

PROTOCOL

PARTICIPATE-CP: OPTIMISING PARTICIPATION IN PHYSICALLY ACTIVE LEISURE FOR CHILDREN WITH CEREBRAL PALSY: A RANDOMISED CONTROLLED TRIAL.

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Author/s:

Dr Leanne Sakzewski, Prof Catherine Elliott, Prof Roslyn Boyd, Prof Jenny Ziviani, Prof Iona Novak, Prof Stewart Trost, Prof Annette Majnemer, Dr David Rowell, A/Prof Keiko Shikako-Thomas, Prof Robert Ware, Ms Sarah Reedman

Sponsor/s:

Not Applicable

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Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

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1 GLOSSARY OF ABBREVIATIONS AND TERMS

Abbreviation	Description (using lay language)
95% CI	Ninety Five Percent Confidence Interval
AEs	Adverse Events
AI	Associate Investigator
CHU-9D	The Child Health Utility 9D
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
COPM	Canadian Occupational Performance Measure
CP	Cerebral Palsy
CPQOL	Cerebral Palsy Quality of Life Questionnaire
ES	Effect Size
GAS	Goal Attainment Scaling
GMFCS	Gross Motor Function Classification System
HPA	Habitual Physical Activity
HREA	Human Research Ethics Application
ICERs	Incremental Cost Effectiveness Ratios
GMFM	Gross Motor Function Measure
ICF	International Classification of Functioning, Disability and Health
MD	Mean Difference
MI	Motivational Interviewing
MVPA	Moderate to vigorous Physical Activity
NHMRC	National Health Medical Research Council
NSW	New South Wales
PEM-CY	Participation and Environment Questionnaire for Children and Youth
QLD	Queensland
RCT	Randomised Controlled Trial
SD	Standard Deviation
SDT	Self Determination Theory
SPIRIT	Standard Protocol Items: Recommendations for Intervention Trials
T1	Time point 1: Baseline
T2	Time point 2: 12 weeks
T3	Time point 3: 26 weeks
T4	Time point 4: 38 weeks (end of waitlist)
WA	Western Australia

2 STUDY SITES

2.1 Study Locations

Site	Address	Contact Person	Phone	Email
Cerebral Palsy Alliance	187 Allambie Road, Allambie Heights, NSW 2100	Prof Iona Novak	0409 078 917	inovak@cerebralpalsy.org.au
University of Queensland, Queensland Cerebral Palsy and Rehabilitation Research Centre	Centre for Children's Health Research, Level 6, 62 Graham Street, South Brisbane, QLD 4121	Dr Leanne Sakzewski	(07) 3069 7345	l.sakzewski1@uq.edu.au
		Professor Roslyn Boyd	(07) 3069 7372	r.boyd@uq.edu.au
Queensland Paediatric Rehabilitation Service, Lady Cilento Children's Hospital	PO Box 3474, South Brisbane, QLD 4101	Dr Leanne Sakzewski	(07) 3069 7345	l.sakzewski1@uq.edu.au
Paediatric Rehabilitation, Princess Margaret Hospital	Hay St Building Princess Margaret Hospital, Roberts Road, Subiaco, WA 6008	Professor Catherine Elliott	(08) 9380 2109	Catherine.Elliott@health.wa.gov.au

2.2 Partner Organisations

Organisation	Address	Contact Person	Phone	Email
Queensland University of Technology, School of Exercise and Nutrition Sciences	Centre for Children's Health Research, Level 6, 62 Graham Street, South Brisbane, QLD 4121	Professor Stewart Trost	(07) 3069 7301	s.trost@qut.edu.au
Curtin University, School of Occupational Therapy and Social Work	Curtin University Building 407.210 Kent Street, Bentley, WA 6102	Professor Catherine Elliott		catherine.elliott@curtin.edu.au
University of Queensland, Faculty of Health and Behavioural Sciences	SHRS, Level 3, Therapies Annexe, The University of Queensland, St Lucia QLD 4072	Professor Jenny Ziviani	(07) 3069 7411	j.ziviani@uq.edu.au
University of Queensland, Faculty of Business, Economics and Law	CBEH, Level 4, PACE, 20 Cornwall Street, Woolloongabba QLD 4102	Dr David Rowell	(07) 3346 4549	d.rowell@uq.edu.au
McGill University, School of Physical & Occupational Therapy	Davis House, 3654 Prom Sir-William-Osler, Montreal, Quebec H3G 1Y5	Prof Annette Majnemer	+1 (514) 398 4501	
		A/Prof Keiko Shikako- Thomas	+1 (514) 398 4400 ext 0802	keiko.thomas@mcgill.ca

3 FUNDING AND RESOURCES

3.1 Source of Funding

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4 INTRODUCTION AND BACKGROUND INFORMATION

4.1 Lay Summary

In Australia, 35,000 people are living with cerebral palsy (CP)¹. People with CP have poorer health outcomes, are less active and have a 1.2 to 1.6 greater risk of chronic health conditions such as diabetes, hypertension and stroke compared with those without a disability^{2,3}. We have promising data about a new intervention called Participate-CP, which is a therapy that improves children's participation in physical activity goals that are meaningful to them. In this trial for 100 children with CP, we will compare Participate-CP to Standard Care to see whether or not the intervention delivers additional benefits over Standard Care.

4.2 Introduction

From as early as three years of age and onwards, children with CP participate less in physically active leisure compared to typically developing peers and participation reduces over time⁴⁻⁶. Participation in physically active leisure is an important source of habitual physical activity (HPA) for children with CP⁷. The Australian Government National Disability Strategy lists personal/community support to promote inclusion and community participation as a major priority area.

Traditionally, therapy interventions for children with CP have targeted impairments (e.g. spasticity) and activity limitations (e.g. walking) with limited translation to enhanced participation in life roles (e.g. mobility in all environments, education, and leisure participation). Our recent systematic review⁸ and another 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. Three small non-randomised pilot studies that directly targeted participation have however demonstrated promising effects to achieve leisure participation goals. These interventions were a paradigm shift as they were individualised, goal directed, and addressed barriers to participation that were multifaceted. They did not, however specifically target participation in physically active leisure or determine whether increased participation improved the overall level of habitual physical activity (HPA).

4.3 Background Information

Community participation and a healthy start to life for Australians with cerebral palsy

In Australia, 600 infants are born annually with CP, making it the most common physical disability in childhood⁹. People with CP have poorer health outcomes (<1.9 standard deviations) compared to age-matched peers², with higher prevalence of sedentary behaviour and significantly increased risk of associated chronic health conditions such as diabetes, hypertension, heart conditions and stroke (odds ratios 1.18-1.59)¹⁰. Children with CP participate in less physically active leisure activities compared to age matched peers⁵ with diminishing participation over time⁴. Parents of children with physical disabilities ranked 'participation research' as their second most important research priority, after 'prevention' of their child's condition¹¹. Additionally, National Disability Research and Development Australia has identified social inclusion research, including participation in community life and access to activities and services, as a top five research priority¹².

A novel intervention to promote increased participation in physically active leisure and habitual physical activity in children with CP

Individually tailored, goal-directed intervention using motivational interviewing to foster an autonomy-supportive environment and enhance child motivation is a novel approach to participation-focused intervention that may increase community participation in physically active leisure and increase time spent in HPA for children with CP.

Four bodies of evidence support our hypotheses:

1. Child and family preferences are a key determinant of participation

Consistently, child¹³⁻¹⁶ and family's preferences^{15, 17,18} are highly associated with participation in leisure-time physical activity. A number of large cross-sectional studies exploring participation preferences in children and adolescents with CP have found inclusion is better when: (a) child preferences for physically active leisure are respected¹⁶; (b) activity and participation intensity reflects the child's motivation and interests¹⁶ and (c) the activities reflect the family's ecology and preferences^{16,19}. These data support a family-centred goal-directed approach, where family values, expectations and preferences are integral to those of the child. These are central to a participation-focused intervention.

2. Barriers and facilitators to participation in physically active leisure for children with CP

Children with CP participate less often in physically active leisure (19% less likely to play sports or ride a bicycle)⁵, with lower intensity²⁰, and reduced diversity compared to their typically developing peers²¹. Owing to societal barriers, they are more likely to only have access to informal physical activities (e.g. backyard games) than organised community sports (e.g. swimming club)^{21, 22}. Over and above their physical disability, children with CP experience more barriers to inclusion, including pain, fatigue, but also attitudinal and built-environment barriers²³⁻²⁶. 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 (e.g. 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 life²⁵. Attitudes and the built-environment are modifiable treatment factors²⁷. 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.

3. Theories of human behaviour and motivation

Intrinsic motivation is a strong correlate and predictor of maintenance of healthy physical activity behaviours, even in the presence of pain from physical disability²⁸. Our work^{29, 30} has shown that motivation in children with CP is low compared to peers. Intrinsic motivation is enhanced by an autonomy-supportive climate in which personal choice is fostered and respected. Self-Determination Theory (SDT) is an influential macro theory explaining a variety of phenomena associated with human motivation^{31, 32}. Intervention based on the principles of SDT has been used to drive increased participation in physically active leisure with typically developing children^{28, 33, 34}. A systematic review of 66 studies found strong associations between SDT predictors and exercise and physical activity outcomes across a wide variety of contexts in both 'healthy' and 'diseased' populations³⁵. Motivational Interviewing (MI) is a SDT complementary intervention used to promote healthy physical activity behaviours in people with chronic health conditions^{39,40}. A systematic review and meta-analysis of 37 MI interventions in paediatric populations found significant effects on both physical ($g=0.18$, 95% CI 0.17, 0.20) and psychosocial ($g=0.22$, 95% CI 0.19, 0.25) health behaviour outcomes. Interventions delivered with the parent and child as a dyad were more effective in achieving health-related outcomes than interventions delivered to the parent or child separately⁴¹. Intervention aimed to increase participation in physically active leisure, underpinned by SDT and using MI delivered to child/parent dyads will promote motivation to sustain changes in physical activity behaviour.

4. Multifaceted intervention to optimise participation: the intervention toolbox

Potential barriers and facilitators to participation in physically active leisure are multifaceted with an interaction of personal, environmental and task specific factors. A single intervention strategy focused on any

one factor alone is, therefore, unlikely to have a significant impact on participation outcomes^{36, 37}. Small pilot feasibility studies of three different multifaceted interventions to improve leisure time participation of children and adolescents with physical disabilities used various combinations of intervention strategies including: (a) goal-setting, coaching and solutions-focused problem solving³⁸⁻⁴⁰; (b) targeting environmental barriers^{38, 39, 41}; (c) activity performance strategies (skills competence)³⁹. Results from these pilot studies support multifaceted interventions to achieve participation goal attainment (ES 0.59)^{39, 40} and increase levels of HPA³⁸.

Limitations of current interventions to increase participation in physically active leisure

Traditional interventions for children with CP have focused on reducing impairments and improving activity limitations (i.e. functional capacity). The ultimate goal of all rehabilitation is to enhance children’s participation in society. A systematic review of interventions to increase participation outcomes for children with disabilities³⁷ and a more recently targeted systematic review and meta-analysis by our group (CIA, CIC) on interventions to increase leisure-time physical activity in children with CP³⁶ (Fig. 2) found: (a) most interventions targeted impairments and activity limitations with participation as a secondary outcome; (b) interventions predominantly utilized generic strength training, aerobic training and activity-based exercise protocols, however, there was limited carryover effect of improved participation and no discernible increase in physical activity levels for interventions primarily aimed at activity limitations; (c) most studies DID NOT: use a personally meaningful goal-directed approach; recognise the preferences of children and families; determine personal, environmental and task related barriers and facilitators to participation goals or actively address these barriers using a multifaceted intervention. One small pilot study (n=8) directly targeted leisure participation using an individualised, goal-directed approach which addressed barriers to participation and showed promising effect to achieve participation goals (ES 0.59)⁴⁰. Two further pilot studies (n=8; n=6) similarly used a goal-directed, multi-faceted intervention strategy with promising effects on leisure participation (Mean Difference 4.5 (SD 1.8) for COPM performance which is greater than the clinically meaningful difference of 2 points)^{39, 41}. This multifaceted intervention approach now needs to be tested definitively in an adequately powered RCT.

Figure 2:
Previous study outcomes, limitations and importance of ParticiPate CP⁸

	TARGETED: <i>Participation primary aim</i>	INDIVIDUALISED: <i>goal focused</i>	Determine barriers and facilitators	Multi-faceted intervention	Participation/ HPA Gains	Cohen's Effect
Intervention studies with participation in leisure time PA as a primary or secondary outcome						
1 Bania 2015	—	—	—	—	NO	0.38
2 Mitchell 2016	—	—	—	—	NO	0.25
3 VanDen Berg Emons 1998	—	—	—	—	NO	Not estimable
4 Van Wely 2014	—	—	—	—	NO	0.02
5 Capio 2015	—	—	—	—	NO	Not estimable
6 Cleary 2016	—	—	—	—	NO	Not estimable
7 Verschuren 2007	—	—	—	—	YES	0.79
8 Maher 2010	✓	✓	✓	✓	YES	0.61
9 Law 2015	✓	✓	✓	✓	YES	0.59
ParticiPate CP pilot^{CIA, CIB, CIC}	✓	✓	✓	✓	YES	1.35

Participate-CP: A novel intervention to increase habitual physical activity through participation in physically active leisure

Participate-CP is a targeted intervention underpinned by Self Determination Theory^{38,39} and using communication techniques of motivational interviewing. It is individualised and specifically tailored to the participation related goals and preferences of children and their family. This is a major paradigm shift in therapy approaches for children with CP. Participate-CP represents a departure from existing interventions tested in RCTs as it does not use a standardized intervention (e.g. standardized, non-individualized strength training with definable characteristics such as repetitions and exercise techniques), found to be **ineffective** to increase physical activity participation in this population³⁰. Participate-CP is a model of pragmatic participation-focused therapy utilising a toolbox of evidence-based strategies. A key feature of Participate-CP is the use of clinical reasoning based on key factors, which likely differ substantially between participating parent-child dyads. These factors include the: (i) choice of participation goals; (ii) identification of barriers and facilitators to participation in physically active leisure; (iii) acknowledgement of child-family-environment-activity-participation interactions and; (iv) stage of parent-child dyad physical activity behaviour change. Essential elements of Participate-CP include:

1. Goal directed, individualised and family-centred: Two to three participation goals (e.g. horseback riding once per week in the community) are first identified by the child and parent. The therapist then explores with the child and family the potential barriers/limiting factors and facilitators to the participation goals (e.g. equipment requirements, community attitudes, child factors).

2. Ecological: The intervention is delivered in the child's home, school, community environment as relevant to each participation goal.

3. Multifaceted intervention strategies: Strategies are targeted to the unique and modifiable barriers to participation for each child will include a combination of: (a) Motivational interviewing strategies used earlier and to a greater extent with dyads who have not yet started thinking about participating in more physical activity; (b) Equipment prescription or loan where access to appropriate equipment is an identified barrier to participation; (c) Cognitive-orientation approaches to motor learning and skill performance used with participants with high motivation to attain a specific skill, and where the lack of skill is a barrier to internally motivated, self-determined participation; (d) Solution-focused problem solving where behavioural strategies such as action planning, scheduling and monitoring (may be appropriate solutions for beginning and maintaining participation or overcoming environmental barriers).

Therapists will video-record all intervention sessions for central monitoring of content and fidelity across sites.

In partnership with our international collaborators (CIG, AI Shikako-Thomas), we will be adding all community-based resources/activity details onto the JOOAY App as an Australian site. The App was developed in Canada by the Childhood Disability Link to help children with disabilities and their families to locate, by GPS, local leisure opportunities which are adapted and/or integrated, reflect their preferences, needs and abilities. This resource will be built as part of the current study (experimental arm) to support families and service providers in the translation of Participate-CP. An overview of the Participate-CP intervention is described in Table 1.



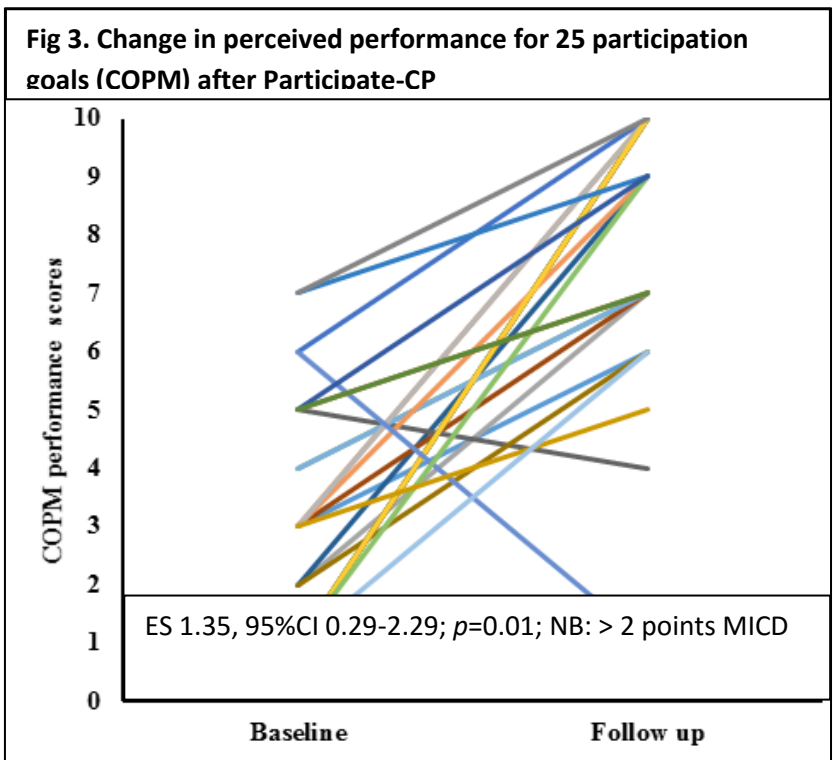
Table 1. Participate-CP intervention content, strategies and aims, tabulated by intervention week			
Week	Main elements	Example contents/strategies	Aim/s
1	Create therapeutic relationship; Explore barriers and facilitators; Set goals	Empathetic listening, reflective listening. Discussion of meaning/properties of physical activities. Explore current, past, and potential physically active leisure activities, barriers & facilitators. Collaboratively set 2-3 participation goals on frequency of attendance and/or involvement	Build client trust and confidence with therapist Specific, measurable, achievable, realistic and time limited (SMART) goals
2 - 11	Explore/assess impact of barriers & facilitators to participation Assess, plan, choose & implement therapy strategies in collaboration with children and families	Motivational interviewing (rolling with resistance, developing autonomy-supportive environment, foster child & family motivation for goal attainment, redirection of questions to elicit child thoughts/feelings and promote control). Strategy formation and planning for intervention; set goals using Goal Attainment Scaling (GAS) relevant to specific intervention strategies Knowledge/awareness strategies: Assist families to explore available adapted community programs that meet child/family needs. Provision of information about programs/services Environmental based strategies: Equipment and/or aid prescription; Referral for funding; Communication & problem solving with stakeholders (e.g. coaches, activity leaders); Site visits (assess barriers in context); Environmental changes and/or universal design (e.g. support physical access) Activity/skills/competence strategies: Sporting drills practice (motor-learning strategies); goal specific strength and balance training; Home program	Promote autonomy-supportive climate in home; Promote +ve interactions; Facilitate independent problem solving; Reduce contextual barriers to participation Increase child and family awareness of options for physically active leisure activity JOOAY App Modify environment or activity to facilitate participation Reduce capacity & impairment-related barriers to participation
12	Overview progress Plan for maintenance and ongoing implementation Score goals	Discuss impact of therapeutic elements on goal performance. Strategy formation and planning for maintenance. Collaborative scoring of participation goals (COPM). Scoring of GAS goals as relevant to specific areas of intervention. Set new COPM goals for children and families to address until final assessment	Facilitate independent maintenance of behaviour change and participation Score goals and invite reflection Determine child/families ability to independently address new goals

Pilot data, which supports this new RCT

We have developed and tested an 8 week program of Participate-CP in a pilot RCT in south east Queensland⁴². Preliminary data for 16 children (Participate-CP n=8; Control n=8) with CP (GMFCS I-III) examined feasibility and short-term effects after intervention (Figure 2).

Feasibility of pilot Participate-CP:

- (a) All participants completed 8 sessions of Participate-CP
- (b) Significant difference between Participate-CP and control for COPM performance of participation goals (MD 2.4, 95% CI 0-4.8; $p=0.05$)
- (c) Of the 25 physically active leisure participation goals set by 8 participants in the intervention group (COPM); 8 (32%) were fully achieved, 15 (60%) changed by a clinically meaningful amount and only 2 (8%) did not achieve a clinically meaningful change (Figure 3).
- (d) Eight weeks of intervention was not long enough to overcome barriers particularly related to sourcing equipment/funding to support sporting activities, therefore a longer program of Participate-CP is recommended. This is supported by a further small pilot study of an 8 week multifaceted participation intervention for adolescents with CP ($n=11$)³⁹, so the current proposed study will deliver Participate-CP over 12 weeks.



5 STUDY OBJECTIVES

5.1 Research Aim

This pragmatic, randomised controlled trial (RCT) in 100 children with cerebral palsy aged 8 to 12 years aims to evaluate the effects of a multi-faceted participation-focused intervention, known as “Participate-CP” versus standard care on:

Primary Outcome immediately post intervention at 12 weeks:

- I Performance and satisfaction with individualized physically active leisure goals
- II Daily time spent in Moderate to Vigorous Physical Activity

Secondary Outcomes at 12 and 26 weeks:

- III Frequency, intensity, diversity, capacity and/or independence of overarching participation goal
- IV Community participation frequency, involvement and environmental supportiveness
- V Contextual barriers to participation
- VI Quality of life
- VII Intrinsic motivation for physical activities
- VIII Child perception of an autonomy-supportive climate for physical activities

5.2 Primary Objectives and Hypotheses

PRIMARY HYPOTHESIS

For children with CP aged 8 to 12 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:

- I Performance and satisfaction scores on the COPM by a difference of 2 points, which is the clinically meaningful important difference⁴³, and
- II Daily time spent in Moderate to Vigorous Physical Activity (MVPA) measured by the Actigraph GT3X+ 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 wait-list control group receiving usual care to:

- III Frequency, intensity, diversity, capacity and/or independence of overarching participation goal according to separate incremented goals using Goal Attainment Scaling (GAS)⁴⁴
- IV increase participation frequency, involvement, and environmental supportiveness scores on the Participation and Environment Measure for Children and Youth (PEM-CY)⁴⁵
- V fewer reported contextual barriers to participation on the Barriers to Participation in Physical Activities Questionnaire (BPPA-Q)⁴⁶
- VI increase domain scores of the parent-proxy and child-reported CP Quality of Life Questionnaire (CP QOL)⁴⁷
- VII increase intrinsic types of motivation for physical activities on the Motives for Physical Activities Measure – Revised (MPAM-R)⁴⁸
- VIII increase perception of an autonomy-supportive climate for physical activities on the Physical Activity Climate Questionnaire (PACQ)⁴⁹

5.3 Outcome Measures

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-waitlist (T4) outcomes.

Primary outcomes at Primary End-Point:

I Canadian Occupational Performance Measure (COPM) performance and satisfaction with physically active leisure participation goals

The COPM⁴³ 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 change⁵⁰. To ensure that goals reflect the participation construct and not the activity domain of the ICF, the Family of Participation-Related Constructs will be employed to frame goals in terms of frequency of attendance and/or involvement⁴⁹. 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.

III Daily time spent in MVPA (Actigraph GT3X+)

ActiGraph GT3X+ will be worn on the hip for seven consecutive days. Activity counts will be transformed via the GMFCS-specific cut-points developed by CIF⁵¹ to time spent in sedentary behaviour, light and MVPA. These cut-points were shown to substantially reduce misclassification error among youth with more severe motor impairments; and provided more accurate assessments of physical activity intensity than previously published validation using cut-points for children and adolescents with CP⁵². A wear time of seven days is required to achieve maximum validity in this population⁵³. Caregivers complete a logbook to record the child's activity and position throughout each day of wear to perform validation of the data if required. Children will be offered a standard elastic belt for wearing the device on the waist and a neoprene cover if required for comfort.

Secondary outcomes:

III Frequency, intensity, diversity, capacity and/or independence of overarching participation goal

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 standardized) with the distance between each increment representing a relatively equal amount of effort or improvement to achieve. Each goal will describe an element of participation, linked to the participant's primary COPM goal, such as frequency, intensity, diversity, or assistance required. Goals will be set collaboratively mid-intervention (rather than at the same time at 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 wait-list 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).

IV Participation frequency, involvement and environmental supportiveness

Participation and Environment Questionnaire (PEM-CY)^{45, 54} is a parent completed questionnaire with good test-retest reliability and internal consistency⁴⁵. Summary scores for participation frequency, involvement and environmental supportiveness will be evaluated

V Contextual barriers to participation

Barriers to Participation in Physical Activities Questionnaire (BPPA-Q)⁴⁶ is a questionnaire based on the Theoretical Domains Framework structure (TDF) and developed by the authors. Questionnaires based on TDF have validity and reliability⁵⁵ to detect the presence and quantity of barriers and facilitators to behaviour

change, and allows categorization 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, and to detect changes following implementation of such strategies.

VI Quality of life

Cerebral Palsy Quality of Life Questionnaire for Children, Child Version and Parent-proxy Version (CP-QOL Child; CP QOL)^{47, 56, 57} developed by CIC and co-authors. Due to potential discordance between child and parent reported quality of life⁵⁸, both perspectives will be sought. The CP QOL has good concurrent validity, internal consistency (α 0.80-0.90) and test-retest reliability⁴⁷.

VII Intrinsic motivation for physical activities

Motives for Physical Activities Measure (MPAM-R)⁴⁸ is a child self-report measure that assesses intrinsic (i.e. interest/enjoyment, competence, social) vs. 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.

VIII Child perception of an autonomy-supportive climate for physical activities

Physical Activity Climate Questionnaire (PACQ)⁴⁹ is filled in by a person (i.e. child) with reference to a specific leading individual (i.e. 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.

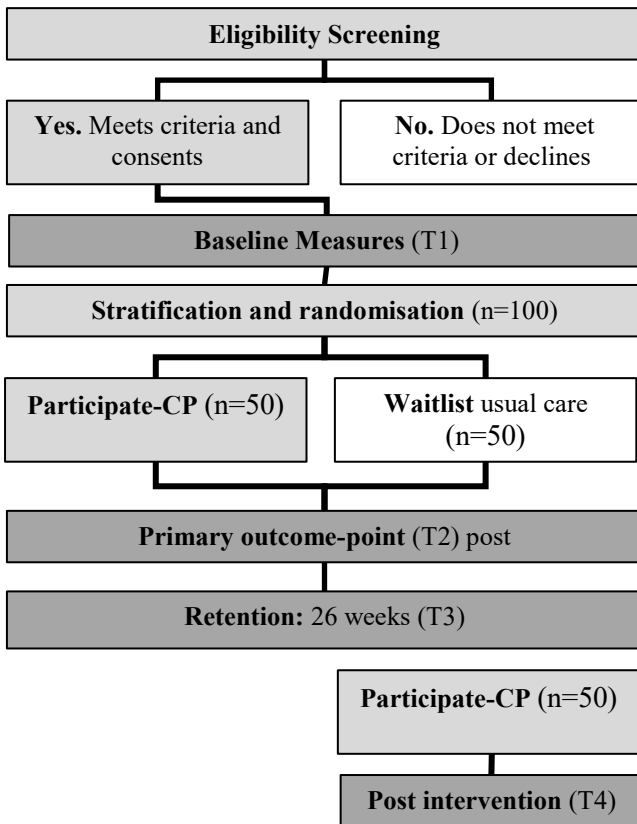
5.4 Economic Evaluation

A within trial cost-utility⁵⁴ analysis will be conducted to synthesize the costs and benefits of the Participate-CP intervention. Resource use (staff time, equipment and facility use) associated with the program will be collected alongside the RCT. Health care utilization will be collected using a resource use questionnaire previously used in our CP child studies⁵⁵. Utility will be derived from the CHU-9D⁵⁶ a child quality of life measure designed specifically for economic evaluation and which has been validated in an Australian population⁵⁷. Al Rowell will provide expertise in developing economic models to analyze costs and outcomes of the Participate-CP intervention. Incremental Cost Effectiveness Ratios (ICERs) will be estimated and where appropriate sensitivity analyses will be undertaken as in previous RCTs by our group⁵⁸.

6 STUDY DESIGN

6.1 Study Design Diagram

Figure 2: Consolidated Standards of Reporting Trials (CONSORT) Study Design and Study Flow Diagram



6.2 Study Type, Design and Schedule

Type of study:

This study is a pragmatic, randomised waitlist controlled trial (RCT) in 100 children with cerebral palsy aims to evaluate the effects of a multi-faceted participation-focused intervention, known as “Participate-CP” versus usual care.

This multi-site randomised waitlist controlled trial has been designed according to the SPIRIT statement⁵⁹, and will be reported according to the CONSORT statement⁶⁰ and registered on the Australian New Zealand Clinical Trials Registry.

Participants:

Children with cerebral palsy, aged between 8 and 12 years and their primary caregiver (parent/guardian)

Sites:

This is a multi-centre RCT across our three collaborating centres (QLD, NSW, WA) with five sites.

Design leading to aim achievement:

We will conduct a RCT to test the effectiveness of a novel multi-faceted participation-focused intervention “Participate CP” to improve time spent in daily moderate to vigorous physical activity and performance of and satisfaction with physically active leisure participation goals in 100 children with cerebral palsy. We have chosen to conduct an RCT, which is the highest quality design for answering an effectiveness of treatment research question.

Data types:

We will collect objective data on habitual physical activity, using the ActiGraph device which is suitable for use with children. Four subjective measures will be collected from children and are appropriate to be used with children eight 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 collection:

Data will be collected in one of three ways:

- Paper forms
- Online survey platform (Qualtrics) instead of/in addition to paper forms
- Devices (ActiGraph and photo/video/audio recording devices) owned by sites/organisations (not personal devices)

Data transfer:

Data will be transferred securely in one of the following ways:

- Data collected on Qualtrics (electronic) will be downloaded and stored on the secure QCPRRC research server and uploaded to RedCap
- 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 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 data collection phase
- Data collected from devices will be downloaded from devices by the site therapist, forwarded using a secure file transfer service such as CloudStor and stored on the secure QCPRRC research server or uploaded directly to RedCap, then deleted.

Data storage:

Data (both working and archived data) recorded on paper will be stored 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 at the Centre for Children’s Health Research, South Brisbane Australia (Dr Leanne Sakzewski, Professor Roslyn Boyd) 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.

Timelines:

	Year 1 2018	Year 2 2019	Year 3 2020	Year 4 2021
Finalise Manual of Operations				
Complete human ethics				
Recruit staff and therapists				
Educate therapists to ensure Participate CP fidelity				
Recruit participants				
Treat participants and collect data				
Analysis, write up and publication				

Home/community visits:

We are conducting “Participate CP in the child’s home or in the community as is relevant to each child’s individual participation goal. This is necessary to ensure the ecological validity of the intervention.

The Queensland Cerebral Palsy and Rehabilitation Research Centre, University of Queensland has a home visiting policy (POLICY 41330) and guidelines for Travel Claims, which will be strictly adhered to by all study sites.

The Queensland Cerebral Palsy and Rehabilitation Research Centre (POLICY 41330)

To mitigate potential risks for conducting home/community visits:

- 1) All staff and students complete the risk assessment and travel form as per Children’s Health Queensland Guidelines prior to conducting the visit:
- 2) Traveler must call a nominated staff member or student at the beginning of a home visit and upon completion
- 3) Traveler must share their electronic calendar with QCPRRC (admin) and Operations Manager
 - Ensure you take your mobile phone to the visit
 - Book appointment for home visit in your electronic calendar – use participant ID
 - Attach a copy of QCPRRC Home Visit Form and Home Visit Risk Assessment Plan to the appointment in your calendar
 - Call or SMS QCPRRC or another QCPRRC clinician when starting/finishing a visit as arranged prior to the visit

QCPRRC Travel Claim Guidelines

The points below are to be used as a guide only and you should seek independent financial advice from an account/tax agent regarding your specific personal circumstances.

A kilometric allowance may be provided to you to perform itinerant therapy services in a research trial. This kilometric allowance is usually funded by a research grant (e.g. NHMRC, CP Alliance Research Foundation etc.) and then administered by a university. The kilometric allowance generally follows the Australian Taxation Office (ATO) amount (66c per kilometre at 2016/17) depending what was budgeted for in the grant.

How to record kilometres travelled

Purchase a pre-made logbook (from Officeworks etc.) or create your own. The logbook should record the minimum details for ATO recordkeeping:

- *when the logbook period begins and ends*
- *the car’s odometer readings at the start and end of the logbook period*
- *the total number of kilometres the car travelled during the logbook period*
- *the number of kilometres travelled for each journey recorded in the logbook (if you made two or more journeys in a row on the same day, you can record them as a single journey). You will need to record the*
 - *start and finishing times of the journey*
 - *odometer readings at the start and end of the journey*
 - *kilometres travelled*
 - *reason for the journey.*
- *the business-use percentage for the logbook period*
- *the odometer readings at the start and end of each income year you use the logbook method*

Example logbook line

Start time	Finish time	Reason/Details	Start Odo	Finish Odo	Date	Signature
12.34	15.52	Home visit to Browns Plains (Carina to Browns Plains return)	14365	14453	12/02/17	<i>An Example</i>

You will need to know exactly how many kilometres you travelled on your itinerant trips to submit your invoices (to receive payment). However, when you are working things out for your tax return, there is only a minimum 12-week logbook period.

Working out business and non-business kilometres

Generally, you cannot claim for travel between your home and your regular workplace (office). When you are completing home visits as part of a trial, however, your own home might be considered your 'office' given the highly itinerant nature of the work. You should always check the current requirements and rules of the [ATO on their website](#). Your logbook only needs to list business trips (and assumes that the missing kilometres are private), though it still needs to comply with the above points.

How to submit an invoice

Use the required template for your administering institution (e.g. UQ has a standard invoice template with a cost centre and lines for each journey – ask the research manager or finance officer for the correct template and information about the correct person to submit the invoice to). You might decide to submit invoices each time you exceed a certain dollar amount (e.g. \$500), or on a periodic basis (monthly/quarterly). It is easier to submit regular invoices.

Car expenses

The kilometric allowance is a payment designed to capture all expenses associated with running a car, not just petrol. These include:

- fuel and oil
- repairs, tyres and servicing
- interest on a car loan or depreciation on the value
- lease payments
- insurance
- registration
- Washing (especially to maintain the quality of the paintwork/value of the car)

Because it is supposed to be an allowance that covers your expenses, any 'profit' that you make from the allowance is considered as income. It is very important that you keep receipt records for ALL expenses for the period in which you are claiming kilometric allowance. **If you exceed 5,000 business kilometres in a financial year (regardless of whether you are an employee or student), your kilometric allowance above that threshold is assessable income.** Assessable income is taxable earnings, and you could be liable to pay tax on the money received through payment of the allowance.

Working out your tax obligations

Each 66c/kilometre over 5,000 will be treated as assessable income. You need to work out your business use percentage to calculate how much of your expenses you can apply as a deduction to reduce your tax liability. Steps:

1. Use representative (minimum) 12-week sample period from your logbook
2. Calculate the business use percentage of your travel (based on your odometer readings) during that period

$$\text{Business use \%} = \frac{\text{Total business kilometres}}{\text{Total kilometres travelled incl. private}} \times 100$$

3. Sum your total expenses for the financial year, including all the expenses listed above (fuel, registration etc.). You **NEED** documented evidence e.g. purchase receipts or at least bank statement records or an estimate of fuel costs based on published local average prices
4. Apply your business use percentage to your total expenses
 $\text{Deduction amount} = (\text{Business use \%}) \times \text{Total financial year expenses}$
5. This is the amount you can deduct against the 'income' you received as kilometric allowance above 5,000 kilometres. This is what you claim as a deduction to your assessable income on your tax return
6. Keep ALL records associated with your calculations together with your tax return and store them for the minimum period

If you receive kilometric allowance for another job, the amount paid to you was less or more than 66c per kilometre (or the current rate), you are leasing or borrowing your car from someone else, multiple people use your car for business purposes, or you also have overnight travel stays as part of your itinerant work, your obligations may be more complex. The steps outlined in this document do not constitute official advice. It is important to get advice from a registered tax accountant if you are unsure of your obligations.

Contingencies

We do not anticipate problems with our plan to recruit 100 children across 3 metropolitan and 2 regional sites. The waitlist design ensures that all participants receive the intervention, thereby enhancing recruitment. Based on data from the Australian Cerebral Palsy Register, there are 2360 children potentially eligible for study

inclusion across the three states. The CIs and AIs have a strong track record of successfully completing NHMRC trials, with all completed studies achieving recruitment targets⁶¹⁻⁶⁵.

Research Students:

This study may involve research higher degree students, who would be identified by CIs. Students would not be involved in the primary analysis of the study, but on peripheral aspects.

Study visits/outcome measure schedule:

Table x: schedule of assessments/procedures					
Assessment/Procedure	Screening	T1 Baseline Assessment	T2 Follow-up Assessment 12 weeks	T3 Follow-up Assessment 26 weeks	T4 End waitlist 38 weeks
Informed Consent	x	x			
Demographic Information	x	x			
Physical Activity Readiness Questionnaire	x				
Gross Motor Function Classification System	x				
Manual Abilities Classification System	x				
Communication Function Classification System	x				
Stage of Behaviour Change Questionnaire	x				
Health Resource Use Questionnaire (P)	x				
OUTCOMES					
Canadian Occupational Performance Measure (C, P)		x	x	x	x*
Actigraph (C)		x	x	x	x*
Participation and Environment Questionnaire – Child and Youth (P)		x	x	x	x*
CP Quality of Life Questionnaire-Child self-report (C)		x	x	x	x*
CP Quality of Life Questionnaire-Parent proxy report (P)		x	x	x	x*
Goal Attainment Scale (P, C)		x	x		x*
Barriers to Participation in Physical Activities Questionnaire (P)		x	x	x	x*

Motives for Physical Activity Measure (C)		x	x	x	x*
Physical Activity Climate Questionnaire (P)		x	x	x	x*
Child Health Utility 9D (C)		x	x	x	x*

Key: C = child completed; P = parent completed; *waitlist group only

Booking appointments:

Study appointments will be booked online by caregivers using a free appointment-booking tool (example: <https://participatecp.simplybook.me/>). Missed appointments can be made up within a two-week period by mutual agreement. The default location for the baseline, 12-week and 26-week appointments is the site office (for example, Centre for Children’s Health Research in the South-East Queensland Site) however home visits for these appointments can be arranged in extenuating circumstances.

6.3 Usual Care and Additional to Usual Care Procedures

Both the Participate-CP and waitlist group receive usual care from T1-T3. Usual care will be highly variable both within and across participating sites. Caregivers will complete a usual care diary that records the number of hours per week their child accessed (rounded up to the nearest hour) of each of the following therapies:

- Physiotherapy
- Occupational Therapy
- Speech/Language Therapy
- Exercise Physiology/ Exercise Therapy
- Psychology/ Counselling

Caregivers will also be asked to report any episodes of Botulinum Toxin-A injections (site/s, date/s) and casting/splinting for hypertonicity/contracture management (site/s, date/s). Participants will complete the diary from the first assessment until follow-up assessment (intervention group) or the end of the intervention (wait-list group). Usual care will be compared between intervention and wait-list participants.

6.4 Randomisation

Al Ware, biostatistician, will create one central randomization schedule using computer-generated random numbers (in permuted blocks of four), to receive Participate-CP immediately or to waitlist standard care. Participants will be stratified by GMFCS (I and II vs III and IV) to ensure treatment balance across both groups. An electronic system will determine allocation, completed by non-study personnel. Group allocation will be concealed to the treating therapist, research team, and the family until after all baseline measures except 7-day ActiGraph are completed.

6.5 Blinding

Participants:

Participants will not be aware of allocation until after the majority of baseline assessments have been completed. It is not possible to blind participants to the treatment received at T2 and T3. Participants will be aware of allocation when children are wearing the ActiGraph however this is an objective measurement of movement and activity levels and it is expected that there will be little to no influence of knowledge of group allocation on the outcome.

Therapists:

The assessing and treating therapist is the same. Therapists will not be aware of allocation until after the majority of baseline assessments have been completed. Children and their caregivers complete questionnaires at home using an online platform, 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.

6.6 Study Methodology

This study involves 10 clinical assessment tools. All of these tools have been described in detail in Section 5.3 (Outcome Measures).

7 STUDY POPULATION

7.1 Recruitment Procedure

Families with a child meeting eligibility criteria will be invited to join the study through our five collaborating sites (QLD, WA, NSW). Children will be recruited across South East Queensland, South West Western Australia, Sydney and one regional site each in the higher population states (NSW, QLD).

Testing the intervention in regional sites is considered essential. There may be additional and unique barriers to participation compared to metropolitan sites, which may have greater opportunities/resources/supports for physically active leisure activities. A sample of children with CP based on functional severity will be recruited (GMFCS I n=40; II n=30; III n=15; IV n=15). Screening for eligibility occurs before participants provide written consent to enroll in the trial.

Recruitment at each site will begin following ethical and governance approvals are obtained. Recruitment will draw upon current databases within each organization, referrals from clinical services and the Cerebral Palsy Clinical Trials Register. Contact with participants will occur via one of the following mechanisms:

1. Child name, basic characteristics, and family contact details are identified on a Clinical Trials Register, clinical and/or research database hosted by one of the partner institutions
 - a. Families who consent to receive information about clinical trials and living within 150km of trial site will be sent up to two emails and one postal package with approved trial invitation letter and flyer
 - b. The Study Coordinator and/or site therapist will then follow-up with a phone call with families (at least one week later) to ascertain interest in the study
 - i. Families who indicate interest will be sent the participant information and consent forms and contacted again after these have been received to discuss enrollment
 - ii. Families who indicate no interest will not be contacted again
2. Children and families attending a clinical service associated with the project (including the Queensland Paediatric Rehabilitation Service (QPRS at the Lady Cilento Children's Hospital), Cerebral Palsy Alliance (CPA), and the Princess Margaret Hospital (PMH) Paediatric Rehabilitation Department) will be identified by treating clinicians and provided with a flyer
3. Electronic and standard billboards at QPRS/LCCH, CPA and PMH will display the approved flyer during the recruitment period
4. A newsletter snippet will be included in the electronic and paper newsletters distributed by QCPRRC, QPRS, CPA, and PMH
5. The flyer and trial information will be posted on the research websites for QCPRRC, CPA, and PMH
6. A facebook page <https://www.facebook.com/participatecpproject> will host the approved trial information and flyer and be shared and 'liked' organically (word of mouth referrals)

7.2 Inclusion Criteria

Child:

- (a) aged 8-12 years;
- (b) confirmed diagnosis of CP from rehabilitation specialist;
- (c) Gross Motor Function Classification (GMFCS) Levels I-IV;
- (d) lives within 150km radius of trial sites

Parent:

- (e) at least one parent understands written and verbal English and can speak English (information and consent materials and questionnaires will not be available in languages other than English)

Both:

- (f) there is a desire to work on goals around participating more often or being more involved physical activities

7.3 Exclusion Criteria

Child:

- (a) limited ability of child to communicate insight into preferred future (needs, wants, desires) in spoken English AND/OR through an interpreter or augmentative/alternative communication (i.e. Communication Function Classification System Levels IV-V);
- (b) significant intellectual disability (IQ<50);
- (c) uncontrolled epilepsy;
- (d) severe asthma exacerbated by exercise, not controlled with medication under an asthma management plan;
- (e) planned orthopaedic surgery 6 months prior to or throughout intervention/follow-up period
- (f) was enrolled and previously received the intervention in the pilot study in South-East Queensland (2016-2017)

7.4 Consent

Informed consent will be obtained from parents/guardians (legal) on behalf of themselves and their child, as children 8-12 years old are not able to provide independent consent.

Potential participants will be provided with a copy of the participant information statement (which contains both a parent/guardian-specific version and child-specific version) after agreeing to enroll in the study via phone or email contact. Potential participants will have at least 24 hours and typically more than one week to read information about the study and decide whether or not they would like to participate. Families will be invited to ask questions and discuss any aspect of the study with the site contact, Chief Principal Investigator and/or Study Coordinator should they require more information to make a decision.

Before completing any screening or baseline questionnaires or attending the first face-face appointment, parents/guardians must return a copy of the consent form by email, mail or text message with their signature. A new copy of the consent form will be signed again at the first face-to-face meeting and countersigned by the assessing/treating therapist and a witness. This will occur after the treating/assessing therapist has explained the study again in an accessible format (verbal, written, signed AUSLAN by an interpreter) to the satisfaction of both the participating parent/guardian and child. The consent conversation including who was present and the child's assent to participate will be recorded on the reverse of the consent form.

Within the therapy intervention itself, informed consent for modalities of treatments will be obtained in accordance with the professional's code of conduct, for example by verbally asking if it is OK to perform a therapeutic treatment after it has been explained.

8 PARTICIPANT SAFETY AND WITHDRAWAL

8.1 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. Risks for children may include:

- Falls
- Minor injuries or muscle soreness
- Being upset if something goes wrong
- Feeling sad after talking about life or problems

Risk for caregivers may include:

- Minor injuries or muscle soreness from assisting in manual handling
- Feeling upset, worried or guilty about something after talking about life or problems, or disclosing sensitive or personal information

Risks for therapists may include:

- Risks associated with home visits (managed as per section 6.1 viii)
- Minor injuries or muscle soreness from assisting in manual handling

There are no additional risks other than the risks usually associated with participation in sports and active recreation, and from coaching/motivational interviewing/empathetic listening style conversations with allied health therapists.

Control strategies can be used to reduce or eliminate hazards. 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 (e.g. contact sports). High risk activities will require a documented risk assessment that is sent to the Study Coordinator. Extreme risk activities should be re-considered and will require approval from the CIA to go ahead.

8.2 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). Minor adverse events include:

- Near miss accidents (such as falling off a bike or falling heavily in a game)
- Sore muscles, bruises, other minor injuries not requiring medical treatment
- Feeling upset, guilty, or sad

Major adverse events include:

- Injuries that require medical treatment (such as moderate-severe strains or broken bones)
- Depression or anxiety

After reporting to the site Chief Investigator, local site processes will be followed as necessary.

8.3 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.

8.4 Replacements

Participants that withdraw will not be replaced, as the a priori power calculation will account for a 10% dropout rate and 10% crossover rate. Data will be analysed on an intention to treat basis.

9 THERAPIST TRAINING AND FIDELITY

9.1 Therapist Attributes

It is required that therapists possess the following attributes:

- Full registration with the Australian Health Practitioner Regulation Agency (AHPRA, Physiotherapists and Occupational Therapists) OR Full members with accreditation from Exercise & Sports Science Australia (ESSA, Exercise Physiologists)
- Current Basic First Aid and CPR certificate
- Willingness and capacity to perform manual handling tasks associated with functional training of sports skills (e.g. hands on facilitation to train bike riding)

It is highly desirable that therapists possess the following attributes:

- 3+ years experience working with children with cerebral palsy and their families
- Experience working within models or frameworks of participation-focused therapy
- Knowledge of and/or training in Motivational Interviewing or a similar empathetic listening style communication technique (e.g. Occupational Performance Coaching etc.)

9.2 Therapist Training

Standardized 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 protocol⁴⁶)
- 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

9.3 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 in order to enable a random sample of sessions to be analyzed for content and alignment with written information (clinical reasoning grids and progress notes) at the conclusion of the study.

10 STATISTICAL METHODS

10.1 Sample Size Estimation and Justification

We will recruit 100 children with cerebral palsy. They will be randomised to experimental Participate-CP immediate group (n=50) and to the waitlist control group - standard care (n=50). Justification – See Below in Section 9.2 Power Calculations

10.2 Power Calculations

Based on our pilot data with standard deviations of 2.03-2.28, a sample size of 31 will detect a difference of four points on the COPM at 90% power and alpha 0.01. 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. According to our pilot data with a SD of 24.2 minutes/day, a sample size of 78 will detect a difference of 16 minutes/day between groups, with 80% power at alpha 0.05. Due to multiple and longitudinal analyses, stratification factors, accounting for site effects, and buffering for 20% attrition, we aim to recruit 100 (50 in each group).

10.3 Statistical Methods to be Undertaken

AI Robert Ware, Professor of Biostatistics, Griffith University, will provide expert advice for guiding and assisting with analyses. 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 co-variables. Effect estimates will be presented as mean difference and 95% confidence interval. 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 (CPQOL-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 sociodemographic and clinical variables for consenters with non-consenters using t-tests (or Mann-Whitney U tests) for continuous variables and chi-squared tests for categorical variables. Possible differential attrition will be assessed by comparing baseline characteristics of drop-outs and continuing participants using t-tests (or Mann-Whitney U tests if appropriate) for continuous variables and chi-squared 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.

11 STORAGE OF BLOOD AND TISSUE SAMPLES

11.1 Details of Records

No blood and tissue samples will be taken.

12 DATA SECURITY AND HANDLING

12.1 Details of Where Records Will Be Kept and How Long They Will Be Stored

Data types, collection, transfer and storage is outlined in section 6.2. Data will not be destroyed.

12.2 Confidentiality and Security

Progress notes taken by treating therapists will be fully identified for legal reasons but will be stored confidentially in accordance with professional code of conduct and relevant legislation.

All other information will be coded with a participant ID number. Any identification codes will be stored in a different place from the data records to which they are linked. All measurable steps will be taken to ensure that health information collected is protected at all times. Access at QCPRRC will be limited to the QCPRRC Chief Investigators and study coordinator (Dr Leanne Sakzewski, Prof Roslyn Boyd, Prof Jenny Ziviani, Ms Sarah Reedman). All consent forms and identifiable information will be stored in a separate, locked filing cabinet to the research data. Data management will comply with relevant privacy protocols, such as the Australian Standard on personal privacy protection.

12.3 Data Sharing

In accordance with the NHMRC Statement on Data Sharing,

"NHMRC encourages data sharing and providing access to data and other research outputs (metadata, analysis code, study protocols, study materials and other collected data) arising from NHMRC supported research"

data will be made available to other researchers or funding bodies including the NHMRC as necessary for the purposes of meta-analysis/systematic review and/or confirmation of statistical results. This data will be made available at group-level. If individual level data is required, a limited, codified dataset will be made available to reduce or eliminate the possibility of re-identification of the data.

A description of the dataset (metadata) will be published so that it can be discovered and/or cited. Data will be shared directly with individuals or institutions that approach the custodians. Future use and sharing of data is addressed on the Parent Information Sheet. Identifiable data will not be available for future use unless by separate ethics application.

13 ETHICS AND DISSEMINATION

13.1 Ethics

This project has received ethical approval from the following committees:

Ethics Committee	Approval Number
CHQ HHS HREC	
UQ MREC	

13.2 Dissemination

Results of the study will be published in:

- Conference abstracts and presentations
- Peer-reviewed articles in scientific journals
- Participant, organisation, and institution newsletters and media releases

At the conclusion of the study after the primary analyses, a summary flyer of the main outcomes of the study will be emailed and/or mailed to participants.

14 APPENDIX

List of attachments included:

Document Name	Version Number	Date (e.g., 18 January 2012)
CHILD OUTCOME STANDARDISED ASSESSMENTS		
Participate COPM Record sheet	1.0	13/11/2017
Participate ActiGraph Instructions	1.0	13/11/2017
Participate ActiGraph Logbook	1.0	13/11/2017
Participate PEM-CY	1.0	13/11/2017
Participate BPPA-Q	1.0	13/11/2017
Participate CPQOL Parent proxy	1.0	13/11/2017
Participate CPQOL Child report	1.0	13/11/2017
Participate MPAM-R	1.0	13/11/2017
Participate PACQ	1.0	13/11/2017
Participate GAS Rating	1.0	13/11/2017
Participate CHU-9D	1.0	21/11/2017
SCREENING		
Participate Demographic Questionnaire	1.0	13/11/2017
Participate Classification Form	1.0	13/11/2017
Participate SBQ	1.0	13/11/2017
Participate GMFCS-ER English	n/a	n/a
Participate MACS English	n/a	n/a
Participate CFCS English	n/a	n/a
Participate HRU	1.0	20/11/2017
ADVERTISEMENT		
Participate Flyer	1.0	16/11/2017
Invitation Letter	1.0	16/11/2017
OTHER		
Participate Risk Assessment	1.0	16/11/2017
Participate Clinical Reasoning Sheet	1.0	21/11/2017
Participate Usual Care Diary	1.0	21/11/2017
Participate Parent/Guardian Information Sheet and Consent form	1.0	21/11/2017
Participate Child Information Sheet	1.0	15/11/2017
Participate NHMRC Peer Review Assessment Sheet	n/a	n/a

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