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Study protocol for Active Start Active Future: a randomised control trial of an early behaviour-change intervention targeting physical activity participation and sedentary behaviour in young children with cerebral palsy living in South East Queensland, Australia

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ABSTRACT

Introduction The benefits of physical activity (PA) are compelling for all ages and abilities. For children with cerebral palsy (CP), two distinct health behaviours, being physically active and reducing sedentary time, are critical to target as an early intervention to reduce long-term morbidity. One approach may be to increase PA participation by empowering parents who are key to making family lifestyle changes. This study will compare Active Start Active Future, a participation-focused intervention, to usual care in a mixed-methods randomised waitlist-controlled trial.

Methods and analysis A total of 40 children with CP (3–7 years), classified in Gross Motor Function Classification System (GMFCS) levels II–V, will be stratified (GMFCS II vs III, IV vs V) and randomised to receive either (1) Active Start Active Future, an 8-week intervention for 1 hour per week in any setting or (2) usual care followed by delayed intervention. Active Start Active Future aims to increase PA and reduce sedentary behaviour of young children with CP by providing participatory opportunities to promote PA behaviour change. Outcomes will be measured at baseline (T1), immediately postintervention at 8 weeks (T2) and at 26 weeks postbaseline (T3). The primary outcomes are the Canadian Occupational Performance Measure for both child and parent participation goals and child physical performance goal. Secondary outcomes include daily time spent in moderate to vigorous PA and sedentary time, gross motor function, quality of life, barriers to participation for the children and parents' PA and sedentary time. Intervention acceptability and experiences of PA participation will be explored using a qualitative descriptive approach.

Ethics and dissemination The Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/23/QCHQ/100850) and The University of Queensland Human Research Ethics Committee (2024/HE000054) have approved this study. The results of the study will be disseminated to families and community agencies as guided by our advisory group and as conference abstracts and presentations, peer-reviewed articles in scientific journals and institution newsletters and media releases.

Trial registration number ACTRN12624000042549, Universal Trial Number: U1111-1300-7421; Australian New Zealand Clinical Trials Registry.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Active Start Active Future will test a novel participation-focused, behaviour-change intervention for young children with cerebral palsy (CP) classified at Gross Motor Function Classification System II–V.
⇒ Active Start Active Future intervention has been informed by our feasibility study and parent advisors.
⇒ The mixed methods, randomised control trial design will provide preliminary evidence for efficacy and understanding of involvement of young children with CP and one primary parent/caregivers physical activity (PA), PA participation and sedentary behaviour.
⇒ The voice of parents/caregivers and community stakeholders on intervention acceptability, and their reflections from interviews on being active and motivating factors to stay active while supporting young children with CP, will inform an ongoing understanding of sustained participation in PA.
⇒ A limitation may be that usual care cannot be standardised.

INTRODUCTION

The benefits of physical activity (PA) are compelling for all ages and abilities.[1] PA guidelines state all children should aim for 60 min/day of moderate to vigorous PA as well as participate in activities to strengthen

bones and muscles three times each week (WHO guidelines).[2] For children of 0–5 years, 180 min of PA including active play, games and outdoor activities are recommended.[2] Despite this, over 90% of children with cerebral palsy (CP) do not meet these guidelines. In children with CP, across all Gross Motor Function Classification System (GMFCS) levels,[3] PA intensities (moderate to vigorous) already plateau by the age of 3 years.[4] In addition, sedentary behaviour (any waking behaviour while in a sitting, reclining or lying posture with low energy expenditure),[5] a modifiable lifestyle risk factor, may be related to greater risk of comorbidities such as stroke, cardiovascular disease and hypertension in people with CP.[6–8] Sedentary behaviour is alarmingly prevalent in young children with CP with sedentary time peaking at 4 years of age.[9] By the age of 4–5 years, children who do not walk (GMFCS IV–V) already spend over 93% of their day sedentary,[4 10] compared with non-ambulant children with CP aged 1.5–3 years (74%).[11] Such studies highlight the need for interventions to address both habitual PA and sedentary behaviour as different but equally important health behaviours, and for these interventions to be implemented early in childhood.

Establishing effective PA interventions to improve health and well-being outcomes is crucial. A multitude of PA interventions is on offer for children with CP and their families more broadly, such as strength training, endurance training, mobility skill development and adapted sports.[12] Despite the number of interventions available, past interventions to increase PA have not commenced in early childhood for children with CP. Interventions also tend to target children 8 years and older, those who walk independently, and none has addressed reduction in sedentary behaviour as an intervention target.[13] Few have been able to translate their gains in physical performance or capacity into sustained changes in PA participation beyond 1–6 months of the intervention.[14] Consequently, children with CP participate less often and are less involved in PA in the community when compared with their typically developing peers.[15 16] Those with limited self-mobility have the lowest levels of participation intensity.[17] The result is a missed opportunity to intervene early for all children with CP and, in particular, in non-ambulant children (37% of children living with CP) who are at highest risk.[18]

One new approach to increase participation in PA is grounded in evidence-based theories of health behaviour change[19–21] and focuses on the key constructs of participation, attendance and involvement, as the primary outcomes.[21 22] ParticiPAte-CP is one such intervention with demonstrated effectiveness, which is goal directed and promotes participation in community PA in children with CP aged 8–12 years classified in GMFCS levels I–III.[21] The approach utilises motivational interviewing, coaching, physical literacy, knowledge translation, motor skill development and collaboration with families and stakeholders to identify and modify barriers to being active.[23] ParticiPAte-CP, however, did not aim to reduce sedentary behaviour, was delivered to older children, and only those able to ambulate (GMFCS I–III).

Using the ParticiPAte-CP framework, we developed Active Start Active Future, which aimed to address the previous limitations. We conducted a pre–post pilot feasibility study of Active Start Active Future in homes, school and the community between 2020 and 2022 for children 4–7 years inclusive of all GMFCS levels (unpublished data). The intervention was delivered over 8 weeks, addressing sedentary behaviours early and promoting increased PA by increasing participation in any activities of choice. Goal attainment, quality of life, barriers to participating and accelerometer-based motion sensor data (worn for 7 consecutive days) were collected at baseline and 8-week follow-up. Interviews were conducted with parents following the intervention to determine the feasibility and acceptability and themes were generated using thematic analysis.[24] Overall, Active Start Active Future was found to be feasible and acceptable in eight young children with CP of all ability levels within home, education and community settings (unpublished data).

Following the intervention, a parent advisory group was established to inform the next steps for Active Start Active Future and future study design. The advisors were a mother of a child who had attended the intervention and a mother with lived experience of CP who has a young child. Recommended changes from the study interviews for future testing of Active Start Active Future were reviewed and adopted. The major changes included (1) ensuring the intervention was promoted as a 'hands off' approach with the aim to increase awareness of PA opportunities and problem-solving barriers, (2) eight sessions could be offered in person and/or virtually, (3) goals should be set with consideration of equipment available to the family, (4) changing the type and positioning of accelerometer-based motion sensors, (5) a review of questionnaires for relevance to the age group and (6) adaptation of the PA log to be less onerous for parents.

Our parent advisors relayed a clear message, that the key to changing early childhood PA participation and health outcomes in CP is parental involvement and engagement in PA lifestyle change. Their recommendation to address parental PA participation and family barriers to being active is supported by the literature.[25 26] For children with CP, the ability and opportunities to participate in PA rely on the support and role modelling of parents/caregivers.[27–29] Parents have a unique role in promoting PA, while also worrying about their child's safety and health when active.[30 31] Children are dependent on their parents to provide PA opportunities, transport, funding, especially those who need assistance moving.[25 32] Parents can help or hinder their child's participation[25] and can face many barriers.[25 32] Parents own PA can influence their child's, with more active parents having more active children.[33–35] Children also rely on their parents to understand their preferences and 'in the moment' experiences to foster ongoing participation.[14 36] However, our knowledge of the parent's own PA motivation and motivation

for promoting and supporting PA participation in young children with CP is limited.

A mixed-methods randomised control trial (RCT) has been developed utilising our feasibility and acceptability study findings and in collaboration with our parent advisors. Active Start Active Future will be delivered at Stage II in the development of a behaviour change intervention, that is, establishing efficacy in the research context, with research-based providers.[37–39] The Active Start Active Future RCT focuses on three distinct health behaviours: PA, sedentary behaviour and participation for young children with CP. Increasing PA, replacing sedentary time with any form or type of PA and promoting 'any movement counts' through meaningful participation are key. By addressing each behaviour early, overcoming barriers and integrating PA into daily, family life, we have the potential to change long-term outcomes for the health and well-being of young children with CP.

METHODS AND ANALYSIS

This mixed method RCT will be conducted in 40 children with CP, GMFCS II–V, aged 3–7 years to test the efficacy of a multifaceted participation-focused intervention, Active Start Active Future, compared with Care as Usual (CAU, any regular therapies or PA participation) (n=20 each group). The study will target PA and sedentary behaviour of young children with CP by collaborating and empowering parents/caregivers to create lifestyle change. Following feedback from our parent advisors, parents' PA and their motives for participation in PA for themselves and their child with CP will be collected.

Primary hypotheses

Child hypotheses

For children with CP, Active Start Active Future will be more effective than CAU immediately postintervention (8 weeks) and 26 weeks postbaseline (retention) in:

Primary

1. Increasing performance and satisfaction on the Canadian Occupational Performance Measure (COPM)[40] by a difference of ≥2 points, for:
   a. Participation—attendance and/or involvement.
   b. Physical performance.

Secondary

2. a. Increasing moderate-to-vigorous PA (MVPA) by ≥10 min/day.
   b. Reducing sedentary time by ≥15 min/day.[21]
3. Improving gross motor capacity (Gross Motor Function Measure (GMFM)-Item Set-66).[41 42]
4. Increasing parent-proxy-reported CP Quality of Life (CP QOL-Child).[43]
5. Reducing contextual barriers to participation (Barriers to Participation in Physical Activities Questionnaire (BPPA-Q)) (detailed in online supplemental file 7).[44]
6. Increasing caregiver-perceived confidence to meet their child's goals (Belief in Goal Self-Competence Scale (BiGSS)).[45]

Parent hypotheses

For the primary parent/caregiver, Active Start Active Future will be more effective than CAU immediately postintervention (8 weeks) and 26 weeks postbaseline (retention) to increase:

Primary

7. Performance and satisfaction on the COPM[40] by a difference of ≥2 points, for their ability to support their child's goals.

Secondary

8. Parent PA and health behaviours.
   a. Increasing frequency of parent/caregiver PA (The Active Australia Survey).[46]
   b. Increasing frequency of self-selected leisure activities to promote health and well-being (Health Promoting Activities Scale (HPAS)).[47]
   c. Reducing frequency of parental sedentary time (Past-day Adults' Sedentary Time (PAST) Questionnaire).[48]
9. Increasing caregiver-perceived confidence in their ability to support their child's goal attainment on the BiGSS.[45]

Questionnaires and semistructured interviews (see online supplemental files 3–6 for details) will be conducted at 8 and 26 weeks to inform research translation by exploring:

a. Acceptability of the intervention.[49]
b. Experiences of participating in PA.
c. Understanding how to create change in PA behaviour.
d. Influence of PA on sleep, pain and fatigue.

Trial design

The study timepoints will be baseline (T1); immediately postintervention *primary endpoint* at 8 weeks (T2); 26 weeks postintervention *retention* (T3). Children allocated to the CAU group will be offered Active Start Active Future following the 26-week time point and will have postintervention (T4) outcomes (Consolidated Standards of Reporting Trials flowchart, figure 1).

Recruitment

Children and their primary parent/caregiver who meet the inclusion criteria will be invited to participate (parent:child dyad) from April 2024 to December 2025. Community stakeholders will be asked to opt into interviews. Recruitment will draw on current databases held by the Queensland Cerebral Palsy and Rehabilitation Research Centre and referrals from clinical services (including the Queensland Paediatric Rehabilitation Service (QPRS) at the Queensland Children's Hospital), Brisbane, Australia. Advertisement will include posts on electronic and standard billboards at QCPRRC and QPRS, newsletters, text messaging, flyers and word of mouth.

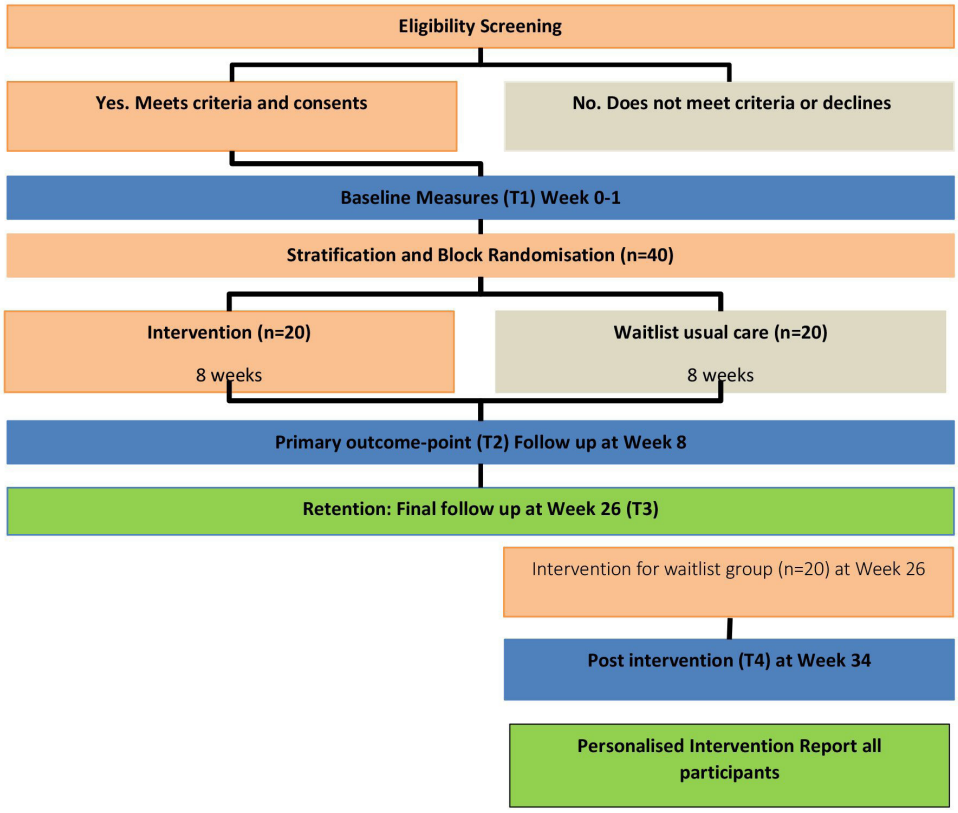

Figure 1 Consolidated Standards of Reporting Trials (CONSORT) study design and study flow diagram.

Recruitment will begin following ethical and governance approvals. Written and verbal informed consent will be obtained by the trial co-ordinator or therapists.

Inclusion criteria

Children meeting the following will be included:

1. CP diagnosis, GMFCS levels II–V[3].
2. 3.00–7.99 years.
3. One primary caregiver can participate.
4. Live within 130 km of South Brisbane, Queensland Australia.
5. If this is the sole therapy intervention research study, they are enrolled in.

Children will be excluded if the child:

1. has orthopaedic and/or neurosurgery within 6 months prior to baseline or planned during the study period.
2. has uncontrolled epilepsy and/or medical fragility.
3. is already participating in a therapy intervention study.

No exclusion criteria were imposed based on medications used.

Adults will be included who:

1. are primary parent/carer of a child enrolled.

Additional adults who are significantly involved with the child's PA participation may be enrolled for the qualitative interviews only if they:

2. support the intervention in the community (community therapists, community members, eg, coaches).
3. support the intervention at preschool, kindy, school (school therapists, education and childcare staff).

Randomisation

Children will be randomly allocated using stratification (GMFCS II–III to GMFCS IV–V) in a 1:1 ratio either to the intervention or CUA (n=20 in each), using block sizes of two and four (block size randomly selected). A computer-generated random number sequence will be used for concealed allocation using REDCap. The allocation sequence will be generated by a biostatistician not involved in the study. Allocation will not be revealed until all baseline assessments have been completed.

Intervention

Active Start Active Future group

Dose

One-hour sessions will be delivered over 8 weeks, with a total training dose of 8 hours of intervention. This will be achieved through:

1. In-person sessions at family location of choice (home and or community).
2. Virtual sessions to replace in-person session can occur as directed by parents.

Mode

Individual intervention with a ratio of 1:1 therapist to child and parent/caregiver. Additional adults involved in supporting the intervention in the community (therapists, coaches) or education setting will also be included.

Table 1 Content and tailoring of Active Start Active Future mapped to International Classification of Functioning, Disability and Health[2]

Function, activity, performance and capacity	Participation	Social/personal factor and health behaviours	Environmental and contextual factors	
Task-specific skills practice (incorporating motor learning strategies)	Set participation goals—attendance (frequency, diversity, duration of participation) and involvement when participating	Motivational interviewing and/or empathetic listening strategies including strategy planning and coaching.	Research (eg, for available programmes that meet the child and family needs)	Provision of information about programmes/ services
Strength, balance and co-ordination training	Participate in the activity with the child and/or techniques to scaffold participation	Building self-efficacy and confidence through deliberate experiences of success. Use of self-determination theory.	Equipment and/or aid prescription or referral to sources of funding	Communication and problem-solving with community stakeholders (eg, pre-school/school staff, coaches, activity leaders)
Interventions that support child sensory and communication needs relevant to participation (eg, social story, explicit teaching)	Site visits (assess barriers to context/ environment, observe participation in action)	Introduction and teaching of specific behaviour modification strategies (eg, scheduling, monitoring, rewarding, consequences).	Environmental changes and/or universal design (eg, modifications that support physical access)	Build partnerships with stakeholders and programme managers

Content and tailoring

Active Start Active Future will use a participation-focused framework[21] to promote PA participation and promote less time sedentary. The essential intervention elements include:

- Family-centred.
- Goal-directed and individualised according to the PA of choice, for example, swapping sitting for standing time, playing at the playground, home, or beach using their walking frame, having a go at roller skating, biking, kayaking, surfing, joining a dance group, team or adapted PA programme.
- Ecological—occurs in families' preferred context.
- Uses multifaceted intervention strategies targeting modifiable barriers and promoting facilitators to PA participation for the child and family.
- Provides support to both child and parent to empower PA participation behaviour change.

The intervention will be delivered at the participation level of The International Classification of Functioning, Disability and Health (ICF) (promoting attendance and involvement in PA participation[22] and may include all categories of the ICF dependent on the goals, identified barriers and planned strategies (table 1)).[2] A collaborative approach will be used between the parent, child, therapist and any other stakeholders involved in the activity to:

1. Set goals that are meaningful and promote opportunities to increase or change frequency, diversity, duration and/or involvement in the selected PA. Parents will set goals for their child (with their child participating as able), and, in addition, the parent most involved in the intervention will also set their own goals to support their child's participation in PA.
2. Identify possible barriers and facilitators to being active and develop strategies to promote behaviour change through motivational interviewing and coaching.
3. Screen the context and environment for PA and goal opportunities.
4. Develop task-specific functional training of goals that can be practised in context (eg, ride trike from the car to slide at local park with supervision at least once a week). Use motor learning principles to promote skill attainment such as positive feedback, whole task practice, graded activities. Modelling will be provided by the therapist to help increase parent and caregiver capacity. Task-specific training of physical activities such as running and biking has been effective in children and adolescents with CP.[50–52]
5. Support goal setting and attainment using a client-centred, problem-solving style of communication such as motivational interviewing.[21] Effective PA participation-focused interventions in children and adolescents with CP have implemented motivation strategies using the principles of Self-Determination Theory (developing autonomy, competence and relatedness).[21]

Intervention providers

Two experienced paediatric physiotherapists will complete Motivational Interviewing and participation-focused training (eg, ParticiPAte training[53] prior to delivering the Active Start Active Future intervention). Training will be focused on how to deliver participation-focused interventions with a behaviour change lens for parents and caregivers of young children with CP. Both interventionalists will be trained to conduct the assessments and deliver

the programme independently, where extra support is needed, or for time considerations, joint sessions may be undertaken.

Location

The intervention will be delivered in the families' location of choice specific to the PA participation goals, for example, home, playground, swimming pool, sports field, preschool/school.

Care as usual

CAU is not standardised for children with CP, especially across GMFCS levels, and we expect variations between children. Children in both groups can participate in any therapies during the study but cannot participate in any other intervention trials. A usual care diary will be completed once by parent/caregiver at the end of the study to provide information about how many hours and what type of usual care therapies were accessed by the child during the study period, to enable reporting of dose.

Screening and descriptive measures

All participants will be classified using the

GMFCS Expanded and Revised

The GMFCS will classify the child's gross motor function for their age on a 5-level ordinal scale. Children in this study will be classified in GMFCS II (walk and require support on uneven terrain and stairs) through to GMFCS V (require the greatest level of support for motor tasks).[3] The GMFCS has established construct validity and good inter-rater reliability between therapists.[42]

Manual Ability Classification System

The Manual Ability Classification System (MACS) uses a 5-level ordinal scale to classify the child's ability to manipulate objects in their hands.[54] The MACS has well-established construct validity and excellent inter-rater reliability (ICC=0.97 between therapists).[54 55] Children may be functioning at MACS levels I (independent use of their hands for all tasks) to level V (dependent for all manipulation tasks).[55]

Communication Function Classification System

Using a 5-level ordinal scale, the Communication Function Classification System (CFCS) will classify the child's level of communication during everyday activities using their preferred method (eg, speech, sign, gestures, augmentative and alternative communication, eye gaze),[56] inclusive of preschool children.[57] Between health professionals, the CFCS has good test–retest reliability, and good inter-rater reliability (0.66).[56 57] In addition, high levels of agreement exist between clinicians and parents' ability to identify communication levels 0.95 (95% CI 0.95 to 0.96, p<0.001).[58]

Demographic information will be collected for PA participation (attendance—frequency, diversity and duration) in the past 12 months (inclusive of all forms of PA such as recreation, exercise and sport) and Physical Activity Readiness and Safety Questionnaire[59] for both the child and parent or caregiver. Questions regarding the child's screen time, sleep, pain and fatigue levels will also be explored and the parent/caregivers sleep.

The following information will be collected, recorded and generated as part of the intervention or will be summarised, described and reported in a deidentified format alongside trial results to provide context or meaning.

1. Therapist progress notes.
2. Therapist clinical reasoning sheet for intervention implementation strategies.
3. Risk assessment and adverse events.
4. Usual care diary.
5. An activity plot from the scored activity monitor data will be used to create 12-hour visualisations of movement and posture. These will be shown to parents/caregivers and the children prior to the midpoint of the intervention to identify time periods of activity/inactivity (eg, prolonged sedentary time) and levels of activity. The feedback from visualising the behavioural data will allow the intervention to be targeted and individualised for each child and their family within the 24 hours of their day.

Outcomes

Primary outcomes

Performance and satisfaction with individualised participation and PA goals

The COPM[40] will be used to measure performance of and satisfaction with individually defined PA participation goals for attendance and/or involvement. Attendance and involvement are the key constructs of participation as defined by the Family of Participation-Related Constructs.[22] A PA physical performance goal will also be set (see, eg, table 2). In total, two to three COPM goals will be set at baseline by parents/caregivers for their child's PA participation and physical performance. Parents/caregivers will be encouraged to consider their child's preferences, enjoyment and what is motivating for themselves and their child when choosing goals. New goals can also be set within the intervention period (0–8 weeks) if the original goals have been achieved. In addition, the primary parent/caregiver will also set one to two goals rating their performance of and satisfaction with *their own ability to support their child's goals.*[40]

Secondary outcome(s)

Daily MVPA and sedentary time.

Daily time in MVPA and sedentary behaviour will be measured using tri-axial accelerometers positioned on the least impaired wrist (ActiGraph GT3X+, Pensacola Florida) and the least impaired anterior thigh, positioned at one-third of the length of the child's thigh (SENS Motion, SENS Motion Innovation, Copenhagen, Denmark). Participants will be asked to wear the monitors for 7 consecutive days. Raw accelerometer signal

Table 2 Examples of participation and physical COPM goals

Goal	Child	Parent
Attendance	To attend swimming lessons 1x/week for a term To go swimming at the pool as a family1x/week for the term	I will help my child attend swimming 1x/week by freeing up 2 hours from my work schedule I will be in the pool with my child once week for at least 20 min
Involvement	To enjoy going to the pool To concentrate when trying new activities in the pool like fetching a toy	I will increase my engagement when playing with my child in the pool I will help my child stay on task in the pool by thinking of ways to motivate them
Physical performance	To float on my back for 5 s with no support by the end of the term To fetch a toy from the bottom of the pool at 1 m depth by the end of the term	Nil parental goals

COPM, Canadian Occupational Performance Measure.

from both devices will be processed into movement and posture metrics using a machine learnt random forest model (movement).[60 61]

Physical capacity

Gross Motor Function Measure-66-IS is a gross motor physical capacity measure using a selected item set (IS) of the GMFM that are appropriate to the child's level of physical ability. The measure is validated for children with CP aged 1–17 years.[41 42] The minimally clinical important difference is 0.8–1.5 points.[62] The GMFM-66 (IS) will be assessed by a rater masked to group allocation.

Quality of life

Cerebral Palsy Quality of Life Questionnaire for Children, Parent-proxy Version (CP QOL-Child):[43] due to the age of our participants, only parents will report on their child's quality of life across all domains. The CP QOL-Child has good concurrent validity, internal consistency (α 0.80–0.90) and test–retest reliability for parent report for children 4–12 years of age.[43]

Contextual barriers to participation

BPPA-Q is a questionnaire based on the Theoretical Domains Framework and was developed by the authors (see online supplemental file 7). The questionnaire includes identified barriers of modulating environmental context and resources, social influences, skills, intentions, knowledge and beliefs about capabilities found in ParticiPAte-CP.[63 64] Behavioural barriers to healthy PA behaviours[44] will be captured including information about PA parenting practices and their motives for PA. The questionnaire has been adapted from ParticiPAte-CP[63 64] to include sedentary behaviour items, wording inclusive of PA opportunities for young children and the parent/caregivers' role in facilitating PA to ensure barriers are captured.

Confidence to achieve goals

BiGSS[45] captures confidence to make change in goals. Parents/caregivers will rate their confidence in: (a) their child's ability to reach the attendance and/or involvement and physical performance goals and (b) their own ability to support their child in attaining the goals. Confidence is rated on a scale of 1 to 10, with 10 indicating the greatest self-confidence.

Parent PA and health behaviours

The Active Australia Survey,[46] HPAS[47] and PAST Questionnaire[48] will be completed by the parent most involved in the Active Start Active Future intervention to indicate their level of PA and health behaviours. The Active Australia Survey (2003) asks participants to recall their PA over the past 7 days, while the PAST Questionnaire captures sedentary time for the prior day using recall. Both questionnaires have been used extensively for Australian adults across many health intervention studies and have good reliability and validity.[46 48] The HPAS was developed in Australia for mothers of children with disabilities and has also been validated for mothers with their own personal health concerns.[47 65] Each parent will be asked to rate the frequency of participation in self-selected leisure activities (eg, spiritual, social, recreation time) on the 7-point scale (never to once/more every day). Findings from the three assessments will be used to identify the participating parents' level of PA and health-promoting activities at baseline (T1) and to determine changes over the intervention. Active Start Active Future will not directly address parent/caregiver PA behaviour (eg, an exercise programme will not be given to each parent) and parental mental health will not be assessed.

As part of the mixed methods design, a questionnaire evaluating the acceptability of the intervention will be administered to both groups, immediately postintervention at 8 weeks (T2 for the intervention group and T4 CAU group). The Theoretical Framework of Acceptability will be used with a focus on the constructs of: affective attitude, burden, ethicality, intervention coherance, opportunity costs, perceived effectiveness and self-efficacy.[49] Parents' experiences will provide valuable feedback for ongoing programme delivery.

Qualitative semistructured interviews will be conducted for the intervention group only due to the study timeline (detailed in online supplemental files 3–5). A qualitative descriptive approach will be used to explore the experiences of main parent/caregiver who interacts with their child during PA as part of this intervention.[66] The qualitative descriptive methodology has been used for children and youth with CP to explore experiences of aquatic therapy,[67] play[68] and PA and balance.[66] The qualitative descriptive methodology was chosen as it is described as a useful approach when topics have previously been underexplored.[69]

Within 2 weeks of the *primary endpoint* at 8 weeks (T2), the first interview will explore the experiences of Active Start Active Future with the following questions:

What changes, if any, in physical activity participation and sedentary behaviour of young children with cerebral palsy have occurred following ***Active Start Active Future***?

What changes, if any, in the physical activity of caregivers of young children with cerebral palsy have occurred following ***Active Start Active Future***?

The second interview at 26 weeks will explore:

What factors support or hinder children to be physically active, reduce sedentary behaviour and to develop a habit for physical activity beyond ***Active Start Active Future***?

Additional adults who play a significant role in the child's PA participation and are involved in the intervention will also be invited to participate. We aim to recruit 15 adults in total through an opt in approach.

Participant timeline

Active Start Active Future schedule of assessments and interventions from baseline T1 to intervention end for the waitlist group at T4 are provided in table 3.

Therapist training and fidelity

Therapist attributes

The interventionists will have a full registration with the Australian Health Practitioner Regulation Agency (Physiotherapists), be experienced in working with young children with CP and their families in a variety of contexts, be trained in first aid and cardiopulmonary resuscitation and have a willingness and capacity to perform manual handling tasks associated with functional training (eg, transfer a child from wheelchair to trike and facilitate trike riding).

Therapist training

Standardised training will be provided to interventionists employed to deliver the intervention. The training

Table 3 Schedule of assessments for active start active future study

Assessment/procedure	T1 baseline assessment	T2 follow-up assessment 8 weeks	T3 follow-up assessment 26 weeks	T4 follow-up assessment waitlist group only
Informed consent	x			
Demographic information	x			
GMFCS	x			
CFCS	x			
MACS	x			
Primary outcome				
COPM (child and parent)	x	x	x	x
Secondary outcomes				
GMFM – 66-IS	x	x	x	x
CPQOL (P proxy)	x	x	x	x
BPPA-Q	x	x	x	x
BiGSS[45]	x	x	x	x
Device measured PA and SED	x	x	x	x
Active Australia, HPAS, PAST[48]	x	x	x	x
Acceptability questionnaire		x		x
Semistructured interviews		x	x	

BiGSS, Belief in Goal Self-Competence Scale; BPPA-Q, Barriers to Participation in Physical Activities Questionnaire; CFCS, Communication Functional Classification System; COPM, Canadian Occupational Performance Measure; CPQOL, Cerebral Palsy Quality of Life Measure Parent Proxy; GMFCS, Gross Motor Functional Classification System; GMFM-66-IS, Gross Motor Function Measure—66-Item Set; HPAS, Health Promoting Activities Scale; MACS, Manual Ability Classification System; P, parent; PA, physical activity; PAST, Past-day Adults' Sedentary Time Questionnaire; SED, sedentary time.

package will include an intervention manual (based on ParticiPAte CP[21] and the feasibility study of Active Start Active Future) and review of past case studies. Behaviour change strategy training including Motivational Interviewing will be provided to assist with parent–caregiver led decision-making, potential sustained change in goal-directed outcomes and retention in the study and physical activities of choice.

Fidelity

The interventionists will have regular meetings throughout all study phases with the study team. Therapists will complete a clinical reasoning grid for each child receiving the intervention for each goal. The goals, grid and initial interview will be reviewed to support and justify the choice of therapeutic techniques. During the intervention period, case studies, clinical reasoning and problems/concerns will be discussed. Initial and last intervention sessions will be videotaped and any other sessions, where possible, to ensure alignment with content delivered, written information (clinical reasoning grids and progress notes) and child/parent goals.

Data types, collection and management

Data types

All goal and questionnaire data will be collected from the child's primary caregiver/parent who is also involved in the study. Personal, demographics, health (inclusive of sleep, pain, and fatigue) and prior PA participation information for the child and parent will be collected as part of the initial screening. Four subjective measures will be collected about the children and four about the nominated primary caregiver/parent. Device-measured PA using the wearable sensors and gross motor skills (GMFM-66-IS)[41 42] will be measured for each child. All measures are standardised. All data are reidentifiable. Caregivers, parents and/or significant others in the intervention group will also complete an acceptability survey and can opt into interviews.

Data collection

Data will be collected as follows:

- Paper forms, for example, written consent.
- Online survey platform (REDCap) completed at home, for example, standardised questionnaires, demographic forms. Paper forms will be available based on families' preference.
- Accelerometer devices (ActiGraph (wrist) and SENS (thigh)).
- Photo/video/audio recording devices owned by sites/organisations (not personal devices).

Data management

Each participant will be given a study ID number. Identification codes and consent forms will be stored in a separate location from the data records to which they are linked. Data in paper format will be converted to electronic format. All electronic and device data will be transferred securely using a secure file transfer service and stored on the secure UQ Research data management system or uploaded directly to REDCap. Data will not be destroyed. Data will only be available to specified investigators and approved study staff.

Statistical methods

Sample size estimation and justification

A total of 40 participants; 20 in each group, will be recruited to the programme. This sample size will give us 80% power to detect a 2-point difference (clinically meaningful difference) on the primary outcome, The COPM,[40] assuming an SD of 2 with α=0.05 and buffering for 10% attrition.[9]

Statistical methods to be undertaken

Analyses will follow standard principles for RCTs, using two group comparisons on all participants on an intention-to-treat basis. Intention-to-treat analysis will be employed to reduce bias and ensure that all participants allocated to either the intervention (Active Start Active Future) or control group are analysed together as representing that 'treatment arm' whether they received the intervention or completed the study. Following checking of assumptions, continuous primary and secondary outcomes will be analysed to determine the effects of treatment group and timepoint using generalised linear models. All analyses will be completed using Stata software (StataCorp, College Station, Texas). Statistical significance will be set at $p<0.05$.

Participant characteristics and tolerability outcomes will be analysed and reported with descriptive statistics. A sensitivity analysis according to GMFCS group stratification (II-III vs IV-V) will be performed to enable exploration of effects according to ambulatory status.

Qualitative analysis

Interviews will be conducted by a researcher not involved in the delivery of the intervention (SER), who has experience in assessing and delivering PA interventions and promoting participation for children with disabilities. All interviews will be audiotaped and transcribed verbatim. Transcripts will be thematically coded using Nvivo software. Recurring concepts and statements will form themes using a qualitative descriptive approach.[70 71] Transcripts from parents/caregivers will be analysed separately from other community member transcripts and compared for similarities and differences. The trustworthiness of the analysis will be established by investigator triangulation to develop emerging themes and resolve any discrepancies through consensus. All team members will discuss and review the themes. Participants will be invited to member check their interview transcripts to correct any misinterpretations and add additional data. Demographic and questionnaire data of each child's parent will also support the transferability of findings. The principal investigator will also keep an audit trail and reflective journal throughout the study.

Participant safety and withdrawal

Risk management and safety

Participation in PA, active recreation, exercise and sports activities may have small to moderate risks of injury associated with participation due to hazards present. Some of the risks cannot be removed due to the nature of the activity. A risk assessment will be completed by the therapist in consultation with the child's parent/caregiver and any relevant community members (such as coaches) prior to participation in activities considered to be high or extreme risk (eg, contact activities such as rugby league). There are also negligible to small risks of psychological harm associated with motivational interviewing/disclosure of personal/sensitive information.

Adverse event reporting

Adverse events will be screened at each study session by verbal questioning between the treating therapists, and any disclosures will be reported to the chief investigator. Local site processes will be followed as necessary. Any major adverse events or those requiring medical treatment will be reported as soon as possible, and within 24 hours.

Handling of withdrawals

Participants can withdraw at any time. Participants who choose to withdraw from the study will not be penalised in any way. 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 and as such any deidentified (including reidentifiable) data collected from participants who later withdraw will be retained and can be included in analyses with permission.

Replacements

Participants who withdraw will be replaced until the desired 40 participants is achieved at T3 timepoint (end of RCT).

Patient and public involvement

Parents from the Active Start Active Future feasibility study and two parent advisors have informed adaptions detailed in the introduction. The advisory group helped determine changes and new assessment tools, for example, inclusion of GMFM-66-IS and rejection of standardised pain and sleep measures with CP due to length, complexity and lack of age appropriateness. One new advisor will join the group prior to recruitment, having recently completed the ParticiPAte CP intervention,[53] therefore has a current understanding of the intervention framework, delivery and possible outcomes. The advisors will continue their involvement, with four meetings a year scheduled, to discuss processes, outcomes and provide advice on support for participating families including promoting retention. Participants and their families will be informed of progress and outcomes of this study via newsletters, presentations and conferences open to consumers. Our parent advisory group will assist in developing and reviewing the consumer and stakeholder information.

ETHICS AND DISSEMINATION

Informed consent process

Written informed consent will be obtained from the legal guardian for all children. Informed consent, both written and verbal, will also be requested for parents and other caregivers who opt in to being interviewed (online supplemental files 2 and 3).

Ethics and dissemination

Active Start Active Future is registered on the Australian New Zealand Clinical Trials Registry (ACTRN12624000042549). The project has received ethics approval from The Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/23/QCHQ/100850) and The University of Queensland Human Research Ethics Committee (2024/HE000054). Results of the study will be published/disseminated in the trial registration database, conference abstracts and presentations, peer-reviewed articles in scientific journals, organisation and institution newsletters and media releases. In accordance with Element 6 of the Australian National Statement on Ethical Conduct in Human Research (2023), results will be provided directly to participants in an appropriate and accessible format.

DISCUSSION

Children with CP participate in less PA and have higher levels of sedentary behaviour compared with children without CP. Addressing PA and sedentary behaviour through early intervention is important, as these behaviours are established early in life and have the potential to be modified. In this research, we will conduct a mixed methods RCT to evaluate the Active Start Active Future intervention with families who want to support their child's PA participation. We aim to determine whether Active Start Active Future intervention is effective in achieving child-related and parent goals of increasing participation in PA and child's physical performance in their preferred setting, for example, at home, in the community, preschool or school. Secondarily, we aim to assess the effect of the intervention on increasing PA, reducing sedentary time, decreasing barriers to being active and improving quality of life. We will ask parents about their understanding and beliefs around PA and sedentary behaviour for their child with CP, explore the parents' own PA and health behaviours and explore ways they can support their child be more active.

Our trial is innovative because it intervenes earlier in the development of PA and sedentary behaviour habits and will be one of the first studies to include children who cannot walk independently. The intervention is

grounded in evidence-based theories of health behaviour change, is multifaceted, goal-directed, individualised for each family and will be delivered by paediatric physiotherapists. Expected research outcomes will be to (a) increase PA participation in home, community and preschool/school environments, (b) reduce sedentary behaviour and (c) explore the experiences of parents of children with CP when participating in PA. Anticipated benefits include gaining a greater understanding of PA participation in young children with CP, the role of their parents and mechanisms to help change behaviours.

The study has several strengths. A feasibility study inclusive of supporting quantitative and qualitative outcomes has been conducted to test proof of concept and the RCT will further test the updated design. Parent advisors have informed changes to the RCT protocol and will remain actively involved in the research. The mixed methods research design values the objective outcomes and the voice of the parents/caregiver and community stakeholders to ensure a nuanced understanding of PA, PA participation and sedentary behaviour is developed. Active Start Active Future RCT will use an established participation-focused framework of ParticiPAte CP[21 53] to establish an early PA intervention of young children with CP of all ability levels. The intervention will be family directed based on their goals and contexts, meeting best practice recommendations.[12 72] The inclusion of parent's PA and participation to support their child will inform the importance of PA, motivators, facilitators and barriers to being active. Furthermore, little is known about whether parents of younger children with CP will be receptive to an intervention that aims to prevent long-term adverse health outcomes, as opposed to one with a more curative focus, which has high priority among caregivers of children with CP.[73]

The following limitations have been identified. Children enrolled in other studies are excluded, which may reduce recruitment numbers. Parents who are inactive may not be attracted to the study, while those who are active may enrol leading to a potential sampling bias. Our parent advisors have provided recommendations on language to use and ways to overcome this potential bias when recruiting. Wearing of accelerometers may be challenging for some children, however, we have changed devices and location for wear in response to our parents' feedback to optimise wear time in the current RCT. Due to a reduced number of PA opportunities for young children GMFCS IV–V, a possible small sample of unbalanced groups will be addressed by the stratification and block design. Usual care cannot be standardised and is likely to vary greatly between the recruited children and their families.

The proposed RCT will address the evidence gap for health behaviours and participation in young children with CP and their parents, which is essential to long-term health and well-being in this population. This Stage II development of a behavioural intervention will inform the appropriate sample size for a larger multisite RCT and a Stage III Real-World 'Efficacy' study, that is, conducted in community settings with community-based providers and their families to establish internal validity.[37–39] The results of the RCT will be disseminated widely to families with CP and stakeholders through peer-reviewed journals and academic conferences, relevant websites and social media forums.

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Contributors SER, SRG, ST, LS and RNB developed and tested the protocol for the feasibility Active Start Active Future study. GK conceived changes from the feasibility study to the RCT. ST developed the protocol for measurement of PA. GK completed the initial draft of the manuscript. GK and SER developed the treatment manual. All authors designed the study, have read, edited, and approved the final manuscript. GK will conduct the trial and implement within home and community settings. SER will conduct the qualitative interviews. ST will analyse the activity monitor data. LS and SER will review goals and clinical reasoning grid. SRG will review and analyse adult questionnaire data. LS and RNB will oversee implementation. RNB is responsible for the overall content as guarantor.

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Competing interests None declared.

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

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