

# BMJ Open Kindy Moves: a protocol for establishing the feasibility of an activity-based intervention on goal attainment and motor capacity delivered within an interdisciplinary framework for preschool aged children with cerebral palsy

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## ABSTRACT

**Introduction** Preschool aged children with cerebral palsy (CP) and like conditions are at risk of performing below their peers in key skill areas of school readiness. Kindy Moves was developed to support school readiness in preschool aged children with CP and like conditions that are dependent on physical assistance and equipment throughout the day. The primary aims are to determine the feasibility of motor-based interventions that are functional and goal directed, adequately dosed and embedded into a play environment with interdisciplinary support to optimise goal-driven outcomes.

**Methods and analysis** Forty children with CP and like conditions aged between 2 and 5 years with a Gross Motor Function Classification System (GMFCS) level of III–V or equivalent, that is, dependent on physical assistance and equipment will be recruited in Western Australia. Participants will undertake a 4-week programme, comprised three, 2-hour sessions a week consisting of floor time, gross motor movement and play (30 min), locomotor treadmill training (30 min), overground walking in gait trainers (30 min) and table-top activities (30 min). The programme is group based with 3–4 children of similar GMFCS levels in each group. However, each child will be supported by their own therapist providing an interdisciplinary and goal directed approach. Primary outcomes of this feasibility study will be goal attainment (Goal Attainment Scale) and secondary outcomes will include Canadian Occupational Performance Measure, 10 metre walk test, Children's Functional Independence Measure, Sleep Disturbance Scale, Infant and Toddler Quality of Life Questionnaire, Peabody Developmental Motor Scale and Gross Motor Function Measure. Outcomes will be assessed at baseline, post intervention (4 weeks) and retention at the 4-week follow-up.

**Ethics and dissemination** Ethical approval was obtained from Curtin University Human Ethics Committee (HRE2019-0073). Results will be disseminated through published manuscripts in peer-reviewed journals, conference presentations and public seminars for stakeholder groups.

## Strengths and limitations of this study

- To our knowledge, this will be the first trial to evaluate the feasibility of a goal directed, activity-based and interdisciplinary programme to support school-readiness in preschool aged children with cerebral palsy (CP) and like conditions that rely on physical assistance and equipment.
- Kindy Moves is designed to develop motor-based capacity for children with CP and like conditions that rely on physical assistance and equipment by integrating locomotor treadmill training into a play-based environment. This has been identified in previous research where there are limited interventions available for children that rely on physical assistance and equipment.
- The trial protocol was designed in partnership with consumers and will be delivered through a community-based organisation.
- The multidisciplinary nature of the programme will make it difficult to differentiate between the effects of the individual elements of the programme.

**Trial registration number** Australian New Zealand Clinical Trials Registry (ACTRN12619000064101p).

## INTRODUCTION

Early childhood is considered to be the most important developmental phase throughout the lifespan.<sup>1</sup> It is widely documented that investments in early intervention yield greater economic rate of return when compared with investments later in childhood.<sup>2–4</sup> Preschool attendance is strongly associated with developmental vulnerability at school entry.<sup>5</sup> This highlights the significance of preschool programmes which have been shown to

provide both short-term and long-term benefits on health, learning, development and well-being.<sup>5</sup> The school readiness framework provides a structured understanding of the individual strength and vulnerability profiles of preschool aged children in the key skill areas of health and physical development, emotional well-being, social competence, approaches to learning, communication, cognitive skills and general knowledge.<sup>6,7</sup> Failure to intervene effectively in these key skill areas during the early years impacts across the lifespan.<sup>5</sup> Therefore, identifying children who are at risk of performing below their peers in these key skill areas can ensure that the necessary supports and early intervention strategies can be implemented to optimise developmental outcomes and a successful transition into school.

Children at risk of performing below their peers at school include those with motor impairments that result from cerebral palsy (CP) or like conditions.<sup>8,9</sup> CP is the most common cause of physical disability in childhood,<sup>10,11</sup> with nearly 40% of children dependent on physical assistance and equipment throughout the day<sup>10</sup> and classified within the Gross Motor Function Classification System (GMFCS) as being levels III, IV and V.<sup>12</sup> Like conditions are where there are also disturbances of movement and posture that can result from conditions that affect the central and peripheral nervous systems with causes ranging from genetic disorders, developmental or congenital abnormalities.<sup>13,14</sup> Children with CP like conditions can also experience motor limitations that similarly result in a dependence on physical assistance and equipment throughout the day. Given the higher prevalence of CP in childhood, recommendations in the current body of evidence commonly relates to CP only, but the growing trend towards a 'top-down' approach means that clinically, interventions employed for children with CP can also be used to inform strategies for like conditions.<sup>15</sup> Collectively, mobility restrictions in this group of children is a barrier for school readiness and participation and as such, warrants the need for the development and implementation of interventions that focus on a 'top-down' approach for meaningful improvement in functional skills.<sup>7,16</sup>

The common thread of effective paediatric functional interventions for children with CP are interventions that are not only adequately dosed to achieve functional goals but also contain the essential active ingredients for motor skill acquisition. Interventions that are highly dosed and provided with intermittent or 'burst' schedules have shown greater likelihood of motor skill attainment when compared with continuous schedules with weekly sessions.<sup>17</sup> The threshold of adequate dosage is yet to be defined with some models using dosages of 90 hours delivered over 2–3 weeks,<sup>18</sup> to models that include at least three sessions a week.<sup>17,19</sup> The threshold for upper limb training for children with CP has suggested a dosage of between 15 and 25 hours for addressing three functional goals<sup>20</sup> and for functional mobility training, a dosage of 18 hours delivered over 6 weeks has shown improvements in

motor function.<sup>21</sup> Beyond intervention dosage, research strongly supports the need for interventions to contain the essential active ingredients for improved motor ability.<sup>22,23</sup> This includes interventions that focus on the activity and participation level of the International Classification of Functioning - Child and Youth (ICF-CY),<sup>24</sup> are task specific and goal directed, focused on function not normality, context specific and require active child involvement in order to achieve functional goals.<sup>22</sup> At the centre of these models, practicality must be considered particularly with regards to costs in both time and resources which ultimately affects research translation into practice. Therapeutic interventions need to balance the importance of being adequately dosed to optimise outcomes with the impact of appointments on immediate and long-term family stress, fatigue and burden.<sup>17</sup>

A collaborative interdisciplinary approach has the advantage of intentionally blurring the traditionally concrete disciplinary boundaries.<sup>25</sup> The adoption of this approach enables a range of expertise and skills that can be used within a single intervention. Such an approach is focused through a strengths-based lens and centred on meaningful goal-directed outcomes rather than discrete discipline specific outcomes only.<sup>25–29</sup> As noted earlier, school readiness encompasses a range inter-related key skill areas, highlighting the importance of a context specific interdisciplinary approach. Early intervention strategies and international recommendations for children with CP strongly support the need for therapies to be delivered within the home context and this is vitally important for babies and toddlers.<sup>30</sup> However, the preparation for school (including kindergarten or preschool) requires a context specific intervention. Therefore, an intervention that is delivered in a context that mirrors a school environment harnessing play within a group setting and set outside of the home is an important transition and consideration for school readiness. Play that is set within a group naturally involves multiple peer interactions, with improvements in some key skill areas of school readiness such as gains in expressive and receptive language,<sup>31</sup> turn-taking, sharing and initiation of peer interaction<sup>32</sup> having been observed. As such, a school readiness programme that includes play within a group context would be an important feature of the intervention.

Though it has been established that more mobile children have increased levels of participation,<sup>33–41</sup> there is a paucity of effective motor-based interventions available for preschool aged children with CP and like conditions that are dependent on physical assistance and equipment throughout the day.<sup>42–44</sup> Locomotor treadmill training, that is, LTT (includes partial body weight supported training and overground gait training) has shown promising improvements in both school-aged children with CP classified within GMFCS levels III, IV and V as well as in children as young as 4 years of age.<sup>45–49</sup> Beyond the diagnosis of children with CP, current evidence of LTT suggests accelerated motor development in preschool aged children with developmental delay.<sup>50</sup> However,

the dosage remains unclear with improvements in motor function being reported with as little as a 'burst' of training consisting of three, 1-hour sessions over 4 weeks.<sup>49 50</sup> Given the potential for accelerated motor development with LTT, the range of key skill areas associated with school readiness that can be supported with an interdisciplinary team through the vehicle of play within a group,<sup>51</sup> and the suggested dosages from previous studies on motor improvements,<sup>20 49</sup> it would be important to test the feasibility of an adequately dosed LTT in preschool aged children with CP and CP like conditions.

Therefore, within the context of supporting school readiness in children that are dependent on physical assistance and equipment throughout the day with CP and CP like conditions, motor-based interventions that are functional and goal directed, adequately dosed and embedded into a play environment with interdisciplinary support has the potential to optimise goal-driven outcomes.<sup>27 28 52–55</sup> This study aims to determine if such an intervention is feasible for preschool aged children with CP and CP like conditions that are dependent on physical assistance and equipment throughout the day, in improving functional goal attainment and motor capacity.

## METHODS

### Aims and hypotheses

The main aim of the proposed study is to determine the feasibility of the Kindy Moves programme (dosage of 24 hours) in improving goal attainment and motor capacity in children with CP and CP like conditions aged between 2 and 5 years. This feasibility trial will be tested in children with CP and CP like conditions that are classified within GMFCS levels III–V that rely on daily physical assistance and equipment.

The feasibility domains that will be assessed are based on the Bowen *et al* framework<sup>56</sup> with acceptability and suitability (the extent to which Kindy Moves is judged to be suitable to parents and participants and their perceptions of its utility beyond the research), motivations for participating (the extent to which Kindy Moves is of interest to participants and their families) and practicality (the personal and environmental barriers and facilitators that affect the implementation and provision of Kindy Moves) assessed at post-treatment. A semi-structured interview with parents of the children attending the programme will be used to assess the feasibility domains with questions based on the F-words in childhood disability.<sup>57</sup>

Limited-efficacy testing is another feasibility domain and this will be assessed using objective measures to determine if Kindy Moves shows promise to be successful and effective in marginally ambulant and non-ambulant children with neurological disorders.<sup>56</sup> For this domain, the primary hypothesis is that Kindy Moves will improve goal attainment on the Goal Attainment Scale (GAS) to a T-score of 50<sup>58</sup> at T2 (after the 4-week programme) with retention at T3 (4 weeks after the conclusion of the programme) when compared with baseline (T1). The

secondary hypotheses are that Kindy Moves will improve perceived performance and satisfaction in activity and participation goals by a mean difference of two points on the Canadian Occupational Performance Measure (COPM),<sup>59</sup> indoor walking speed on the 10-metre walk test (10mWT) by 0.1 m/s,<sup>60</sup> functional independence on the Children's Functional Independence Measure (WeeFIM),<sup>61</sup> fine motor skills on the Peabody Developmental Motor Scale Version 2 (PDMS-2),<sup>62</sup> sleep behaviour and disturbances on the Sleep Disturbance Scale for Children<sup>63</sup> and parent-reported quality of life on the Infant and Toddler Quality of Life<sup>64</sup> at T2 (after the 4-week programme) with retention at T3 (4 weeks after the conclusion of the programme) when compared with baseline (T1). Given that CP is the most common cause of physical disability we also hypothesise that children with CP will improve their gross motor function on the Gross Motor Function Measure—GMFM-66 by 3 points.<sup>65</sup>

### Ethics

Human ethics approval has been obtained from the Human Research Ethics Committees (HREC) at Curtin University, Perth Australia. Written and informed parent/guardian consent will be obtained prior to study commencement by the chief investigator. The study protocol is reported according to the Standard Protocol Items: Recommendations for Interventional Trials guidelines. Any changes in study protocol will be reported to the Australian New Zealand Clinical Trials Registry and HREC.

### Study sample and recruitment

Recruitment will occur through The Healthy Strides Foundation's Facebook and Instagram pages. The Healthy Strides Foundation is a community-based not-for-profit organisation that provides intensive, multidisciplinary therapy for children with neurological conditions and injuries in Perth, Australia. After parents have read the eligibility criteria on the social media platforms, parents can complete an online form which will help determine eligibility. This initial self-referring online screening form will require parents to describe (selecting from prewritten options) how their child moves around the home and community and their child's hand function and communication development. Once reviewed, a phone screen will occur with the chief investigator to further clarify eligibility and provide an opportunity to discuss the study and their child's potential involvement. If the child meets the criteria, the participant information sheet will be sent electronically to parents and a baseline (T1) assessment scheduled. At the baseline assessment, confirmation of eligibility will be established with the consent form signed and witnessed. The study will run from March 2019 to December 2021. Due to the disruption to recruitment that occurred during COVID-19 restrictions in 2020, recruitment will continue throughout 2021.

## INCLUSION AND EXCLUSION CRITERIA

Participant inclusion criteria include children aged between 2 and 5 years, with CP or a CP like condition that results in functional mobility described as GMFCS levels III, IV and V or for non-CP conditions, are dependent on physical assistance and equipment throughout their day. Children must also have identified functional multidisciplinary goals in the area of mobility, communication or socialisation with peers and functional upper limb skills. Exclusion criteria include uncontrolled seizure disorder (defined as a seizure disorder that does not consistently respond to medical treatments and frequently (>two times per month) requires the administration of rescue medication and emergency call for the ambulance), orthopaedic surgery in the past 6 months, unstable hip subluxation or have engaged in LTT in the past month.

## Sample size determination

Sample size for this single group feasibility trial is based on within group differences for the primary outcome measure GAS. A sample size of 34 participants was determined with a large effect size ( $d=1.0$ ) hypothesised on the GAS t-score (80% power; two-sided test at  $p<0.05$ ). To account for attrition, 40 children will be recruited.

## Blinding

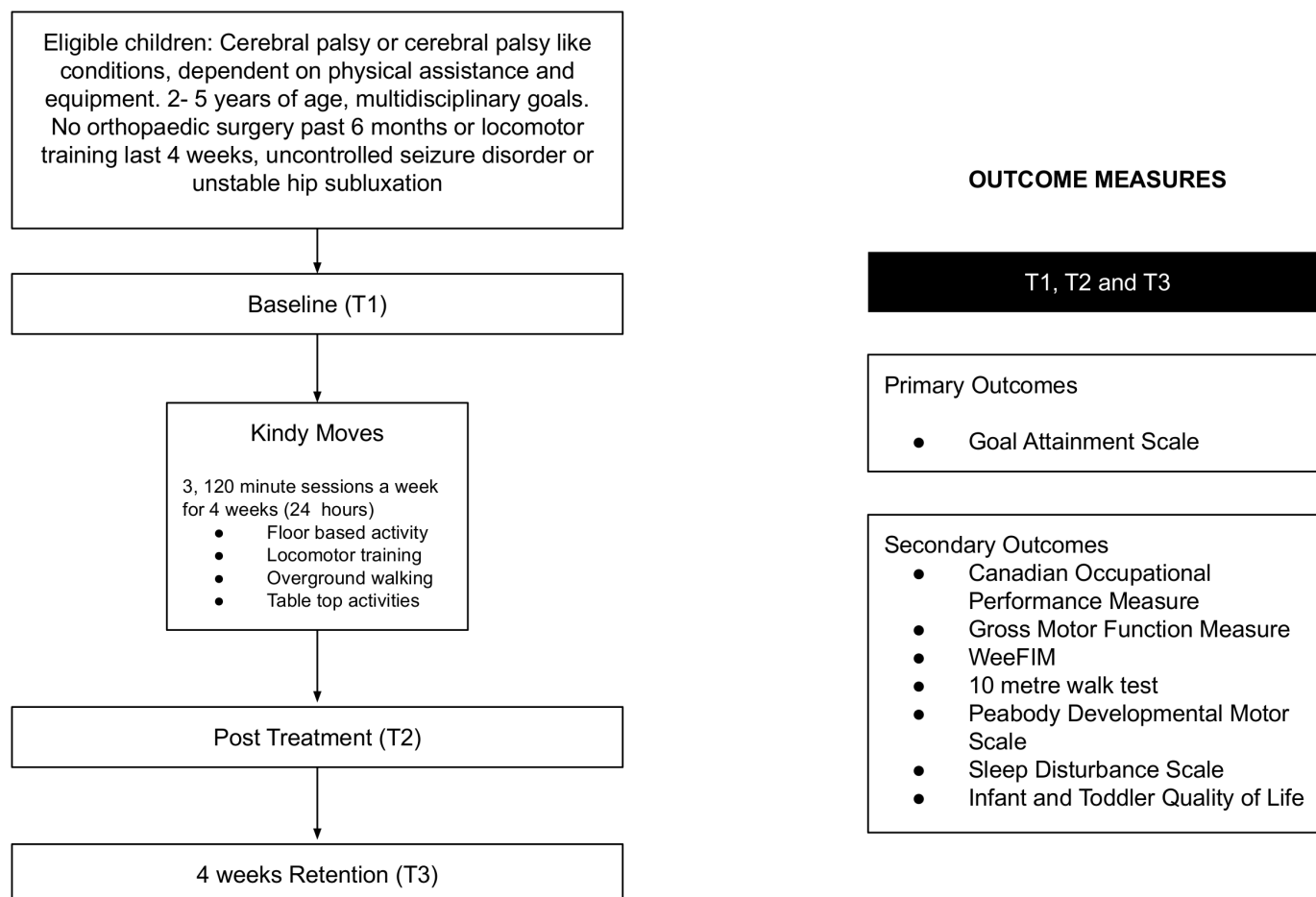
The GMFM and PDMS-2 will be video recorded and scored by a blinded physiotherapist and occupational therapist respectively who will be unaware of the order of the videos being filmed (ie, T1, T2 or T3). The qualitative interviews will be conducted by an independent interviewer.

## Safety and adverse events

To monitor any adverse events, parents will be questioned by the team at the beginning of each session. All events will be reported to the chief investigator and recorded on a database with any major events referred to their physician immediately, reported to the ethics committee with the programme discontinued. As all sessions are onsite, all interventions will be provided by allied health therapists with current and updated first aid and resuscitation certificates. All seizure management plans will be documented with parents required to bring their medications to sessions.

## Study procedure

This feasibility trial is a single group study (figure 1) with three assessment time points (preintervention T1: baseline/preprogramme: 2 weeks prior to the commencement



**Figure 1** Study design and outcome measures. WeeFIM, Functional Independence Measure.

of the programme. T2: postprogramme: the week following the end of the 4-week programme (primary endpoint). T3: follow-up: 4 weeks from time point B (secondary endpoint). Participants will be screened for eligibility after registration of interest through an online form. The baseline T1 assessment will be completed at The Healthy Strides Foundation and once eligibility is confirmed, written consent is then obtained, and the child is scheduled to commence the programme.

### Demographic and classification measures

At T1 baseline, each participant will be assessed with demographic details collected to confirm diagnosis, seizure management plan, hip status, history of botulinum neurotoxin type A injections, history of orthopaedic intervention, recent or upcoming planned hospitalisations, allergies, medication, height and weight. Each child will also be classified according to functional classification measures to include the GMFCS Expanded and Revised (for children with CP),<sup>66</sup> the Manual Ability Classification System,<sup>67</sup> Communication Function Classification System<sup>68</sup> and Functional Mobility Scale.<sup>69</sup>

### Primary outcome measures

#### Individually specific goals—GAS

The GAS enables individualised goal setting and evaluation in areas beyond motor capacity measures and can be used for determining meaningful changes in socialisation, communication and participation.<sup>70 71</sup> The GAS is a valid and reliable measure that is not diagnostic specific and is sensitive to detect real change within groups in paediatric research.<sup>70 71</sup> The assessment consists of a five-point ordinal scale measuring outcomes from -2 (set as the baseline or starting point of how the child is currently performing) to +2 (much more than the expected outcome), with 0 being the expected outcome following intervention which indicates that the goal has been achieved.<sup>58</sup> For this study, goals for the participants will be first established through the COPM which will be completed collaboratively between parents and the chief investigator at T1. The GAS enables more detail of the COPM to be objectively assessed.<sup>72</sup> For example, a COPM goal of 'improve play skills and attention during class' may have a GAS of 'to be able to sit at a table and complete the play dough activity with verbal cues only'. The ordinal scale score is then converted to a t-score for statistical analysis and is normally distributed about a mean of 50 and an SD of 10, with a score of greater than 50 being considered clinically meaningful.<sup>58</sup>

### Secondary outcome measures

#### Individually specific goals—COPM

The COPM is a client/family-centred valid, reliable and responsive measure for activity and participation in children with CP.<sup>71</sup> The COPM has three main areas and subareas where occupational performance problems can be identified. This includes the area of self-care (subareas include personal care, functional mobility and community

management), productivity (subareas of school and play) and leisure (quiet recreation, active recreation and socialisation). A performance and satisfaction score out of 10 is obtained for each problem (1 being the lowest and 10 being the highest score). A change score of two or more is considered clinically significant.<sup>71</sup>

#### Indoor walking speed—10mWT

The 10mWT is a task-specific objective measure of stepping or walking speed within an indoor environment. The test can be completed both with or without a gait trainer and is not diagnostic specific.<sup>39 46 55 73 74</sup> The 10mWT has excellent measurement properties.<sup>46</sup> This measure was used in a previous study also using LTT in children with GMFCS levels III, IV and V.<sup>21</sup> For children that cannot initiate steps within a 30 s time frame, physical facilitation for one step is provided. A maximum time of 10 min (600 s) is provided to complete the 10 m and for children that cannot complete the 10 metres, a time of 600 s is recorded.<sup>21</sup> A change of 0.1 m/s is considered to be clinically meaningful.<sup>26</sup>

#### Burden of care—WeeFIM

The WeeFIM has excellent measurement properties that is used to measure consistent performance of activities of daily living, functional independence and burden of care in children with disabilities.<sup>61</sup> The WeeFIM is a semi-structured interview that is guided by a specific manual to determine the level of assistance required for (1) self care; (2) transfers and mobility; (3) cognition and communication. A total of 18 items are scored on a scale of 1 (indicating total assistance required for completion of the task) to 7 (complete independence) giving a total score out of a possible 126.<sup>37 38</sup> The WeeFIM is recommended for detecting change in activities of daily living over time in children with neurodevelopmental disabilities.<sup>61</sup>

#### Peabody Developmental Motor Scale Version 2

The PDMS-2 is a non-diagnostic specific assessment that is frequently used to assess motor skills. It has excellent measurement properties in children aged between 2 and 5 years with CP and is standardised and normed for children aged from birth to 6 years.<sup>34 62</sup> There are three composites of the PDMS-2 that evaluate motor change (in percentage scores) following therapy and include Gross Motor, Fine Motor and Total Motor composites. The Fine Motor composite (PDMS-FM), consisting of 98 items from two subsets will be used to measure the use of small muscle systems. The two subsets of the Fine Motor composite evaluate grasp (ability to hold an object and progressing to controlled use of fingers of both hands) and visual motor integration (ability to perform complex hand-eye coordination tasks such as reach and grasping an object to build blocks and copy designs) and are scored on a 3 point criterion-referenced scale.<sup>62</sup> The PDMS-2 will be video-recorded and then scored by an experienced occupational therapist, blinded to assessment time point.



### Sleep Disturbance Scale for Children

The Sleep Disturbance Scale for Children (SDSC) is validated for preschool children in the measurement of sleep disorders. The questionnaire is completed by primary caregivers and explores the occurrence of sleep disorders in 26 items that are scored on a Likert scale with values ranging from 1 to 5 (with 5 representing higher severity of symptoms). A total sleep score is derived (out of 130) and correspondingly a T-score; where a T-score of more than 70 describing abnormal sleep behaviours.<sup>63</sup> The SDSC can be used to measure previous 4 weeks of children's sleep and is a useful screening tool for evaluating comorbid sleep disorders in preschool aged children.<sup>63 75</sup>

### Infant and Toddler Quality of Life

This measure was developed for infants and toddlers from 2 months of age to 5 years, adopting the WHO's definition of health.<sup>64</sup> The survey is comprised 97 items and scored on a Likert scale based on concepts of overall health, growth and development, moods and temperaments, general behaviour and getting along and perceptions of changes in health. Items are summed and transformed on a continuum that ranges from 0 (lowest and worst possible score) to 100 (best possible score) following a standard scoring procedure. If more than half of the items of a scale are not scored by the primary caregivers, their responses will not be included in the analyses.<sup>64</sup>

### Gross Motor Function Measure

Given that CP is the most common cause of physical disability in childhood, the GMFM will be used in children with CP only. The GMFM-66 will be used because of its high construct validity and test-retest reliability in detecting change in gross motor capacity in children with CP.<sup>76</sup> The GMFM-66 is a specific and sensitive outcome measure,<sup>77</sup> and is more sensitive when detecting change in children under 5 years of age.<sup>76</sup> Each of the 66 items will be scored based on criterion-referenced observations on a 4-point scale.<sup>76</sup> Clinically meaningful change for the GMFM-66 in children with CP aged 1.5–7 years old is 1.23 for individuals classified as GMFCS level III, and 2.88 for

GMFCS levels IV and V.<sup>78</sup> The GMFM-66 assessment will be video recorded and scored by an experienced physiotherapist blinded to assessment time point.

### Semi-structured interview

At the end of the programme, parents will be interviewed using a semi-structured interview guide based on the F-words. The purpose of the interview is to explore and understand the parent, child and family experience of the programme. The interviews will be conducted by a researcher that is not involved in the Kindy Moves intervention but has extensive experience in interviewing families of children with CP. All interviews will be conducted at Healthy Strides, in a separate room to enable privacy and audio recording (with consent). The interview guide is shown in [table 1](#).

### Kindy Moves intervention

The dosage of the Kindy Moves intervention is 24 hours, made up of three, 2-hour sessions a week for 4 weeks. Sessions will be scheduled to ensure there are only 2 days that are consecutive, that is, Tuesday, Thursday and Friday. A maximum of four children with similar goals and age will be allocated to each group. The group setting and environmental set up of the intervention space aims to mimic a kindergarten context. Participants are able to continue with standard care during Kindy Moves.

### Allied health team

The Kindy Moves allied health team will consist of physiotherapists, occupational therapists, speech pathologist, therapy assistants and undergraduate allied health student volunteers. Each child will be allocated one therapist (regardless of discipline) for each session to ensure consistency and continuity. The speech pathologist will only be involved remotely by observing videos of children's interactions during the baseline T1 assessment and provide communication strategies to the treating team. A review of the child's communication strategies will be videoed during a session in the second week of the programme to enable the speech pathologist to

**Table 1** Key topics and prompts in the semi-structured interview guide

Topic	Prompts	
	Parents	Questions
Experience	Explain the child and parent experience in the intervention	eg, Tell me about participating in Kindy Moves
Fitness	Strength, tone, postural control, etc; unexpected outcomes	eg, Is anything about your child's body that seems different?
Function	Mobility, transfers, self-care, etc	eg, Have you noticed any changes to how your child moves?
Friends	For child and family; attendance and involvement at home, school, community	eg, What was the experience of being in a group setting (both for your child and yourself)?
Contextual factors	Community-based; role of staff; interaction with other families; role demands; intervention equipment	eg, How did your involvement in Kindy Moves affect your daily life?
Impact	Goals for child; impact on parent and family; maintaining outcomes	eg, How would you explain this programme to other families?

adjust the recommendations for the team. Each child will subsequently have an individualised approach addressing their goals and this will be consistently reinforced by the team providing the intervention. Prior to each session, the goals of each child attending the programme will be reviewed and reinforced to ensure the team providing the intervention are focused on the individually task-specific strategies.

The 2-hour programme will be divided into three main sections to mirror activities that would occur during kindergarten. This includes morning floor time, gross motor movement and play as well as table-top activities. Each child will have their own visual schedule board so that the upcoming activities can be described to each child prior to commencing the session.

#### *Morning floor time (30 min)*

To commence the programme, a morning routine will be adopted to mirror routines at school. The floor time session will be led by a therapist or therapy assistant to set the pace of the morning routine and encourage active involvement and each child will be allocated their own therapist or therapy assistant. The routine will commence with children introducing themselves to their peers through a good morning song (with the assistance of pre-recorded audio clip of the child's name on a hand activated switch if required) followed by turn taking and choice making (through picture card options) for a song selection. Each song choice will incorporate key word signing and motor actions such as hands on head, sit to stand, clapping and dancing for commonly sung children songs including 'Five Cheeky Monkeys', 'Five Little Ducks', 'Dingle Dangle Scarecrow', 'Row-Row-Row Your Boat'. Following a song choice from each child, the floor session will conclude with a book reading. The lead therapist will encourage involvement from each child in the book reading time by pausing on pages to ask questions about what is happening or what is about to happen. Strategies to promote active involvement include hand activated switches with pre-recorded lines of the book, eye-gaze boards to enable children who are non-verbal or not able to independently turn pages to answer 'who', 'what', 'where' and 'when' questions. The same book will be used at each session to promote repetition, routine and turn taking. Individually specific gross motor goals will be incorporated into this session such as independent sitting, crawling, kneeling or standing.

#### *Gross motor movement and play through LT and over-ground walking (60 min which includes donning and doffing)*

LT will be provided through partial body weight supported treadmill training with a dosage of three sets of 8min with 2min of standing in the harness while engaging in an upper limb activity for example, posting, throwing a ball to a target. After the 30 min of LT over the treadmill, over-ground walking in a gait trainer will follow for a further 20 min. The purpose of the over-ground walking is to promote exploration and

play around a busy classroom environment or during morning recess time where children can be in their gait trainers with other children. The LT and over-ground walking will be carried out by two therapists/therapy assistants. The partial body weight supported treadmill training protocol is based on Behrman and Harkema (2000)<sup>79</sup> protocol and Day *et al* (2004)<sup>47</sup> with standardised hand positioning during the swing and stance phase. Optimal speed is determined by establishing a spatially and temporally coordinated walking pattern (0.8–1.5 km/hour) with straps attached to the anterior and posterior part of the harness to optimise hip, knee and ankle kinematics during gait. Synchronisation of the timing for foot clearance and simultaneous heel strike of one limb and toe-off on the other limb for swing is provided with songs used to support timing and motivation. Ankle foot orthoses will be used if they are already prescribed for the participant as part of standard care. The duration of the session will be determined by (1) participant fatigue, (2) maintenance of step patterns and weight shift.

The over-ground walking will follow immediately after the partial body weight supported treadmill training session with children being placed in a gait trainer. Children will be encouraged to actively step, explore and play, for example, going around obstacles, play ball games or read and interact with a book. The progression of movement within the gait trainer will be dependent on individual goals and as much as possible, a hands-off approach will be adopted to promote active involvement of the child, enabling exploration and problem solving. For example, for some children the goal may be to self-propel in a gait trainer or direct and steer themselves in a gait trainer. For children with less mobility restrictions, their progression may be for unassisted indoor walking and to negotiate obstacles.

#### *Table-top activities (30 min)*

During this session, goal directed upper limb skills will be targeted with aim to promote purposeful and task specific movements. This session will be dependent on individual goals and may include increasing the consistency of activating hand switches for play, swiping or direct access on a tablet, bilateral or bimanual hand use to complete craft, playdough, building and drawing activities. Children will be seated at a table and supported as required or as directed by the goals, for example, chair with postural support, kindergarten style school chair with feet supported or sitting on a bench without back support.

### **Training and intervention fidelity**

#### *Training fidelity*

All physiotherapists and occupational therapists will be registered under the Australian Health Practitioner Regulation Agency and the speech pathologist registered under Speech Pathology Australia. All therapists and therapy assistants have credentialed

competency in the provision of the intervention (LT facilitation, set up of as well as donning and doffing into the harness and gait trainer). This is an annual competency that is signed off by the chief investigator. The chief investigator will complete all COPM having completed the online COPM training module. The GMFM will be videoed and assessed by a physiotherapist with extensive experience in GMFM assessments having completed the training prior (noting it is no longer available). All therapists and undergraduate allied health volunteers will complete an 8-hour training programme on the Kindy Moves intervention. The training will include key word signing, knowledge of all songs and corresponding key word sign, use of communication boards, programming hand activated switches for toys and audio recordings and LT support and facilitation. Only allied health students who have passed the competency standards can support the provision of the intervention.

#### Intervention fidelity

Several strategies will be undertaken to ensure fidelity of the intervention.

- ▶ Training sessions for all therapists and therapy assistants with set competency standards that need to be demonstrated and passed by the chief investigator.
- ▶ All children attending the programme will have their own individualised programme outlining the goals and strategies.
- ▶ Planning session prior to the commencement of a programme for all individual strategies to be discussed among the treating team and chief investigator. The framework for the planning sessions will be in line with the functional therapy guidelines.<sup>22</sup>
- ▶ Stand-up meeting prior to each session to review the goals of each child, feedback from prior session and reinforce child specific strategies.
- ▶ Where possible, the same therapist or therapy assistant will be with the child in the session to ensure consistency within the session.

#### Consumer involvement

The design of the intervention (including the dosage, scheduling of sessions, individualised sessions within a group setting) and selection of outcome measures was not only directed by current published evidence but also from the input of parents and therapists from a previous qualitative feasibility study of intensive LT in children with CP functioning that were either marginally ambulant or non-ambulant, aged between 5 and 12 years (awaiting publication). In addition to this, the Healthy Strides Advisory Research Group which includes consumer representatives (parents of children with CP under 10 years of age) were part of the planning and development of the study protocol and intervention.

#### Participant and data management

The number of self-referrals, screened to be eligible, offered placements and those not proceeding with the programme will be recorded. Progress notes regarding session progress, intervention dosage or reported adverse events and attendance will be completed after each session throughout the study period. In case of study withdrawal or loss to follow-up, intention to treat will be applied. All data will be electronic including signed consent forms, assessment forms and video recordings of assessments accessible only to the study team with two stage password access at The Healthy Strides Foundation's secure database. Identification codes will be allocated to the GMFM and PDMS-2 assessment due to the blinded assessor. These codes will be generated by another investigator using a random number allocation sequence so that the time point of the video recording cannot be identified.

#### Statistical methods

The assumption of normality will be tested for all measures through examining distributional plots, Q-plots and the Shapiro-Wilk test. For data normally distributed, parametric tests will be applied with means and SD for each group at each assessment time point reported. For ordinal data, or where data are not normally distributed despite transformations, non-parametric tests will be applied with medians and IQRs reported. Intention to treat analysis will be applied. Authors MH and DP will individually categorise the GAS and COPM according to the Family of Participation Related Constructs (fPRC).<sup>80</sup>

An Analysis of Covariance (ANCOVA) will be used to determine group mean differences and 95% CIs, with statistical significance being set at  $p < 0.05$ . Following GAS classification, mean differences in T-scores will also be determined for the activity and participation-based goals as classified by the fPRC. Clinically significant changes (for the GAS and COPM) will be reported as a percentage of goals achieved and not achieved. Attendance rates will be tallied based on attendance sheets from progress notes and the group mean attendance established as a proportion of 12 possible sessions attended. No interim analysis will occur with data only analysed at the conclusion of the trial (with 40 participants recruited).

#### Qualitative analysis

The interviews will be transcribed verbatim with all identifiable features such as names removed and replaced with pseudonyms. After reading the transcripts multiple times, data will be analysed thematically using an open coding process to identify meaning units. After applying the open coding framework, meaning units will be categorised into themes and grouped into higher order categories. This process will be completed by two reviewers, enabling comparisons and connections between themes to be explored within the context



of the F-words.<sup>57</sup> Several methods of trustworthiness will be undertaken, including credibility (through member checking), credibility through a critical friends approach, transferability through purposive sampling and dependability through overlap methods with triangulation of data with the quantitative measures.<sup>81–83</sup>

## DISCUSSION

This paper outlines the protocol and background for establishing the feasibility of an intensive activity-based intervention on goal attainment and motor capacity delivered within an interdisciplinary framework for children with CP and CP like conditions functioning with GMFCS levels III, IV and V (or equivalent to if non-CP). The intervention is designed to meet the individual needs of school readiness for children with CP and CP like conditions. Outcome measures have been selected to represent the ICF-CY domains. We hope that the findings from this research will be published and disseminated in a peer-reviewed journal. Individualised adaptations will be necessary to ensure the child's individual goals are met. However, every effort will be made to standardise each element of the intervention. The intervention is comprised several elements in order to meet the multiple key skill areas of school readiness. This is a limitation of the intervention as it will not be possible to differentiate between the effects of each of the individual elements.

## Ethics and dissemination

Kindy Moves has been approved by the Human Research Ethics Committee of Curtin University. Participant information will be provided to all participants prior to entry into the study. Written and informed consent will be obtained from all participants.

Knowledge translation will be guided by the Knowledge Translation Planning Template.<sup>84</sup> Project partners include researchers, consumers and practitioners who will be supported by the project investigators. Specific knowledge translation strategies will be targeted throughout the Kindy Moves project, in partnership with our stakeholders. This will include any peer-reviewed publications, plain language summaries (digital and written), media case studies and conference presentations.

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