, children and youth with CP experience a greater number of barriers to participation in leisure-time PA.[16–19] In a cross-sectional study using the Participation and Environment Measure for Children and Youth (PEM-CY), parents of children and youth aged 5–17 years with (n=282) and without (n=294) various disabilities reported that environmental factors (eg, physical access, attitudes of others, adequacy of programmes and services, availability of equipment) and/or personal and intrapersonal factors (eg, lived experience, motivation, peer relations) were barriers to participation in addition to activity limitations.[18] It has been suggested that the interplay of activity limitations and environmental factors is important,[20] and that the environment has a mediating role in explaining the participation of children with disabilities.[21]

Physical activity is defined as any body movement using skeletal muscles that results in energy expenditure (varying continuously between low and high levels).[22] Habitual physical activity (HPA) is PA performed during the usual activities of daily living throughout a period of time (day, week, etc) varying through periods of rest, work and leisure.[23] HPA may be categorised with intensity-related thresholds (called cut-points). The categories establish the amount of energy expenditure: sedentary (little to no energy expenditure above rest), light PA (LPA, moderate levels of energy expenditure) or moderate-to-vigorous PA (MVPA, highest levels of energy expenditure).[24] Participation in leisure-time PA may be an important source of HPA for youth with CP.[25] A cross-sectional study of 62 children with activity monitors in free-living (unrestricted, usual activity at home, school and weekend) conditions identified that ambulant children and young people with unilateral and bilateral CP aged 7–13 years (Gross Motor Function Classification System (GMFCS I–III)) were less active on weekend compared with week days.[25] Children who were more physically active on weekends were more likely to participate in organised sports.[25]

The Australian recommendation for PA is 60 min of MVPA per day for children aged 5–12 years.[26] A study of energy expenditure measured by accelerometry and calibrated to basal metabolic rate has been completed in eight ambulant children aged 7–12 years with bilateral CP (GMFCS II–III).[27] Compared with age-matched and sex-matched typically developing controls (a convenience sample of children without disabilities), in free-living conditions, children with CP had lower levels of HPA by, on average, 2092 kJ/day.[27] In a recent cross-sectional study of 102 ambulant youth with mild-to-moderate unilateral CP (GMFCS I–II) aged 8–17 years in Australia, only 25% of participants met the Australian recommendation for PA on at least 1 day of measurement.[28] Lower levels of HPA and increased sedentary time has implications for the health and well-being of children with CP with respect to factors such as cardiovascular disease risk, bone density, metabolic disturbance risk and obesity.[29]

The broad nature of participation and the complexity of interactions with personal and environmental (contextual) factors leads to challenges in the conceptualisation, development, delivery and measurement of outcomes in participation-focused experimental interventions. A model of participation-focused therapy has been proposed, whereby the intervention is goal-oriented, family centred, collaborative, strength-based, ecological and self-determined.[20] In participation-based therapy, interventions are carried out using a five-step process: (1) develop collaborative relationship with the family and child, (2) determine mutually agreed on goals for participation, (3) assess child, family and environment strengths and what needs to occur, (4) develop and implement the intervention plan and (5) evaluate processes and outcomes with child and family.[20] The participation-based therapy model stresses the importance of individuality—optimal participation is an individually defined (and family/culturally influenced) construct and therefore individualised outcome measures, such as Goal Attainment Scaling (GAS), may offer a more valid means to evaluate the success of a participation intervention.[20]

A recent systematic review investigating interventions aimed at improving participation outcomes for children with disabilities found that only three out of the seven included studies had participation as the primary outcome.[30] The majority of studies targeted body structure and function and activity domains of the ICF-CY, with participation considered a secondary outcome. The

systematic review of seven comparison intervention trials in children with developmental disabilities aged 5–18 years, concluded that interventions such as strength training and activity-based exercise programmes had minimal impact on participation outcomes, while individually tailored programmes incorporating coaching, mentoring and education achieved favourable results on discrete aspects of participation.[30] A second systematic review evaluated PA and behaviour change interventions aimed to increase participation in active physical recreation and HPA in children and youth with CP aged 5–18 years.[31] Included interventions predominantly used strategies (such as skills practice) targeting body structure and function and activity domains of the ICF, assuming there would be secondary improvements in participation frequency and/or HPA level.[31] Results did not support this assumption; there were no clinically meaningful effects of therapy and behaviour change interventions on HPA level and leisure-time PA participation frequency and intensity.[31] Additionally, only two of the eight studies incorporated mutually agreed on goals for participation,[32 33] in line with the model of participation-based therapy.[20] The review highlighted that PA is a complex health behaviour, and the majority of interventions tested were not underpinned by theories of human behaviour and motivation.[31]

Self-Determination Theory (SDT) is an influential theory explaining a variety of phenomena associated with human motivation.[34 35] Basic Psychological Needs Theory describes three basic psychological needs associated with motivation: (i) autonomy (being the initiator and regulator of one's actions), (ii) competence (feelings of self-efficacy and the capacity to produce behaviour that achieves desired outcomes) and (iii) relatedness (the feeling of being connected to others and experience of meaningful reciprocal relationships).[34] According to SDT, internally generated (intrinsic) motivation for sustaining behaviour is promoted through the fulfilment of these needs.[36] An autonomy-supportive climate is one whereby a person's autonomy is fostered and respected, fuelling intrinsic motivation. The opposite, a controlling climate, pressures people to behave in certain ways and undermines intrinsic motivation.[36] Intrinsic motivation is often identified as a strong correlate or predictor of maintenance of healthy PA behaviours.[37]

Interventions to increase leisure-time PA participation or levels of HPA in typically developing children that are based on SDT have demonstrated positive outcomes.[37–39] A systematic review of 66 empirical studies that have measured SDT-related constructs with respect to exercise and PA behaviours, found that overall there is good evidence to support the use of SDT in explaining exercise and PA behaviour across a wide variety of contexts in both 'healthy' and 'diseased' populations.[40] One behavioural intervention approach that is aligned with SDT is Motivational Interviewing (MI), a clinical 'brief intervention' counselling technique.[36]

MI has been used to promote PA behaviours in people with chronic health conditions.[41] MI is a style of communication that is practical to implement in healthcare settings and in the community.[42] A systematic review and meta-analysis identified 37 MI interventions conducted in paediatric populations with health behaviours as the target outcome (such as management of obesity, asthma, dental health or sleep).[43] Based on effect size calculations (Hedge's *g* thresholds; small <0.2, medium <0.5, large >0.8), there were small, significant effects on both physical (*g*=0.18, 95% CI 0.17 to 0.20) and psychosocial (*g*=0.22, 95% CI 0.19 to 0.25) outcomes. Interventions delivered to the parent and child as a dyad were shown to be more effective in achieving health-related outcomes than interventions delivered to parent or child separately.[43] The essential elements of MI are communication techniques which promote 'partnership', 'compassion', 'evocation' and 'acceptance' within and between the patient and practitioner.[44] These communication techniques can be used by therapists seeking to promote an autonomy-supportive climate and work towards modifying PA and health behaviours.[45] Four fundamental processes of MI evolve from building a relational foundation ('engaging'), to communicating with the client in a guiding fashion with a direction or goal in mind ('focusing', 'evoking') and finally discussing strategies or actions ('planning').[44] These processes align with participation-based therapy.[20]

Behaviour changing interventions including MI typically have complex mechanisms of action, involving multiple interconnected elements.[46] The Theoretical Domains Framework (TDF) is an integrative framework of behaviour change theories comprising 14 domains.[47 48] The TDF can be a useful means of categorising barriers and facilitators to behavioural change and behaviour changing strategies and processes within interventions.[47–49] The TDF can be used in multiple ways to apply a theoretical lens to behaviour change, including as the basis for qualitative interviews, process examination and quantitative questionnaires.[50 51] The TDF has been commonly used in implementation science fields, although has a broader application that may help explain the clinical trial outcomes of behaviour changing therapies.[51]

An individually tailored and goal-directed therapy intervention incorporating elements of MI may be effective in improving leisure-time PA participation in children with CP. This intervention would identify and target child and family-specific barriers and facilitators (across all domains of the ICF-CY and TDF) to individually defined participation goals. The intervention would create an autonomy-supportive environment to foster intrinsic motivation for sustainable participation in PA, through fulfilment of basic psychological needs. It is important to test participation-focused therapy in a randomised trial to determine the effect on participation outcomes. ParticiPAte CP is an individualised, goal-directed, family centred, ecological, participation-based and motivational physiotherapy intervention. Our proposed pragmatic, randomised, waitlist controlled trial seeks to determine

if ParticiPAte CP can result in increased leisure-time PA participation goal attainment, translating into increased HPA level, compared with usual care in children with CP aged 8–12 years.

METHODS

Aims and hypotheses

The main aim of the proposed study is to determine if 8 hours of an individualised ParticiPAte CP programme can increase child and parent perceived performance of and satisfaction with participation in three to five self-identified leisure-time PA participation goals, compared with usual care. The intervention will be tested in a randomised waitlist controlled trial in children with CP (GMFCS I–III, all motor types) aged 8–12 years and their primary caregiver. Secondarily, the intervention aims to reduce the impact of contextual (personal and environmental) barriers to child participation in active community recreation, sports and leisure pursuits, improve objectively measured PA health behaviour (increase levels of HPA and reduce levels of sedentary behaviour) and improve child-reported, condition-specific quality of life.

The primary hypothesis to be tested is:

1. In a randomised waitlist controlled trial for children with CP (aged 8–12 years) and their parent/caregiver, ParticiPAte CP will be more effective than a waitlist control group receiving usual care to improve perceived performance and satisfaction with leisure-time PA participation goals by a mean difference of two points on the Canadian Occupational Performance Measure (COPM).[52]

Secondary hypotheses:

ParticiPAte CP will be more effective than a waitlist control usual care group at improving:

1. HPA (increased minutes per day spent in MPVA, decreased sedentary time as a ratio of MVPA and greater proportion of participants achieving 60 min of MVPA per day) as measured with body-worn triaxial accelerometry.
2. Parent-reported contextual barriers to participation (increased total point score and domain averages on TDF-based questionnaire[50 53] on a questionnaire designed for the current study, Barriers to Participation in Physical Activities Questionnaire (BPPA-Q)).
3. Child-reported condition-specific quality of life (increased mean participation and physical health, and emotional well-being and self-esteem domain scores, Cerebral Palsy Quality of Life Questionnaire for Children, Child Version (CP QOL-Child).[54]
4. Parent-reported child participation frequency and involvement in the community setting (increased summary score, PEM-CY).[55]

Secondary analyses will explore potential predictors of increased participation goal performance and satisfaction for pooled data from intervention and waitlist groups following completion of ParticiPAte CP. It is hypothesised that the following will predict the amount of change in child participation goal performance and satisfaction in both groups following the intervention:

1. Attainment of incremental, individualised treatment goals during the intervention measured by GAS. Goals will align with identified barriers to participation across body structure and function, activity, personal and environmental domains of the ICF-CY and/or behavioural domains of the TDF (aggregate T scores).[56]
2. Higher parental autonomy-supportiveness, parent-report (Problems in Schools Questionnaire (PISQ)).[57]
3. Higher child intrinsic motivation for PA, child-report (Motives for Physical Activities Measure Revised (MPAM-R)).[58]
4. Autonomy-supportive climate for physical activities, child-report (Physical Activity Climate Questionnaire (PACQ)).[59]
5. Readiness for change in PA behaviour, parent-report (stage of behaviour change).[60]

Ethics

Full ethical approval has been obtained from the Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/15/QRCH/162) and The University of Queensland Medical Research Ethics Committee (2015001609). Full written and informed consent will be obtained from legal parents/guardians of all participants, and assent from participants aged 12 years, by the study coordinator prior to entering the trial. Important protocol amendments will be communicated with the ethics committees and updated on the trial registry. The ParticiPAte CP clinical trial has been prospectively registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12615001064594).

Study sample and recruitment

Children with CP aged 8–12 years will be recruited across South East Queensland, Australia. Potential study participants will be identified through a population-based research database at the Queensland Cerebral Palsy and Rehabilitation Research Centre (QCPRRC), and the Queensland Paediatric Rehabilitation Service at the Lady Cilento Children's Hospital, South Brisbane, Australia. A facebook page will be created to host the recruitment flyer for advertisement online.

INCLUSION AND EXCLUSION CRITERIA

Child participants

Children with a confirmed diagnosis of CP from a paediatric rehabilitation specialist or child neurologist meeting the following criteria will be included: (1) GMFCS I–III; (2) aged between 8 years 0 months and 12 years 11 months at baseline and (3) live within a 200 km radius of South Brisbane, Australia as the intervention will be delivered in the child's community. Children will be excluded if they (1) have limited ability to communicate insight into

a preferred future (needs, wants and desires) in spoken English and/or through an interpreter or augmentative and alternative communication (ie, Communication Function Classification System (CFCS) levels IV–V and/or children with moderate-to-severe intellectual disability as defined by the 10th revision of the International Statistical Classification of Diseases and Related Health Problems as IQ<50[61] ; (2) have uncontrolled epilepsy (as this may impact on safety to engage in certain PA); (3) have a severe visual impairment or blindness (defined as 6/60 or lower vision, when appropriately corrected, in the better eye or in the written opinion of an ophthalmologist the cortical visual impairment, visual field loss and/or other deficits result in a combined approximate acuity of 6/60 or lower); (4) have severe asthma exacerbated by exercise that is not controlled with medications under an asthma management plan and/or (5) have orthopaedic and/or neurological surgery 6 months prior to and/or planned during the entire study period including follow-up assessments. When eligibility for inclusion is unclear, permission will be sought from parents/caregivers to contact the child's treating therapists and/or doctors to determine eligibility. It is expected that approximately 25%–30% of eligible participants will be recruited (see figure 1).

Parent/caregiver participants

Each included child's primary caregiver (one person who has a long-term parenting role including a biological parent, step parent, adoptive parent or foster parent and has at least 30% of caregiving responsibilities) will also be a participant. Primary caregivers must consent to the therapist travelling to their place of residence or a place convenient to them (eg, outside school hours care centre) to deliver the intervention. Caregivers must be able to communicate their wants, needs and thoughts about the future in spoken English. Caregivers will be excluded if they: (1) have a diagnosed moderate-to-severe intellectual disability or significant communication impairment (self-reported).

Sample size

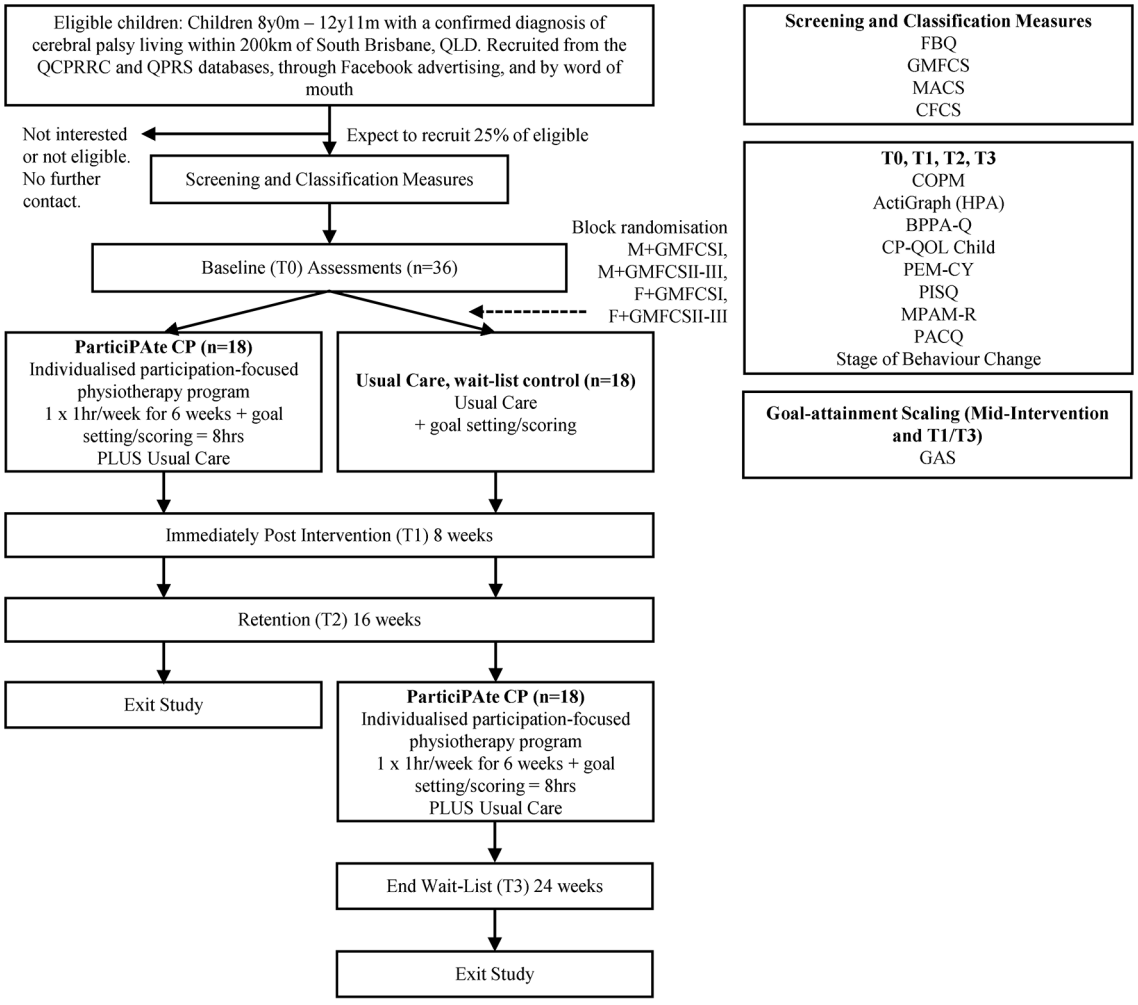
The sample size calculation is based on adequate power for comparison between ParticiPAte CP and usual care on COPM goal performance at the primary end point (T1, 8 weeks, immediately postintervention, figure 1). A change score difference of two points on the COPM performance subscale would be clinically meaningful.[52] A previous pilot study using the COPM as an outcome measure for activity and participation goal attainment in six children and youth with physical disabilities yielded SD between 1.4 and 1.7 for COPM performance.[33] Based on a conservative estimate using a mean change of two points (Stata V.13.1, power 0.8, two-tailed, p<0.05), we require 22 parent-child dyads (11 per group). Allowing for 20% drop out and missing data on actigraphy, a total of 36 parent-child dyads (18 per group) will be recruited. This study has been powered to detect a difference on the primary outcome of interest. Effects on secondary outcomes are not able to be accurately estimated due to limited previous evidence, and the results of this trial will assist in power calculations for future studies.

Randomisation

Parent-child dyads will be recruited in cohorts of 6–12 prior to baseline assessment. When a cohort is filled, further prospective participants will be directed to wait for the next cohort. The allocation sequence will be determined by computer-generated random numbers in blocks of four, stratified into one of four groups based on GMFCS (I or II vs III) and gender (male vs female). These factors were chosen for stratification as they are associated with participation and PA outcomes in the study population.[62] Participants will be allocated to either immediate treatment or waitlist control. The randomisation process is as follows: (i) the child's name, the position at which they had been recruited into the study and their strata (eg, participant name, 13, GMFCS III, female) will be written on the front of an opaque envelope and given to a non-study personnel (who has access to the randomisation sequence that is hidden from the investigators); (ii) the non-study personnel will identify the next available allocation (immediate treatment/waitlist) within the child's strata, cross it off so that it may not be allocated again, then place a folded piece of paper stating child's allocation into the envelope and seal it; (iii) the child's envelope is opened in front of the parent-child dyad after completion of baseline outcome measures except 7-day HPA monitoring.

Blinding

As per allocation procedure, allocation will be blinded to both the treating/assessing therapist and participating parent-child dyads until completion of baseline (T0) COPM goal-setting and questionnaire-based outcome measures. Parent-child dyads will be aware of their group allocation during HPA monitoring at baseline, as this will occur in the 7 days immediately following the baseline goal-setting. The treating/assessing therapist and parent-child dyads will be aware of group allocation during the remaining study time points. As this is a pragmatic study, the COPM is being completed as it would be in a clinical scenario (set and scored by the treating therapist). The COPM and GAS goals are however being assessed by a blinded rater against criteria for goal content, scaling and technical proficiency (see the 'Goal Attainment Scaling' section). Questionnaire-based outcomes will be completed by the child and parent/caregiver directly onto Qualtrics (an online survey platform). Where participating children require assistance to read questions or operate the computer, they will be requested to seek the help of a trusted adult not involved in the study (eg, other family member or teacher) to avoid introducing bias. The survey responses are not able to be modified by the researcher.



Key:
BPPA-Q: Barriers to Participation in Physical Activities Questionnaire
CFCS: Communication Function Classification System
COPM: Canadian Occupational Performance Measure
CP QOL-Child: Cerebral Palsy Quality of Life Questionnaire for Children
FBQ: Family Background Questionnaire
GAS: Goal Attainment Scaling
GMFCS: Gross Motor Function Classification System – Expanded & Revised
MACS: Manual Abilities Classification System
MPAM-R: Motives for Physical Activities Measure – Revised
PACQ: Physical Activity Climate Questionnaire
PEM-CY: Participation and Environment Measure – Children and Youth
PISQ: Problems in Schools Questionnaire
QCPRRC: Queensland Cerebral Palsy and Rehabilitation Research Centre
QPRS: Queensland Paediatric Rehabilitation Service

Figure 1 ParticiPAte CP CONSORT flow chart.

Adverse events and safety

Any minor (eg, delayed-onset muscle soreness requiring ice or rest, injuries not requiring medical attention, psychological distress) or major (eg, injuries requiring medical attention) adverse event associated with ParticiPAte CP will be screened on a weekly basis by the treating therapist by verbal questioning and recorded. Minor or major adverse events will be reported to senior study personnel RB and LS, and referred to the ethics committees if of a serious nature. No data monitoring committee has been implemented as the study is not a drug trial. The treating therapist will be trained in first aid and cardiopulmonary resuscitation. Swimming activities will be completed with direct parent/caregiver supervision. Risk assessments with mitigation strategies will be completed prior to participation in activities considered to be high-risk by mutual agreement between therapist and parent/caregiver (eg, activities in open water, contact sports). Prior to baseline assessment, parents/caregivers will complete a PA readiness questionnaire to record their child's medical conditions and medication regime relevant to leisure-time PA participation. Any decision to describe interim results, stop or terminate the trial will be made by the

investigators with oversight from the ethics committees where necessary.

Study procedure

The efficacy of ParticiPAte CP will be tested using a waitlist randomised controlled trial (RCT) conducted according to CONSORT guidelines (see figure 1).[63] A waitlist design allows for comparison against usual standard of care, without disadvantaging the control group by prevention of access to a potentially effective treatment. Approximately six cohorts of 6–12 participants will be recruited from December 2015 and commenced between April 2016 and April 2017. It is aimed to run cohorts consecutively over the study period to reduce bias introduced by the seasonal nature of many available community PA programmes. All parent-child dyads will attend QCPRRC at the Centre for Children's Health Research in South Brisbane for baseline assessments including COPM goal-setting (T0, 0 weeks) prior to randomisation to either:

1. Immediate treatment group—parent-child dyads begin to receive ParticiPAte CP immediately. Children continue to receive usual care (including physiotherapy, occupational therapy, speech and language therapy, behavioural counselling/psychology, exercise physiology, intramuscular botulinum toxin-A injections and/or serial casting) throughout study involvement. Outcomes will be assessed immediately postintervention (T1, 8 weeks) and at retention (T2, 16 weeks), then dyads will exit the study.
2. Waitlist usual care group—children receive usual care throughout study involvement. Outcomes will be assessed immediately postintervention (T1, 8 weeks) and at retention (T2, 16 weeks). Parent-child dyads will then receive ParticiPAte CP from T2, and outcomes are collected again at end waitlist (T3, 24 weeks) before dyads exit the study. It is important to recognise that goal-setting can have behaviour-changing intervention effects,[64] and therefore it will be included in the description of interventions received by the waitlist control group.

ParticiPAte CP intervention

The ParticiPAte CP intervention consists of eight sessions of 60 min duration each, spread over 8 weeks (generally one session per week). The first and last sessions will be focused on COPM goal-setting and goal-scoring, respectively. Make-up sessions will be scheduled within 1 week if participants and/or the physiotherapist need to cancel a scheduled session. The location of the middle six sessions is expected to be at the child's home, with community (eg, park, swimming pool, basketball court) and/or school visits dependent on the specific participation goals identified by the child and their parent/caregiver. The child with CP and their primary caregiver are the primary targets of the intervention, however, other family members may be involved to varying extents (eg, by being present at sessions, completing activities and/or participating in discussions), depending on both the goals and the broader family/community context. ParticiPAte CP will be:

- Family-centred: both the child and their primary caregiver will be equal and active participants in the intervention with the caregivers recognised as the people who know their child best. Siblings and other family members will be involved as appropriate.[65]
- Ecological: the intervention will be conducted primarily in the participant's home and community setting, with respect to the lifestyle, cultural practices and priorities of the family.[66]
- Goal-directed: clinical reasoning and treatment choices will be driven by participation goals, and all strategy planning and outcome measurement will be linked to these goals.[20]
- Collaborative: COPM participation goals will be set, and strategies for goal attainment will be planned, together between the therapist and family. Responsibilities for actions will be shared. The therapist will take a guiding role,[44] providing a framework while facilitating family ownership and problem solving.[20]
- Context-focused: the participation goal itself will be recognised as occurring within a context (setting that includes people, place, activity, objects and time).[67]
- Individualised: within the boundaries of the main elements (table 1), the selection of evidence-based treatment modalities and the proportion at which these are used will be shaped directly by the unique goals, barriers and facilitators identified by each individual participant.
- Multimodal: intervention elements will be chosen to target modifiable barriers, potentially across all ICF-CY and TDF domains. Barriers identified in the impairment and activity limitation domains of the ICF-CY will only be addressed insofar as they are relevant to individualised participation goals.
- Behaviour-oriented: participation in leisure-time PA will be recognised as a health behaviour. The family's readiness for PA behaviour change and behavioural barriers across multiple domains of the TDF will be used to guide the intervention pathway.
- Self-determined: the overarching intervention framework will recognise the importance of child and family self-determination for leisure participation.[68 69]

The intervention is influenced by models of participation-focused therapy including solution-focused coaching[70] and participation-based therapy.[20] The dosage for ParticiPAte CP has been chosen to strike a balance between efficacy of intervention components and feasibility. An average of four sessions of MI have been demonstrated to have effects on health-related behaviours in a paediatric population.[43] It is possible that some identified barriers to PA participation may not be overcome in 8 weeks (eg, complex equipment prescription and funding). The main elements, examples of intervention

Table 1 ParticiPAte CP intervention content, strategies and aims, tabulated by intervention week

Week	Main elements	Example contents/strategies	Aim/s
1	Create therapeutic relationship Explore barriers and facilitators Set goals	-Empathetic listening, reflective listening -Discussion of meaning and properties of physical activities -Discussion of current and past LTPA participation -Discussion of potential LTPA participation targets, in the context of individual barriers and facilitators and child/family preferred future -Collaborative setting of 3–5 participation frequency of attendance and/or involvement goals (COPM goal performance, confidence and satisfaction)	Build therapeutic alliance, introduce family to role as leaders and key persons and the therapist as guide/facilitator Set SMART goals that are realistic according to the family context and within the constraints of the intervention and therapist expertise
2–7	Further explore and assess impact of barriers and facilitators to participation Assess existence and impact of interactions between child-family-environment-activity-participation Assess, plan, choose and implement therapeutic strategies for (if necessary): body structure and function impairments, limitations in performance of sport-specific skills or activities required for participation, personal (child and family) factors, and environmental barriers	-Motivational interviewing (rolling with resistance, developing autonomy-supportive environment, promote child and family intrinsic motivation for goal attainment, redirection of questions to elicit child thoughts/feelings and promote child control) -Strategy formation and planning for treatment -Set GAS goals as relevant to specific areas of intervention -Research (eg, for available programmes that meet child and family needs) -Sporting drills practice (incorporating motor-learning strategies) -Strength and balance training -Provision of home exercise programme -Provision of information about available programmes/services -Equipment and/or aid prescription -Referral to sources of funding -Communication and problem solving with community stakeholders (eg, coaches, activity leaders) -Site visits (assess barriers in context, observe participation in action) -Collaboration with child's existing therapists -Introduction and teaching of specific behaviour modification strategies where relevant (eg, scheduling, monitoring, rewards and consequences) -Environmental changes and/or universal design (eg, modifications that support physical access) -Interventions that support child sensory and communication needs as relevant to participation (eg, social story, explicit teaching)	Maintain therapeutic alliance, facilitate development of family and child into leadership role, reaffirm role of therapist as guide/facilitator Facilitate fulfilment of child and family basic psychological needs Promote autonomy-supportive physical activity climate in the home Reduce capacity and impairment-related barriers to participation Reduce contextual barriers to participation Reduce impact of negative child-family-environment-activity-participation interactions, and promote positive interactions Improve family awareness of barriers to participation, and facilitate independent problem solving
8	Overview progress Plan for maintenance Score goals	-Discussion of impact of therapeutic elements on COPM goal performance, confidence and satisfaction -Strategy formation and planning for maintenance -Collaborative scoring of 3–5 participation frequency of attendance and/or involvement goals (COPM goal performance, confidence and satisfaction) -Scoring of GAS goals as relevant to specific areas of intervention	Facilitate independent maintenance of behaviour change and participation Score goals and invite reflection

COPM,Canadian Occupational Performance Measure; GAS, Goal Attainment Scaling; LTPA, leisure time physical activity; SMART, specific, measurable, achievable, realistic, time-bound.

content and strategies and aims for each weekly session are summarised in table 1.

Tailoring

The ParticiPAte CP intervention will be highly tailored to each individual family. Without a standardised intervention (eg, strength training with definable characteristics such as repetitions and exercise technique), ParticiPAte CP represents a departure from existing interventions tested in RCTs.[31] ParticiPAte CP is instead a model of pragmatic participation-focused therapy using a toolbox of evidence-based strategies in the individualised treatment of children with CP. At the minimum, all participants will receive some combination of:

- goal-setting and goal-scoring of participation-focused goals;
- strategy formation and planning;
- communications guided by principles of SDT using strategies of MI;
- child-focused strategies (eg, practice of activities/skills using a goal directed motor learning approach);
- context/environment-focused strategies (eg, referral to funding sources for equipment, coaching of community members, site visits).

A key feature of ParticiPAte CP is the use of clinical decision making based on key factors which likely differ significantly between participating parent-child dyads. These key factors include the (i) choice of participation goals, (ii) barriers and facilitators to leisure-time PA participation, (iii) child-family-environment-activity-participation interactions and (iv) stage of parent-child dyad PA behaviour change. Examples of potential tailoring include:

- MI strategies used earlier and to a greater extent with dyads who have not yet started thinking about participating in more lesiure time PA.
- Equipment prescription or loan used where access to appropriate equipment is an identified barrier to participation (eg, the child requires access to a tricycle to participate in recreational cycling).
- Cognitive-orientation approaches to motor learning and skill performance used with child participants with high motivation to attain a specific skill and adequate problem solving and intellectual capacity, and where the lack of skill is a barrier to internally motivated, self-determined participation.
- Solution-focused problem solving used more frequently where behavioural strategies such as action planning, scheduling and monitoring may be appropriate solutions for beginning and maintaining participation (eg, a parent would like to identify solutions to a perceived lack of time to facilitate running at the park once per week).

Intervention strategies and clinical reasoning to support choice of strategies will be recorded for every participant using a standardised tool (supplementary appendix 1).

Usual care waitlist control

Usual care is highly variable for children with CP and can range from weekly clinic-based therapy sessions to school-based consultative services provided on a monthly, quarterly or yearly basis. It is anticipated that the majority of children in this study will not receive direct therapy services for the duration of the study. In order to understand the variability in usual care received, all families in both groups will complete a usual care diary for the duration of their involvement (supplementary appendix 2). This diary will record the frequency and duration of physiotherapy, occupational therapy, speech and language therapy, behavioural counselling and exercise physiology. Carers will report location and dates of intramuscular botulinum toxin-A injections and/or serial casting. Contact details for the child's usual care therapists will be recorded by parents on an optional basis. The therapists will then be contacted to ascertain the content of usual care therapy sessions (eg, goal-directed training, constraint-induced movement therapy, etc) and this will be recorded. It will be important to describe the content and parameters of usual care control groups in as much detail as possible.[71]

Training and fidelity

The physiotherapist delivering the intervention will have an undergraduate degree in physiotherapy accredited by the Australian Health Practitioner Regulation Agency and will be a registered practitioner under that scheme. The physiotherapist will have at least 2 years of postgraduate work in participation-focused paediatric physiotherapy within a community setting. The physiotherapist will have formal training in MI consisting of 2 days of postgraduate intermediate-level theoretical and practical training. The physiotherapist will be aware of funding programmes and supports available for children and families in South East Queensland that help to enable participation in active community recreation, sports and leisure. To enable adequate exploration and reporting of the intervention content and model, the following steps will be taken:

1. Where consent is provided by trial participants, all intervention sessions will be filmed and recorded. Exceptions will be when sessions occur in a setting where children or other people are present that have not provided consent to be filmed.
2. Standardised forms and worksheets will be used for the identification and exploration of barriers and facilitators, documentation of goals, strategy planning and reporting back to participants.

It will not be possible to assess fidelity of individual intervention components (eg, cognitive orientation approaches to motor learning) due to varied application across the cohort. Instead, video recordings and treatment documentation will be reviewed by a panel of therapists with significant experience in creating, assessing and/or delivering models of participation-focused therapy and behaviour changing interventions. The Behaviour

Change Taxonomy[49] coding framework will be used to categorise behaviour change elements and link to potential mechanisms of action (using the TDF domains) by at least two independent reviewers on a random sample of video recordings. This will enable specification of mediators of behaviour change as a result of ParticiPAte CP.

Participant and data management

Electronic data will be managed through a secure database managed by the University of Queensland. Participants will be allocated a 4-digit participant identification code generated by a random number sequence, which will be used to deidentify participant files and forms. Paper documents will be deidentified and stored in a locked filing cabinet at QCPRRC, separate from demographic information and consent forms. Classification measures, child and family demographic and related information will be taken prior to baseline for the purposes of stratification and description of the sample.

Classification measures

Gross Motor Function Classification System–Expanded and Revised

The GMFCS is a 5-level system to classify children with CP aged 4–18 years into categories of gross motor ability. The GMFCS is age specific (there are different classification descriptors depending on the age of the child); the age bands between 6–12 years and 12–18 years will be used in the present study.[72] It is valid and reliable and frequently used to classify functional abilities of children with CP both clinically and in research applications.[72] The GMFCS level has been shown to predict participation in PA in Australian children with CP.[73]

Manual Abilities Classification System

The Manual Abilities Classification System (MACS) is a valid and reliable 5-level system to classify children with CP into categories of age-specific manual skills ability (hand use).[74] The MACS level is a significant predictor of participation in PA.[73]

Communication Function Classification System

The CFCS is a 5-level system to classify children with CP into categories based on their typical ability to send and receive communicative messages (considering all ways in which the child communicates, including augmentative and alternative communication). It has been validated in children with CP aged 2–18 years with moderate inter-rater (κ=0.66), fair parent-professional (κ=0.49) and strong test–retest (κ=0.82) reliability.[75]

Parents will rate their child's GMFCS, MACS and CFCS levels for the purposes of screening and this will be confirmed (or reclassified if necessary) by the treating physiotherapist.

Family Background Questionnaire

The Family Background Questionnaire (FBQ) is a parent-report questionnaire designed for the study to collect information about child and family factors and demographic variables such as child age, school type, family income level, family structure and parental education. Parents will report whether their child has any comorbid conditions including autism spectrum disorder, attention deficit hyperactivity disorder and intellectual disability. A measure of socioeconomic advantage will be calculated based on postcode using the Index of Relative Socioeconomic Advantage/Disadvantage 2011.[76] These factors may influence participation in youth with disabilities.[19] Parents will be asked what PA their child regularly participates in across home, school and community settings. The FBQ will identify any children who may have difficulty engaging in PA for safety reasons and confirm the other eligibility criteria for the study. Identified children will be excluded from participating (eg, the child has uncontrolled epilepsy) or provided with appropriate supports (eg, child's asthma medication readily available).

Primary outcome

Canadian Occupational Performance Measure

The COPM is a semi-structured interview-based outcome measure that captures child and family self-perception performance of and satisfaction with occupational performance goals.[52] Participants will be encouraged to set between three and five active community recreation, sports or leisure goals (the full assessment includes other goal areas related to self-care and productivity which will not be used in this study). Goal performance and satisfaction are both rated from 1 (lowest) to 10 (highest).[52] The viewpoint, interests and preferences of the child will be taken into account in the primary instance. Where the child's perception differs significantly from that of their parent/caregiver, this will be discussed and negotiated at the time of setting or scoring goals.

Participants will also rate goal confidence on the same scale. This adjunct measure called the Belief in Goal Self-competence Scale captures the child and family confidence that they could address the identified goals and reach their expected level of performance.[77] This measure has not yet been validated and is being used for descriptive purposes.

To ensure that goals reflect the participation construct and not the activity domain of the ICF, the Family of Participation-Related Constructs (fPRC) will be used guide development of goals.[67] The fPRC describes two essential elements of participation. The first is attendance which can be measured as frequency of attending and/or the diversity or range of activities the person does. The second is involvement which reflects the experience of participation and might include aspects of engagement, motivation, persistence, social connection and affect.[67] For example, goals that measure frequency of attendance include 'Play a game with the local soccer team, once per week' and 'Ride my tricycle at the park with friends, twice a week'. A goal to measure participation involvement might be 'play all roles (catching, bowling, batting) in the weekly cricket game'. At the time of goal-setting, participants will

be encouraged to reframe goals not meeting the definition of participation frequency or involvement.

Secondary outcomes

Habitual physical activity (ActiGraph wGT3X-BT)

HPA will be measured using triaxial accelerometry with ActiGraph wGT3X-BT devices (ActiGraph, Pensacola, Florida, USA). The device samples the magnitude of acceleration of the trunk in three planes at a set frequency (typically 30 Hz). The raw data are rectified by proprietary software to activity counts, which are proportionate to the HPA of the wearer.[78] Accelerometry has good concurrent validity with oxygen consumption (VO_2) for PA intensity in youth with CP GMFCS I–III.[79] Monitoring of HPA with ActiGraphs over consecutive days (in free-living conditions) has demonstrated good to excellent reliability in Australian children with CP (6 days of monitoring to achieve ICC 0.8 in children).[80] Cut-points published for typically developing children have been used to classify PA in children and adolescents with CP GMFCS I–III.[81] These cut-points may, however, have the potential to misclassify PA for youth with CP, especially those with GMFCS II and III.[24] Activity counts will therefore be transformed via the best available GMFCS-specific cut-points available at the time of analysis, to time spent in sedentary behaviour, LPA and MVPA. Daily, weekday, weekend and weekly averages of duration of PA intensities will be reported. Days of wear and wear duration, step counts and raw activity counts will also be reported. Activity counts will be expressed as vector magnitudes.

At each timepoint, ActiGraph units will be worn by the child for 7 days (5 weekdays and two weekend days) during waking hours while they perform usual activities of daily living in their home, school and community environments. Units will be returned via registered post after day 7 for data extraction and analysis. Caregivers will complete an activity diary so that occasion and duration of wear can be validated against captured data. Recordings of a minimum of 4 days,[80] and with ≥4 hours/day of wear will be retained for data analysis. ActiGraphs will be worn on an elastic belt situated above the iliac spines, with the unit on the right side (although non-compliance with side of wear does not invalidate results).[79] ActiGraph units are not able to be worn during water-based activities including swimming. Parents/caregivers will record daily wear time and what activities, including swimming, the child undertook when the unit was not being worn (supplementary appendix 3 log sample page). A neoprene sleeve will be offered to cover the unit if the child finds the unit to be uncomfortable against the skin.

Barriers to Participation in Physical Activities Questionnaire

The BPPA-Q is a 60-item parent report measure of determinants (barriers and facilitators) to PA behaviour change (supplementary appendix 4). The questionnaire was developed by the authors SR and LS, and is based on the Determinants of Implementation Behaviour Questionnaire (DIBQ).[50] The DIBQ demonstrated good construct validity, high internal consistency and discriminant validity in a sample of physical therapists in the setting of an implementation behaviour intervention.[50]

On the BPPA-Q parents respond to statements such as "I am confident that my child can do enough physical activity to be healthy" on a 7-point likert-type scale (1=strongly disagree to 7=strongly agree). Some statements are worded in the negative, and the scale is reversed for scoring. A lower score indicates more parent-reported barriers to PA behaviour change. All 14 TDF domains are represented in the BPPA-Q (1–10 statements per domain). The BPPA-Q will detect the presence of barriers and facilitators to behaviour change and will enable categorisation of those barriers and facilitators based on established theories of behaviour change. Questionnaire responses will be used as evidence to support the selection of behaviour change strategies in the intervention, and to detect changes following implementation of such strategies.

Cerebral Palsy Quality of Life Questionnaire for Children, Child Version

The CP QOL-Child is a 52-item, condition-specific self-report measure of child quality of life (QOL) that is specifically developed for measuring QOL in children with CP.[82] The majority of items have the stem "How do you feel about…" with a response scale of 9 points from 1=very unhappy to 9=very happy. The domains covered in the child self-report version include physical well-being, social well-being, emotional well-being, school and acceptance by others.[82] It has good concurrent validity, internal consistency (Cronbach's α 0.80–0.90) and test–retest reliability for children aged 9 years and over.[82] Significant discordance exists between child and parent proxy reports in many health-related QOL instruments and the child perspective will be sought in the present study.[83] The CP QOL-Child will therefore be completed by all children, including children aged 8 years and children with intellectual disabilities. An adult who is not participating in the study as the primary parent/caregiver will read the questionnaire alongside the child, and clarify the meaning of the questions and response scale if necessary.

Participation and Environment Measure for Children and Youth

The PEM-CY is a parent-report measure designed to evaluate the participation of children with disabilities across three contexts: home, school and community.[55] For each of 10 items in the home and community settings, and 5 items in the school setting, parents indicate their child's frequency of participation (eight options: daily to never) and typical involvement while participating (five options: very involved to minimally involved). Parents indicate whether they desire change in the child's participation frequency and/or involvement (yes or no, five options for the type of change desired). The PEM-CY also contains items for parents to rate the extent to which environmental factors, supports and resources for each setting are barriers and/or facilitators (13 items for home, 17

for school and 16 for community). Summary scores for participation frequency, involvement, desire for change, environmental supportiveness, supports and resources will be calculated for all domains. In a sample of parents of children with and without disabilities in North America, the PEM-CY demonstrated moderate-to-good test–retest reliability (≥0.58) and internal consistency (≥0.59).[55] In a small pilot study of a 12-week environmental intervention to increase participation in adolescents with mobility restriction, participation frequency on the PEM-CY community domain increased.[84]

Predictors of change

Goal Attainment Scaling

GAS is an objective method of quantifying goal attainment.[56] 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 are personally relevant to the individual family (rather than standardised) with the distance between each increment representing a relatively equal amount of effort or improvement to achieve.[56] Three to five GAS goals will be set, each linked to identified barriers to the overarching COPM participation goals and therefore specific intervention strategies (which align with a component of the family of participation-related constructs, such as activity competence), not the participation outcome itself. The GAS goals will be set in approximately the second week of the intervention, as some change in goal content is expected due to the iterative nature of the intervention and the ongoing process of barrier discovery and assessment. The waitlist control group will not set GAS goals until they receive the intervention. Outcome scores on an individual's goals will be converted to an aggregate T score (regardless of the domain to which the GAS goal is aligned) which will be the unit of analysis.

As recommended by Kiresuk *et al*, a technical proficiency checklist will be employed and a second independent rater familiar with the fPRC (LS, CE) will (i) review all COPM goals to determine whether they are measuring a concept of participation (attendance, involvement, engagement and/or preference) and all GAS goals to determine whether they are measuring a related construct (activity competence, sense of self, context and/or environment) and are (ii) technically proficient (no overlapping or gaps between levels, measurement of only one variable, clarity on how the variable is measured/scaled). Goals not meeting these standards will be excluded from analysis.

Problems in Schools Questionnaire

The PISQ measures the extent to which individuals in a position of authority (ie, the primary caregiver of the child in this study) tend to motivate others in controlling versus autonomy-supportive ways.[57] It consists of a series of eight vignettes describing an incident, and then lists four ways in which the adult in the situation might respond to the child. Parents rate the appropriateness of each of the four response options for each vignette on a likert-type scale (1=very inappropriate to 7=very appropriate). Each response option corresponds to one of four subscales (highly controlling, moderately controlling, moderately autonomy-supportive and highly autonomy supportive). Scores for each subscale can be combined by weighted average to determine an overall representation of the adult's orientation towards control or autonomy support with children.[57] The PISQ has good internal consistency (subscale Cronbach's α=0.63–0.80) and fair test–retest reliability (subscale coefficients 0.77–0.82, total score 0.70).[57] The PISQ was originally developed for use in schools as completed by teachers, however, has been used in parenting research.[85] This questionnaire has been shown to predict the change in intrinsic motivation of children over a period of time in a classroom taught by an autonomy-supportive versus a controlling teacher.[57]

Motives for Physical Activities Measure Revised

The MPAM-R is a 30-item child self-report measure that measures the extent of intrinsic (ie, interest/enjoyment, competence, social) versus extrinsic (appearance, fitness) types of motivation for physical activities undertaken by the child (motivational orientation).[58] Children respond using a 7-point likert-type scale (1=not at all true for me to 7=very true for me) to the stem "I like to do (or I want to do) my chosen physical activity or sport…" with different leafs corresponding to an intrinsic (eg, 'because it is fun') or extrinsic (eg, "because I want to improve my body shape") type of motivation. Motivational orientation has also shown to explain changes in PA behaviour following an autonomy-supportive PA intervention in healthy adults.[86] The original validation study for the MPAM-R of attitudes and perceptions towards exercise in a sample of young adults (mean age 19.5), demonstrated high internal consistency within subscales (Cronbach's α=0.78–0.92).[58] Respondents with greater intrinsic motivations (competence, $F=9.02$, $p<0.01$; enjoyment, $F=9.34$, $p<0.01$; social, $F=4.01$, $p<0.05$) were more likely to be adherent to their exercise regime.[58] Motivational orientation as measured by a questionnaire based on the MPAM-R has shown responsiveness to an autonomy-supportive PA intervention in typically developing school children aged 14–16 years in England.[38] The MPAM-R has not been used in children with CP.

Physical Activity Climate Questionnaire

The PACQ (supplementary appendix 5) is a 15-item, child-report measure of the perceived motivational 'climate' created by the caregiver with respect to the child's participation in physical activities.[59] Children rate each statement (eg, "My parent/caregiver showed confidence in my ability to do well in physical activity") on a 7-point likert-type scale (1=strongly disagree to 7=strongly agree). Higher average scores represent a higher level of child-perceived parental autonomy support for physical

activity participation.[87] A 12-item version of this questionnaire has demonstrated discriminant, convergent (with behavioural regulation for exercise) and cross-cultural (British and Estonian) validity to assess physical activity climate in 432 typically developing youth (mean age 13.95 years).[59] One study of youth athlete's perception of their coach including 362 children aged 11–16 years demonstrated moderately good test–retest reliability for a 6-item of the PACQ (α=0.80–0.81).[87] The PACQ however has not been used previously in children with CP.

Stage of behaviour change

Participants follow a short flowchart consisting of prompts (eg, "is your child currently doing about 60 min of moderate-vigorous intensity physical activity each day?") to arrive at one of five stages of behaviour change specified in the Transtheoretical Model of Behaviour Change (supplementary appendix 6)[60]: (i) precontemplation, (ii) contemplation, (iii) preparation, (iv) action or (v) maintenance. According to the Transtheoretical Model, individuals have different stages of readiness and motivation to change health behaviours, and therefore may respond differently to behaviour changing interventions.[60] Identification of the participants' baseline stage of behaviour change will assist the physiotherapist to tailor the intervention correctly.

Statistical analysis

The primary outcome of the intervention will be assessed using generalised estimating equations for longitudinal analysis to evaluate differences in continuous data at postintervention and 8-week follow-up assessments, on an intention-to-treat basis. This method takes into account the repeated measures on each participant and the potential for missing data. The distributional family with be Gaussian and the identity link will be used. For the COPM performance score, the covariables will be time (three level: 0, 8 and 16 weeks), stratification factors (GMFCS, sex) and group (immediate treatment and waitlist), with a group-time interaction (which will test for the differences between groups at different time points). Further analyses using t-tests will compare outcomes between groups at the primary (8 weeks) and retention (16 weeks) end points for the secondary outcome measures. The GAS goal attainment T scores will be analysed on a within-groups basis with paired t-tests for the whole cohort at end-intervention. A secondary paper will report on post hoc analyses (two-group comparisons for change scores and logistic regression for predictors) to determine the characteristics associated with the greatest change in participation outcomes (best responders). Statistical significance will be set at $p<0.05$ with adjustments for multiple comparisons where relevant. Validity of results will be checked using baseline and general descriptive information available for all eligible families. This includes comparing key characteristics of families who completed the study with those who enrolled in the study but did not complete, and those who did not enrol using the best available information from current population-based statistics.

Knowledge translation

Should the intervention be effective in improving leisure-time PA participation, the authors plan to initiate a knowledge translation plan. This will involve determining the knowledge translation capacity of the project partners, process and timing, impact and evaluation, likely knowledge users and audience (eg, paediatric therapists), main messages and goals, strategies, resources, budget and implementation.

DISCUSSION

This paper presents the study protocol for a waitlist RCT investigating the efficacy of a motivational physiotherapy programme. ParticiPAte CP is aimed to increase child-parent dyad perceived performance and satisfaction with self-identified leisure-time PA participation goals, in children aged 8–12 years with CP classified at GMFCS I–III. This protocol describes a strong theoretical basis for the ParticiPAte CP intervention, and the model of therapy using a toolbox of strategies across ICF and TDF domains including communications consistent with MI. The intervention is tailored to individual parent-child dyads, based on an assessment of modifiable barriers to participation. To the best of our knowledge, this will be the first pragmatic randomised trial investigating a model of participation-focused physiotherapy. Secondary outcome measures including triaxial accelerometry will help to identify whether an effect on goal attainment translates into HPA performance. Other measures of barriers to behavioural change and motivational climate will support or refute the hypothesised mechanism of action; the development of child and family self-determination. It is expected that the results of this trial will be published in peer-reviewed scholarly journals and international academic conferences.

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Contributors SR, RB and LS conceived the study and defined the original study protocol. SR developed the intervention parameters. SR, RB and LS are responsible for all ethics applications and the ethical reporting of the study. CE, RB, SR and LS are responsible for the funding applications associated with the study. CE is responsible for rating GAS goals against a technical proficiency checklist. SR, RB and LS are responsible for recruitment, data collection and implementation of the study. SR, RB and LS will lead the preparation of publications of the clinical outcomes of the study. LS and RB will supervise SR (PhD student) during the trial. All authors have read and approved the final manuscript.

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