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Kindy Moves: the feasibility of an intensive interdisciplinary programme on goal and motor outcomes for preschool-aged children with neurodisabilities requiring daily equipment and physical assistance

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ABSTRACT

Objectives To determine the feasibility of an intensive interdisciplinary programme in improving goal and motor outcomes for preschool-aged children with non-progressive neurodisabilities. The primary hypothesis was that the intervention would be feasible.

Design A single group feasibility study.

Setting An Australian paediatric community therapy provider.

Participants Forty children were recruited. Inclusion criteria were age 2–5 years with a non-progressive neurodisability, Gross Motor Function Classification System (GMFCS) levels III–V or equivalent, and goals relating to mobility, communication and upper limb function. Exclusion criteria included orthopaedic surgery in the past 6 months, unstable hip subluxation, uncontrolled seizure disorder or treadmill training in the past month.

Intervention A goal-directed programme of three 2-hour sessions per week for 4 weeks (24 hours total). This consisted of treadmill and overground walking, communication practice, and upper limb tasks tailored by an interdisciplinary team.

Primary and secondary outcome measures Limited-efficacy measures from preintervention (T1) to postintervention (T2) and 4-week follow-up (T3) included the Goal Attainment Scaling (GAS), Canadian Occupational Performance Measure (COPM), Gross Motor Function Measure (GMFM-66) and 10-Metre Walk Test (10MWT). Acceptability, demand, implementation and practicality were also explored.

Results There were improvements at T2 compared with T1 for all limited-efficacy measures. The GAS improved at T2 (mean difference (MD) 27.7, 95% CI 25.8 to 29.5) as well as COPM performance (MD 3.2, 95% CI 2.8 to 3.6) and satisfaction (MD 3.3, 95% CI 2.8 to 3.8). The GMFM-66 (MD 2.3, 95% CI 1.0 to 3.5) and 10MWT (median difference −2.3, 95% CI −28.8 to 0.0) improved at T2. Almost all improvements were maintained at T3. Other feasibility components were also demonstrated. There were no adverse events.

Conclusions An intensive interdisciplinary programme is feasible in improving goal and motor outcomes for preschool children with neurodisabilities (GMFCS III–V or equivalent). A randomised controlled trial is warranted to establish efficacy.

Trial registration number ACTRN12619000064101.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ To our knowledge, this is the first trial evaluating the feasibility of an intensive, goal-directed and interdisciplinary programme for preschool-aged children with non-progressive neurodisabilities who require equipment and assistance for mobility.
⇒ The Kindy Moves intervention is consistent with the best available evidence for children with neurodisabilities and is underpinned by recent international clinical practice guidelines and high-level evidence.
⇒ The intervention and methodology are comprehensively described in our previously published protocol paper.
⇒ The interdisciplinary design of the programme makes it difficult to differentiate the effects of individual elements of the programme.
⇒ As a feasibility study, the results can only suggest the potential efficacy of the intervention.

BACKGROUND

Clinical practice guidelines[1 2] and systematic reviews[3 4] equip clinicians and researchers to deliver evidence-based interventions for children with cerebral palsy (CP) and non-progressive neurodisabilities. The literature recommends high intensity goal-directed and task-specific interventions that encourage child-generated movement in an enriched environment.[1–4] With higher research quality and quantity in CP populations, these

recommendations can be applied to broader neurodisability populations until greater literature emerges for these groups.[5] Neurodisability has been described through consensus[6] as 'a group of congenital or acquired long-term conditions that are attributed to impairment of the brain and/or neuromuscular system and create functional limitations. A specific diagnosis may not be identified. Conditions may vary over time, occur alone or in combination, and include a broad range of severity and complexity. The impact may include difficulties with movement, cognition, hearing and vision, communication, emotion, and behaviour.' Examples of neurodisability include CP, spina bifida, KAT6A syndrome, acquired brain injury and Down's syndrome.[6] CP is a neurodisability that is most commonly cited and studied due to its relatively higher prevalence.[7] Genetic and metabolic aetiologies are being increasingly recognised in the description of CP, and advice on the inclusion or exclusion of CP in registers has been provided for nearly 200 disorders.[8] CP is often associated with pain (3 in 4), intellectual disability (1 in 2), epilepsy (1 in 3), visual impairment (1 in 10) and hearing loss (1 in 25).[9] Most co-occurring impairments are more frequently present in children with greater motor impairment.[9] The five-level Gross Motor Function Classification System (GMFCS)[10] is used to describe functional mobility performance in CP, with approximately 40% of children with CP in Australia functioning within GMFCS levels III–V, indicating a dependence on daily equipment and physical assistance for mobility.[11] These children predominantly mobilise in their homes and the community using a wheelchair and/or walking device.[10] Although the GMFCS was developed specifically for children with CP, descriptors of functional mobility can apply to the broader neurodisability population.[10] Children with neurodisabilities other than CP who function within the equivalent of GMFCS levels III-V similarly use equipment such as wheelchairs and walking devices.[10] However, many children functioning within GMFCS levels IV–V may not have the capacity to mobilise with a walking device and require physical assistance to do so.[10] For the children who do have this capacity in a standardised clinical setting, they may not have the capability for this performance independently in an uncontrolled or dynamic environment.[10 12] This group of children have a greater reduction in physical activity and participation levels than their more mobile peers,[13–16] contributing to a greater risk of adverse long-term health outcomes.[17] There is a scarcity of exercise-based interventions in those with lower functional mobility[18] despite this being a highly ranked research priority.[19]

Early intervention is of paramount importance to optimise a time of peak neuroplasticity while establishing a foundation for a physically active future.[2 3 20–22] Early intervention also yields higher rates of economic return when compared with intervening later in childhood.[23 24] Children with CP classified within GMFCS III–V reach 90% of their gross motor function potential before the age of 5 years[25] and experience a functionally relevant decline into adolescence.[26] This warrants early intervention to increase peak gross motor ability and provide opportunities early in life to participate and be physically active with peers.[2 27] Neurodisability predisposes vulnerabilities in school preparedness with the rapid introduction of new cognitive, gross motor, social and upper limb challenges in a foreign environment.[28] Practice of new skills across these domains that are relevant to real-life tasks and environments may assist in preparing children with neurodisabilities for these challenges in school transition.[28] Wide-ranging school preparedness goals require input from different health professionals, and interdisciplinary teams can collaboratively tailor an intervention according to family-centred goals while streamlining service provision.[1 29]

Walking-related goals are common in children with neurodisability, with locomotor treadmill training (LTT) being increasingly used as a targeted approach to address these.[30–32] LTT involves a combination of partial body weight supported treadmill training with overground walking to allow for safe, intense and repetitious practice.[33] Treadmill and overground training increase walking speed and endurance, and likely improve gross motor function in children with CP.[1 4] Benefits extend into broader populations of preschool children with neuromotor delay who demonstrate accelerated motor development following treadmill interventions.[34] There is a substantial variation in dosages delivered for LTT, often ranging from 4 weeks[27] to 3 months,[22] with the optimal frequency and duration yet to be defined.[34] Although, intensive blocks and higher doses of therapy are recommended over lower doses and regular distributed therapy.[1] Intensive blocks are frequently described as involving at least three sessions per week for a period of time.[35] There are no specific guidelines regarding the required dosage of these intensive blocks for LTT and many other activity-based interventions. The upper limb literature does, however, recommend 14–25 hours of intervention to improve upper limb function goals for children with CP.[36] Consistent with this dosage, improvements in motor function have been shown following 18 hours of LTT over 6 weeks in children aged 5–12 years old with CP (GMFCS III–V),[33] and following 14 hours of treadmill training in preambulatory children aged 1–5 years old with neuromotor delay.[34] However, research has repeatedly been conducted with older children with CP who are more functionally mobile, with less consideration of younger children who have greater motor impairment. Because of this, there are substantial gaps in the literature for LTT in children classified within GMFCS levels III-V[30 32 37] and those under the age of 5 years.[27 38] This is an important literature gap to be filled not only for the missed neuroplastic window but for an opportunity to increase peak gross motor ability prior to a functional plateau and decline while potentially delaying this decline.[21 26]

Therefore, an LTT-focused intensive programme underpinned by clinical practice guidelines and overviews of systematic reviews has the potential to improve

goal-directed outcomes for preschool-aged children with non-progressive neurodisabilities (GMFCS III–V or equivalent).[1–4 34 39] To date, no studies have explored LTT delivered within an interdisciplinary framework for preschool-aged children with neurodisabilities. It is not known whether there is sufficient demand to recruit for such an intervention, or whether intensive therapies are acceptable, practical and can be implemented as planned for this population. The impact of this intervention on motor or goal outcomes for this population is also yet to be determined. A cohesive interdisciplinary team can align the intervention with caregiver-reported goals for school across areas of mobility, socialisation and hand use. With motivation and enjoyment being vital in young children,[4 40] a group-based environment to encourage play while addressing socialisation goals is warranted. As such, this study aims to determine the feasibility[41] of LTT embedded within an interdisciplinary framework in preschool-aged children with non-progressive neurodisabilities requiring daily equipment and physical assistance (ie, GMFCS levels III–V or equivalent). The primary hypothesis was that this intervention would be feasible as measured by limited-efficacy testing, acceptability, demand, implementation and practicality.

METHODS

Design

This single group feasibility study aimed to determine the feasibility of the Kindy Moves intervention.[42] Children with non-progressive neurodisability aged 2–5 years were recruited. Participants undertook 4 weeks of intervention, completing a 2-hour session three times per week. Feasibility was assessed through limited-efficacy testing (testing the effect of an intervention in a limited way), acceptability (how the participants reacted to the intervention), demand (the demand of the intervention), implementation (how the intervention was implemented as proposed) and practicality (how the intervention was delivered with constrained resources, time or commitment).[38] Limited-efficacy testing was determined by comparing objective changes from baseline 2 weeks before the intervention (T1) to the week following intervention completion (T2) and at follow-up 4 weeks postintervention (T3). The shorter 4-week follow-up period was chosen to limit the effect of maturation on results. Acceptability was measured according to attendance rates and adverse events. Demand was determined through the ease and extent of recruitment during a 2-year time frame. Implementation was assessed by comparing the delivered intervention to the planned protocol and practicality was determined by attendance rates and an intervention dosage evaluation. The research team met on completion of the study to discuss the results and establish what changes could be made to the methodology in a future definitive trial. The intervention was completed at The Healthy Strides Foundation, a not-for-profit community therapy provider in Western Australia that delivers intensive intervention for children and adolescents with neurological conditions and injuries. An interdisciplinary team of physiotherapists, occupational therapists, allied health assistants and a speech pathologist delivered the intervention. An exploration of patient and caregiver perspectives, levels of enjoyment and engagement will be reported in a future qualitative paper. This study was reported according to the Consolidated Standard of Reporting Trials (CONSORT) 2010 statement: extension to randomised pilot and feasibility trials.[43 44]

Patient and public involvement

Patients and the public were involved in the design, conduct and dissemination plans of our research. The listed consumer advisors on the Healthy Strides Research Advisory Council supported the development of the intervention protocol and were involved in planning for the dissemination of findings.

Participants

Children were included in the study if they were aged between 2 and 5 years old with a non-progressive neurodisability and were dependent on daily equipment and physical assistance for mobility (GMFCS III–V or equivalent). Neurodisability was defined according to the published consensus definition.[6] Participants also needed to have family-created goals based on improving mobility, socialisation or communication skills, and upper limb function. All levels of communication and upper limb function were included according to the Communication Function Classification System (CFCS)[45] and Manual Ability Classification System (MACS)[46] levels I–V (or equivalent). Lastly, children with all motor presentations such as increased tone, reduced tone and varying tone were included. Children were not included in the study if they had orthopaedic surgery within 6 months of the study, unstable hip subluxation, uncontrolled seizure disorder or engagement in LTT in the month prior to the study. A semistructured interview was used for caregivers to answer open-ended questions to state diagnoses, medical conditions and co-occurring impairments. The sample size was based on practical considerations for the 2-year period such as year-by-year funding parameters and resource availability (staffing, equipment, time and space). Participants were recruited through The Healthy Strides Foundation social media pages.

Intervention

A standardised protocol of the Kindy Moves intervention was followed (online supplemental material 1).[42] Kindy Moves is an intensive programme that incorporates treatment approaches consistent with the best available evidence for non-progressive paediatric neurodisabilities.[1–4] The intervention is underpinned by motor learning theory and incorporates goal-directed and task-specific practice in an enriched environment where the child initiates movement at a high intensity. Children attended three 2-hour sessions per week for 4 weeks (24 hours of

Figure 1 Treadmill training.

therapy). LTT was a large focus of the programme, but this was incorporated into an interdisciplinary framework with dedicated time to address communication, socialisation and upper limb function goals. The unique use of an interdisciplinary team allowed for multiple goal domains to be practised simultaneously throughout the session. For example, a child was encouraged to practice communication goals during activities that focused on walking or upper limb function. To facilitate real-life practice of these goals in preparation for a new school environment, a group-based setting with 3–4 participants at a time was implemented. The 2-hour intervention was separated into 30 min of floor time as a group to practice gross motor, socialisation and play skills through games, songs, and book reading. This was followed by 1 hour of LTT, separated into 30 min of partial body weight supported treadmill training (figure 1) and 30 min of overground walking in a mobility device which was designed based on the formative work of Pool *et al*.[33] Physical assistance was provided to assist the child's stepping when required, but maximal opportunity for active child-initiated movement was given. During overground walking in a mobility device that can provide trunk and/or head support, children functioning within GMFCS levels IV–V, in particular, may have been able to initiate or take steps before needing assistance to propel forwards. Other children may have been able to independently propel their mobility device but required assistance to steer. Lastly, participants engaged in 30 min of tabletop activities such as craft, building or playdough to address upper limb function goals. Each intervention component was individualised to every child according to their goals but was consistently underpinned by evidence-based recommendations.[1–4] The intervention was tailored to account for individual co-occurring impairments of the participants where possible. For example, activities for children with visual impairment involved high-contrast images and supplementary auditory and tactile stimuli. A Template for Intervention Description and Replication document can be viewed in online supplemental material 2.

Outcome measures

Canadian Occupational Performance Measure

The Canadian Occupational Performance Measure (COPM)[47] was used to establish family-created goals. Families outlined key performance areas that were related to school preparedness. Performance and satisfaction scores were obtained by the caregiver for each performance goal using a 10-point scale. Performance and satisfaction scores that increased by 2 or more points on the scale are considered clinically meaningful.[47] The COPM is valid, reliable and has been used extensively in CP and broader populations.[48]

Goal Attainment Scaling

The Goal Attainment Scaling (GAS)[49] is an individualised outcome measure that calculated the extent to which a child's goals were met. At least one GAS was created for each COPM goal and categorised according to the family of participation-related constructs (fPRC).[12] The fPRC conceptualises a health condition and the interplay of various constructs based on the WHO's International Classification of Functioning, Disability and Health (ICF).[50] The GAS is valid and reliable,[51] and has detected change across a variety of paediatric populations.[52] The GAS produces a t-score for analysis, with a t-score of 50 or more indicating clinical meaningfulness.[53] Both the GAS and COPM were selected due to being family-centred outcome measures that allow for the collaborative setting of individualised goals that span across multiple levels of the ICF and fPRC.

Gross Motor Function Measure

The Gross Motor Function Measure (GMFM-66) is a valid and reliable[54] measure of gross motor function for children with CP. The clinically meaningful change in the GMFM-66 is 1.23 for children classified within GMFCS level III, and 2.88 for GMFCS levels IV and V.[55] The Gross Motor Function Measure Evolution Ratio (GMFMER) was used, with a ratio of greater than one indicating improvement greater than what was expected from natural maturation.[56] The proportion of participants who achieved a ratio of greater than one at T2 and T3 was reported. The GMFM-66 assessment was video recorded and scored by an experienced Physiotherapist who was blinded to the assessment time point of the video.

10-Metre Walk Test

The 10-Metre Walk Test (10MWT) is a standardised measure of indoor walking speed with good psychometric properties for children with a range of neurological

presentations.[27 32 57] However, there is less evidence of reliability and validity for children within GMFCS levels IV–V (or equivalent).[51] Participants walked as fast as possible in a mobility device across a 10 m distance. Facilitation of one step was provided for children who did not initiate stepping after 30 s.[33] If a child did not complete the 10 m distance in 360 s, this time was recorded as the maximal result.[33] The clinically meaningful change in 10MWT speed is 0.1 m/s.[58] The GMFM-66 and 10MWT were selected as activity-based outcome measures according to the ICF because of the activity-focused nature of the intervention. These outcome measures also demonstrated meaningful improvements in a similar study protocol for children aged 5–12 years with CP (GMFCS III–V),[33] warranting investigation in a younger age group.

Statistical analysis

Intention-to-treat analysis was applied. Data were presented as means and SD for continuous data, or medians and IQRs when the data were skewed and required transformation. Linear mixed models were used to compare within-group differences for all outcomes except the 10MWT where quantile regression was used due to the skewed distribution. Mean or median differences were produced along with their corresponding 95% CIs. The Smithers-Sheedy *et al*'s[8] list of disorders was used to define which participant's aetiologies were consistent with CP and which were not. The proportion of participants that achieved clinically meaningful improvements at T2 and T3 was reported for all outcome measures. Authors MH and DP individually categorised the GAS and COPM goals, with any discrepancies being addressed via discussion or removal of the goal if agreement could not be made. Published definitions of fPRC terms[47] were used to categorise GAS across relevant domains including activity capacity, activity performance, participation (attendance), participation (involvement) and self-regulation. Descriptors of the COPM domains and subdomains were also used to categorise these goals.[47 59]

RESULTS

A total of 42 participants were assessed for eligibility with two being excluded due to having a progressive neurodisability (figure 2). It was difficult to distinguish between GMFCS levels II and III for two participants (aged 4 years 8 months and 3 years 8 months) who were able to walk short distances indoors independently but often required constant physical assistance or securing in a stroller for safety. On review of their preintervention GMFM-66 scores, these children functioned within the GMFCS level III curves at the 80th and 90th percentiles, respectively. Both children demonstrated a range of skills relevant to GMFCS level III but could also complete some skills within GMFCS level II. These children were included in the study. The participant characteristics are outlined in table 1. The participants with neurodisabilities other than CP have KAT6A syndrome, GRIN-1 neurodevelopmental disorder, global developmental delay and epilepsy, mosaic

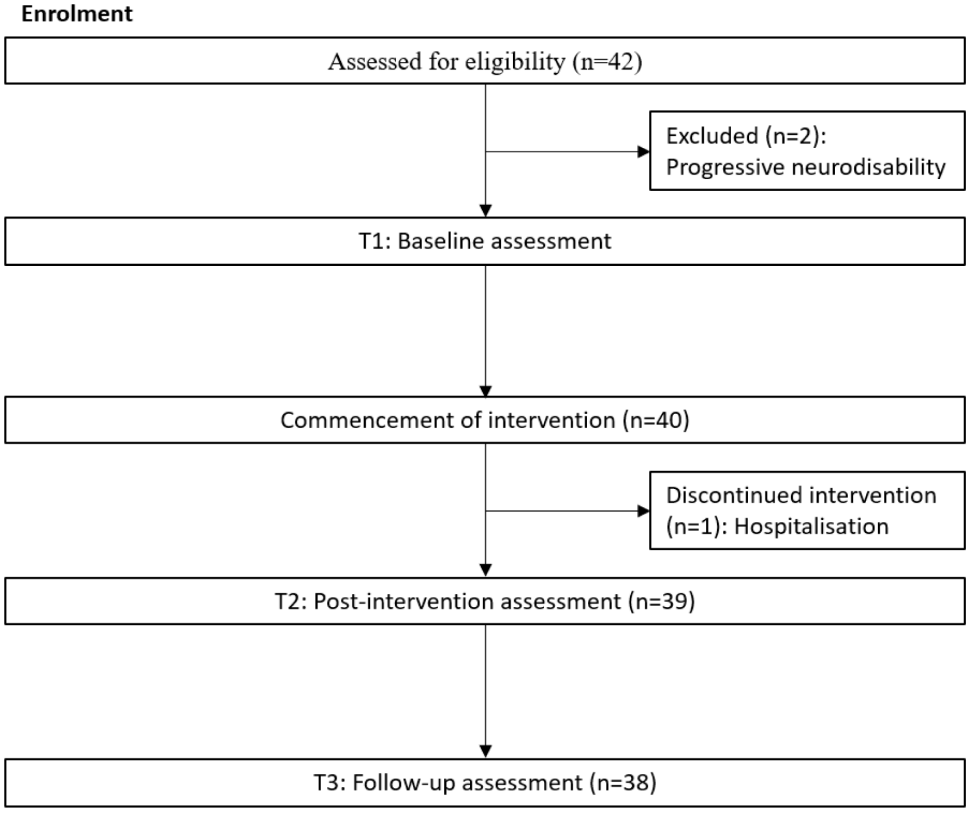

Figure 2 Consolidated Standard of Reporting Trials (CONSORT) flow diagram.

Table 1 Characteristics of participants

Participants, n	40
Gender, n males (%)	20 (50.0)
Age, mean (SD)	3 years 4 months (11 months)
Age range	2 years 0 months to 5 years 6 months
Cerebral palsy description, n (%)	34 (85.0)
Other neurodisability, n (%)	6 (15.0)
GMFCS level, n (%)	
III	16 (40.0)
IV	14 (35.0)
V	10 (25.0)
MACS level, n (%)	
II	2 (5.0)
III	5 (12.5)
IV	14 (35.0)
V	19 (47.5)
CFCS level, n (%)	
I	1 (2.5)
III	4 (10.0)
IV	11 (27.5)
V	24 (60.0)
Total COPM goals set, n	157
COPM goals set per participant, mean (SD)	3.9 (0.7)
COPM goals set per participant, range, n	3–5
COPM leisure: socialisation goals, n (%)	44 (28.0)
COPM productivity: school and/or play goals, n (%)	53 (33.8)
COPM self-care: functional mobility goals, n (%)	53 (33.8)
COPM self-care: personal care goals, n (%)	7 (4.5)
Total GAS, n	193
GAS per participant, mean (SD)	4.95 (1.2)
GAS per participant, range, n	3–9
Activity capacity GAS, n (%)	106 (54.9)
Activity performance GAS, n (%)	74 (38.3)
Self-regulation GAS, n (%)	8 (4.2)
Participation (involvement) GAS, n (%)	5 (2.6)
Participation (attendance) GAS, n (%)	0 (0)

CFCS, Communication Function Classification System; COPM, Canadian Occupational Performance Measure; GAS, Goal Attainment Scaling; GMFCS, Gross Motor Function Classification System; MACS, Manual Ability Classification System.

ring chromosome 18, epileptic encephalopathy and polymicrogyria. Caregiver-reported co-occurring epilepsy was present in 72.5% of participants, visual impairment in 22.5%, and hearing impairment in 10.0%. Three GAS were removed during the categorisation process due to being deemed invalid. The COPM goals were distributed across leisure: socialisation, productivity: school and/or play (where most goals related to upper limb function for play) and self-care: functional mobility (table 1). Most GAS were categorised as activity-based (93.3%).

Feasibility

All components of feasibility were met. Demand for the intervention is supported with 42 participants (40 eligible) being recruited via social media over a 2-year period. There was one participant drop-out due to hospitalisation for respiratory illness, with 39 participants completing the intervention. There were no adverse events. Attendance rates were high with an average attendance rate of 21.9 out of 24 hours with the main reason for non-attendance being illness. The full dosage was received by 23/40 participants, 5/40 received 22 hours, 6/40 received 20 hours, 3/40 received 18 hours, 2/40 received 16 hours and 1/40 received 8 hours. All outcomes measured were assessed as per the study protocol, however, 18 participants could not complete the 10MWT within the designated 360 s at baseline. The intervention delivered was consistent with the study protocol other than 17 participants who did not complete the full 24 hours of therapy. Acceptability was, therefore, demonstrated with no adverse events and high attendance rates, implementation by the ability to follow the planned protocol, and practicality by attendance rates and intervention dosage. Lastly, the potential efficacy of the intervention (limited-efficacy testing) was demonstrated through trends for improvement and clinically meaningful improvements across all outcome measures as outlined in table 2.

Improvements were shown for all outcome measures from baseline to postintervention and baseline to follow-up, with non-overlapping CI for all measures other than the 10MWT from T1 to T3 (table 2). All outcome measures remained stable from T2 to T3 except for the GAS t-score which showed a trend for ongoing improvement. At T2, 87.2% of participant mean COPM performance scores and 84.6% of mean COPM satisfaction scores showed clinically meaningful improvements. This remained stable at 86.8% for performance and 89.5% for satisfaction at T3. The mean GAS scores were clinically meaningful for 41.0% of participants at T2 and 65.8% at T3. For the GMFM-66, 41.2% of participants had clinically meaningful improvements postintervention and 51.4% at follow-up. When using the GMFMER, 76.5% showed GMFM-66 improvements greater than expected natural evolution at T2 which reduced to 70.3% at T3. Individual 10MWT speed improvements were clinically meaningful for 32.4% of participants at T2 and T3.

DISCUSSION

Feasibility

This study aimed to determine if implementing Kindy Moves, a 4-week intensive LTT programme delivered within an interdisciplinary framework, was feasible for preschool-aged children with non-progressive neurodisabilities. Following this intervention, there were improvements in the GAS, COPM performance and satisfaction,

Table 2 Outcome measure changes across all time points

	Assessment time point			Outcome measure changes		
	Mean (SD)			Mean difference (95% CI)		
Outcome	T1	T2	T3	T2 vs T1	T3 vs T1	T3 vs T2
GAS t-score	20.2 (1.4) n=39	47.9 (5.5) n=39	51.1 (7.0) n=38	27.7 (25.8 to 29.5)	30.9 (29.1 to 32.8)	3.3 (1.4 to 5.1)
COPM performance	2.5 (1.0) n=39	5.7 (1.7) n=39	5.8 (1.6) n=38	3.2 (2.8 to 3.6)	3.3 (2.9 to 3.7)	0.1 (–0.3 to 0.6)
COPM satisfaction	3.1 (1.5) n=39	6.4 (1.8) n=39	6.4 (1.8) n=38	3.3 (2.8 to 3.8)	3.3 (2.8 to 3.8)	0.0 (–0.5 to 0.5)
GMFM-66	33.7 (16.3) n=38	35.6 (15.3) n=34	36.4 (15.9) n=37	2.3 (1.0 to 3.5)	2.1 (0.8 to 3.3)	–0.2 (–1.5 to 1.1)
	Median (IQR)			Median difference (95% CI)		
Skewed data	T1	T2	T3	T2 vs T1	T3 vs T1	T3 vs T2
10MWT time (s)	294.3 (33.2, 360.0) n=39	66.0 (32.7, 360.0) n=37	81.6 (28.3, 336.0) n=37	–2.3 (–28.8 to 0)	–8.3 (–20.9 to 0)	0.0 (–3.2 to 2.2)

COPM, Canadian Occupational Performance Measure; GAS, Goal Attainment Scaling; GMFM-66, 66-item Gross Motor Function Measure; 10MWT, 10-Metre Walk Test.

GMFM-66 and 10MWT. These improvements were largely maintained 4 weeks after programme completion. This demonstrated the potential efficacy of the feasibility study according to limited-efficacy testing. Attendance rates were high with no adverse events to report (indicating acceptability and practicality), recruitment was successful and achieved solely through social media posting (reflecting demand), and the intervention accurately followed protocol (supporting implementation). These results highlight the feasibility of Kindy Moves as an intensive goal-directed programme in children aged 2–5 years with non-progressive neurodisabilities (GMFCS levels III–V or equivalent).

Goal outcomes

Improvements in goal attainment following Kindy Moves add to the growing literature in young children with neurodisabilities. Several interventions have shown results consistent with this study in improving goal attainment in children with neurodisabilities.[60–63] Two of these studies investigated goal-directed therapy in children with CP who were 4–5 years and classified across most GMFCS levels.[60 62] However, there was much less representation of children who have more severe motor impairments in these two studies, with only 10 out of the 66 total participants across both studies functioning within GMFCS levels IV–V.[60 62] As such, there is less certainty about the effects of such interventions in non-ambulant children with neurodisabilities. Improvements in COPM goal performance and satisfaction have also been reported frequently across a range of interventions.[63–65] Although, research in this area often includes school-aged children[63 64 66] or infants,[65] with trials involving children aged 2–5 years being less frequently completed.[67] Data exploring the retention of outcomes in a period after programme completion are important in establishing the extent of real-life skill application. Goal performance and satisfaction remained high 4 weeks after this intervention, suggesting that participants maintained their level of goal-related function without additional intensive therapy input. Further research into retained outcomes with longer-term follow-up may help to establish the required frequency of intensive therapy programmes throughout a child's lifespan.

With nearly all GAS in this study being activity-based and many participants functioning within levels IV–V (or equivalent) according to GMFCS (n=24), MACS (n=33) and CFCS (n=35), it is clear that families set skill acquisition goals irrespective of gross motor, upper limb or communication ability. Parents report that exercise interventions for non-ambulant children with CP are a high priority.[19] This is consistent with the literature shift in developing approaches beyond the level of body functions and structures for these children.[4] The demand for Kindy Moves as an activity-based intervention is supported by this literature alongside the demonstrated ease of recruitment solely via social media. Non-ambulant children with neurodisabilities also more frequently receive compensatory management approaches or interventions with lower levels of evidence and can miss the opportunity to learn new skills.[68] With continually strengthening evidence and a better understanding of neuroplasticity in childhood neurological conditions, these children should be given the opportunity to improve goal-driven function, particularly at a young age. Children with more severe motor deficits are also more likely to have co-occurring impairments.[9] A relatively high proportion of the children in this study had visual and hearing impairment, or epilepsy, suggesting that these comorbidities do

not always limit the possible benefits of an appropriately individualised intervention. Good attendance rates and the absence of adverse events also demonstrate the safety and acceptability of this intensive intervention in a population with complex medical backgrounds. However, future studies may take into consideration the potential for illness, reduced intervention dosage received and hospitalisation in these populations as was observed in this trial. The incompleteness of some in-person outcome measure assessments at postintervention (15.0% incomplete GMFM-66 data) and follow-up (7.5% incomplete GMFM-66 and 10MWT data) may be partly explained by the medical complexity of participants. This differs from the nearly fully complete dataset for assessments that could be completed over the phone (2.5% incomplete at T2 and 5% incomplete at T3 for GAS and COPM data) which allowed for assessment if participants were in hospital or had unavoidable commitments. Phone call alternatives to complete particular assessments may help to accommodate family preferences and additional commitments. Improvement in goal outcomes following this intervention highlights promising evidence for the use of activity-based interventions for children who have more severe motor and communication impairments with increased rates of associated disorders. This also demonstrates the successful application of clinical practice guidelines[1 2] to a young neurodisability population with diverse comorbidities while bringing to light assessment considerations that may reduce the burden of time on families.

Over one-third of GAS were related to activity performance according to the fPRC; this domain refers to the skills that a child uses in their everyday settings, reflecting the real-life application of skills learnt.[12] Interestingly, just over half (54.9%) of caregiver-reported goals related to activity capacity, meaning the focus was on skill attainment without a specific real-life context or application.[12] One possible explanation of this is that at the early stage of these children's development before school and involvement in other life situations, caregivers may have a larger focus on what skills their child needs to learn before considering the context of using those learnt skills. The use of a clinical space for the intervention rather than a school environment may have also meant that the application of skills in real-life settings was less apparent. However, categorised COPM goals covered the breadth of areas required for school preparedness,[28] with a relatively even distribution across functional mobility, socialisation, and school and/or play goals. Improvements in COPM goals across this range of areas highlight the effective use of an interdisciplinary team in streamlining service provision for an intensive therapy programme. This also shows the potential efficacy of an interdisciplinary team following clinical practice guidelines to facilitate goal-directed outcomes for preschool-aged children with wide-ranging comorbidities and functional ability levels. Future research may involve part, or all of the intervention being delivered in the school or home environment to facilitate context-focused practice.[1 2] Although goal performance and satisfaction related to school preparedness improved, a randomised controlled trial with a longer duration follow-up would be needed to determine the effect of Kindy Moves on future school performance and functioning. Very few GAS were participation based (2.6%), which according to the fPRC constitutes attendance or involvement.[12] This is to be expected of an activity-based intervention with the aim of improving functional capacity.[4] There are many barriers to participation for children with disabilities, activity capacity being just one, requiring a dedicated and comprehensive approach to address each of these.[69] Assessment tools such as the Child Engagement in Daily Life[70] or the Young Children's Participation and Environment Measure[71] can be used to evaluate these participation interventions. Participation-focused interventions have emerged in recent years and initial results show great promise.[63 72]

Motor outcomes

The positive changes in gross motor function and walking speed following this intervention support the current literature for improving motor outcomes in neurodisability populations. Many locomotor training and goal-directed interventions are consistent with our findings of improved motor capacity in older[73–75] and younger[27 38 76] children with neurodisabilities. For CP populations, there is a strong evidence supporting locomotor training for walking speed, and promising literature for gross motor function.[1 4] Although, there is limited evidence for these effects in children with other neurodisabilities.[34] Among the available literature, children requiring equipment and assistance throughout their day are highly underrepresented. One of the few studies that did include these children with greater mobility requirements showed similar changes to Kindy Moves in four children with CP aged 1.7–2.3 years who completed 40–50 hours of therapy over 4 months.[77] Despite being a promising pilot study,[77] it is probable that natural maturation affected the results in the 4-month intervention, particularly at an age of rapid motor development. To account for this in Kindy Moves, a shorter intervention timeframe and only a 4-week follow-up period were selected. Although longer follow-up periods beyond 3 months provide vital information into retained clinical outcomes, we aimed to limit the extent of maturation as a confounding factor in interpreting the results of this feasibility study. In addition, the GMFMER was implemented to evaluate change in the context of this maturation.[56] Children with neurodisabilities receive regular therapy under the Australian funding model, meaning that a shorter follow-up duration also limited the impact of such external factors on results. At postintervention assessment, 76.5% of participants improved their gross motor function more than what was expected due to natural maturation as estimated by reference curves.[56] Without a control group in this study design, the GMFMER provides greater certainty that the changes observed were due to the intervention itself

and not maturation. Such changes show promise that a larger trial of Kindy Moves may demonstrate meaningful improvements in gross motor function.

Walking speed is related to functional ability, health-related quality of life and social participation in people with neurodisabilities.[78 79] With participants in this study having more severe functional limitations, a ceiling effect which skewed the data was noted in the 10MWT, with 18 participants not completing the distance in 360 s. This was particularly evident in children functioning within GMFCS levels IV–V (or equivalent). The 6 min Walk Test may be an appropriate alternative for this population to reduce the ceiling effect and record distance rather than time.[51] Although community ambulation may not be an achievable goal for all participants in Kindy Moves, newly learnt walking skills act as a means of daily exercise and an opportunity to reduce sedentary behaviour in line with the 24-hour activity guidelines for children with CP.[80 81] Improvements in walking speed postintervention may suggest that the participants have a greater ability to exercise during their day by walking with a mobility device. The possible implications of intensive activity-based programmes for sedentary populations are diverse and yet to be fully understood. Expanding beyond goals and motor capacity, benefits may relate to chronic disease,[80] bone mineral density,[81 82] sleep,[80 81] contractures[2 4 81] and hip displacement.[2 81] Parents of children with CP (GMFCS III-V) have reported similar desired health outcomes beyond motor function from a locomotor training intervention,[83] further warranting activity-based interventions irrespective of motor ability. Important research in this field of health and well-being is much needed with the hopes of positively impacting quality of life, hospitalisations and mortality.

The dosage required to achieve goals and improve motor function for children with neurodisabilities varies in the literature. Although greater consensus has been reached for upper limb goal attainment and function in children with CP,[36] a large variety in treatment dosages remains. Some locomotor training interventions have shown meaningful improvements in as little as three 1-hour sessions per week for 4 weeks (12 hours total),[27] whereas others have explored up to 3 months of 1 hour sessions four times per week (48 hours total).[22] Hand-arm bimanual intensive therapy including lower extremity (HABIT-ILE) is an intervention that has shown to be effective in improving upper and lower limb functioning for children with CP (GMFCS II–IV) following 84 hours of therapy over 13 days.[64] A similar protocol of HABIT-ILE in children with unilateral CP aged 1–4 years resulted in goal and gross motor improvements after 50 hours of therapy over 2 weeks.[67] The outcomes of Kindy Moves highlight improvements in goals and motor function after 24 hours of therapy across 4 weeks. With many interventions showing clinically meaningful improvements at starkly different dosages, the question arises as to the minimum input required for a favourable and economical outcome. The lives of children with disabilities should not centre around therapy, and the importance of family, fun, friends, rest and leisure cannot be forgotten when considering dosing intervention. The burden of travel, cost and time associated with therapy on families must also be considered. As such, the shortest possible time required to achieve desired outcomes needs to be determined.[36] The commitment involved in the Kindy Moves intervention appeared to be practical for participants, with high attendance rates. The intervention dosage is also reasonably low compared with other intensive interventions reported in the literature while achieving meaningful outcomes. With the knowledge that intensive block practice is recommended over regular distributed therapy,[1] the Kindy Moves intervention dosage may be practical when considering funding limitations for families. However, the ideal intervention dosage is difficult to establish and may vary depending on the type and number of goals set, the heterogeneity of individuals and presence of co-occurring impairments such as cognitive or visual disturbances, or whether the desired outcome of the intervention is goal attainment or improved function. For this reason, single-subject research designs can be used to individualise treatment dosage while accounting for the heterogeneity of children with neurodisabilities.[84] This is particularly pertinent for children who have genetic or metabolic presentations with individually distinct traits. Such designs may assist in guiding intervention dosage for future populations to achieve desired outcomes in a family-centred and economical manner.

Limitations

Although the results support this intervention to improve goal-driven outcomes and motor capacity, there are several study limitations to note. First, including the two children whose GMFCS levels were unclear (between levels II and III) reduces the clarity of our selected population and increases the heterogeneity. The variability in these participants' daily function reflects the differences between activity capacity and performance.[12] Both children functioned comfortably within GMFCS level III but did demonstrate some skills that are appropriate within GMFCS level II and were consequently included. The GMFMER increased the certainty of true changes in gross motor function but is less reliable in smaller populations of children. Due to the interdisciplinary design of the programme and targeting several areas of school preparedness, it is difficult to determine what elements of the intervention contributed to each outcome. However, Kindy Moves was a feasibility study that did not aim to differentiate such factors. In addition, caregivers were asked about the participant's diagnoses or medical conditions as open-ended questions meaning that diagnoses or co-occurring impairments may have been under-reported. This study uniquely included children with neurodisabilities other than CP, strengthening the literature for this broader population but increasing the study population heterogeneity. Lastly, assessors were only blinded to the

assessment time points and not the intervention, introducing the risk of assessor bias to the results.

Implications for future research

Findings from this feasibility study have highlighted changes that could be made to the methodology of a future randomised-controlled trial of the Kindy Moves intervention. First, sample size calculations in a future study involving a young and medically complex population may account for a degree of participant drop-out and up to 15% of in-person assessment data being incomplete at postintervention assessments. The data from this study may also be used to complete future sample size calculations. An offer of phone or video calls for goal scoring and subjective assessments may reduce the burden of time associated with attending assessment time points, possibly improving programme satisfaction and acceptability. To reduce the possibility of a ceiling effect, the 6 min Walk Test may be a more appropriate objective indicator of supported walking ability than the 10MWT for children functioning within GMFCS levels IV–V (or equivalent). The GAS, COPM and GMFM-66 remain appropriate assessment tools for this population in future research, but the GMFMER is less warranted in a randomised-controlled trial that already controls for maturation. When participant GMFCS levels are unclear from caregiver semistructured interviews alone, consultation with local tertiary hospital treating teams and GMFM-66 reference curves may assist in confirming this classification. Similarly, a truer reflection of participant's comorbidities such as epilepsy, pain and intellectual impairment may be achieved through hospital liaison with consent. Lastly, a larger study of the Kindy Moves intervention could consider home or school-based sessions for context-focused practice.

CONCLUSION

Kindy Moves has highlighted that an intensive LTT-focused programme delivered within an interdisciplinary framework is feasible according to limited-efficacy testing, acceptability, demand, practicality and implementation. The intervention shows promise in improving goal attainment, caregiver-reported goal performance and satisfaction, gross motor function, and walking speed in preschool-aged children with non-progressive neurodisabilities. Further research investigating intensive activity-based interventions should be conducted in children with neurodisabilities classified within GMFCS levels IV–V (or equivalent), with a focus on early intervention to optimise neuroplasticity and functional outcomes. The optimal dosage and parameters for locomotor training and other activity-based interventions need to be established, with consideration of participant heterogeneity and desired outcomes. Single-subject research designs may assist in determining intervention dosages while being adaptable to the needs of heterogeneous populations. The Kindy Moves programme is a feasible intervention that highlights preliminary evidence for improving goal-driven outcomes and motor capacity in this population, warranting a well-powered randomised controlled trial to establish its efficacy.

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Contributors All authors meet the ICMJE criteria for authorship, making substantial contributions to the study design, drafting the manuscript and proofing the final version for submission. MH delivered the intervention, conducted outcome measure assessments, and completed the literature review for the manuscript. LW codeveloped the intervention and conducted outcome measure assessments. CE also conceptualised and wrote the study protocol. CW delivered the intervention, conducted outcome measure assessments and sought relevant figures to include in the manuscript with appropriate consent. NB completed all statistical analyses. JV informed the reporting of diagnostic and aetiological labels when writing the manuscript. DP is the guarantor who also conceptualised, planned, developed and wrote the study protocol.

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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.[1] It is widely documented that investments in early intervention yield greater economic rate of return when compared with investments later in childhood.[2–4] Preschool attendance is strongly associated with developmental vulnerability at school entry.[5] 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.[5] 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.[6 7] Failure to intervene effectively in these key skill areas during the early years impacts across the lifespan.[5] 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.[8 9] CP is the most common cause of physical disability in childhood,[10 11] with nearly 40% of children dependent on physical assistance and equipment throughout the day[10] and classified within the Gross Motor Function Classification System (GMFCS) as being levels III, IV and V.[12] 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.[13 14] 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.[15] 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.[7 16]

The common thread of effective paediatric functional interventions for children with CP are interventions that are not only adequate 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.[17] The threshold of adequate dosage is yet to be defined with some models using dosages of 90 hours delivered over 2–3 weeks,[18] to models that include at least three sessions a week.[17 19] 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[20] and for functional mobility training, a dosage of 18 hours delivered over 6 weeks has shown improvements in motor function.[21] Beyond intervention dosage, research strongly supports the need for interventions to contain the essential active ingredients for improved motor ability.[22 23] This includes interventions that focus on the activity and participation level of the International Classification of Functioning - Child and Youth (ICF-CY),[24] are task specific and goal directed, focused on function not normality, context specific and require active child involvement in order to achieve functional goals.[22] 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.[17]

A collaborative interdisciplinary approach has the advantage of intentionally blurring the traditionally concrete disciplinary boundaries.[25] 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.[25–29] 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.[30] 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,[31] turn-taking, sharing and initiation of peer interaction[32] 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,[33–41] 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.[42–44] 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.[45–49] Beyond the diagnosis of children with CP, current evidence of LTT suggests accelerated motor development in preschool aged children with developmental delay.[50] 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.[49 50] 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,[51] and the suggested dosages from previous studies on motor improvements,[20 49] 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.[27 28 52–55] 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[56] 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.[57]

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.[56] 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[58] 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),[59] indoor walking speed on the 10-metre walk test (10mWT) by 0.1 m/s,[60] functional independence on the Children's Functional Independence Measure (WeeFIM),[61] fine motor skills on the Peabody Developmental Motor Scale Version 2 (PDMS-2),[62] sleep behaviour and disturbances on the Sleep Disturbance Scale for Children[63] and parent-reported quality of life on the Infant and Toddler Quality of Life[64] 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 will CP will improve their gross motor function on the Gross Motor Function Measure—GMFM-66 by 3 points.[65]

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

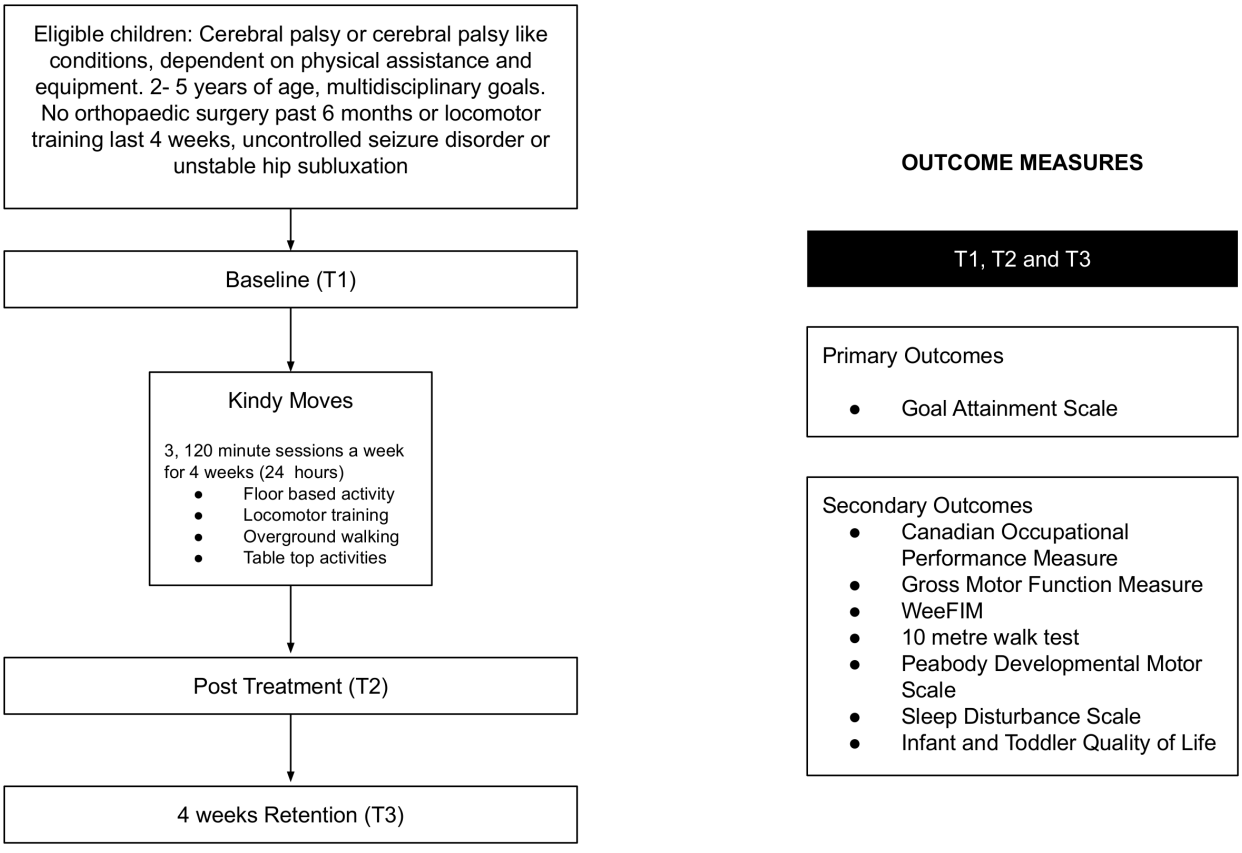

Figure 1 Study design and outcome measures. WeeFIM, Functional Independence Measure.

of the programme. T2: postrogramme: 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),[66] the Manual Ability Classification System,[67] Communication Function Classification System[68] and Functional Mobility Scale.[69]

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.[70 71] 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.[70 71] 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.[58] 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.[72] 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.[58]

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.[71] 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.[71]

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.[39 46 55 73 74] The 10mWT has excellent measurement properties.[46] This measure was used in a previous study also using LTT in children with GMFCS levels III, IV and V.[21] 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 metresm, a time of 600 s is recorded.[21] A change of 0.1 m/s is considered to be clinically meaningful.[26]

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.[61] 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.[37 38] The WeeFIM is recommended for detecting change in activities of daily living over time in children with neurodevelopmental disabilities.[61]

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.[34 62] 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.[62] 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.[63] 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.[63 75]

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.[64] 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.[64]

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.[76] The GMFM-66 is a specific and sensitive outcome measure,[77] and is more sensitive when detecting change in children under 5 years of age.[76] Each of the 66 items will be scored based on criterion-referenced observations on a 4-point scale.[76] 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.[78] 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

	Prompts	
Topic	**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 8 min with 2 min 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)[79] protocol and Day *et al* (2004)[47] 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.[22]
- 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).[80]

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.[57] 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.[81–83]

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.[84] 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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Contributors All authors meet the ICMJE criteria for authorship, making substantial contributions to the study design, drafting the manuscript and proofing the final version for submission. DP conceptualised, planned, developed and wrote the study protocol. CE conceptualised and wrote the study protocol.

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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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Template for Intervention Description and Replication	**4-week, intensive, Kindy Moves program**
Why Rationale, theory and goal of elements in the intervention	Improving functional goal achievement in preparation for attending school **Motor Learning** The activities chosen are child-centered, goal-directed, performed with repetition and incremental challenges underpinned by motor learning theory and the functional guidelines for the development and maintenance of essential functional skills needed for attending school.
What Materials needed for the intervention delivery	Communication switches, adapted books, age-appropriate toys, mat and benches, treadmill, overhead hoist and walking harness, walking frames and balls.
What Procedures and activities used in the intervention	1. Floor play (30 minutes): To commence the program, a morning routine was adopted to mirror routines at school. The floor time sessions were led by a therapist or therapy assistant who set the pace of the morning routine and encouraged active involvement from each child. The session commenced 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 it was required) followed by turn-taking and choice-making (through picture card options) for a song selection. Each song choice incorporated key word signing and motor actions such as hands on head, sit to stand, clapping and dancing for commonly sung children's songs. Following a song choice from each child, the floor session concluded with a book reading. The lead therapist encouraged involvement from each child in the book reading time by pausing on pages to ask questions about what was happening or what was about to happen. Strategies to promote active involvement included 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 was used at each session to promote repetition, routine, and turn-taking. Individually specific gross motor goals were incorporated into this session such as independent sitting, crawling, kneeling, or standing. 2. Partial Body Weight Supported Treadmill Training (60 minutes) comprised of three, 8-minute sets separated by 2-minute rest periods. Training was provided on a treadmill with an overhead treadmill hoist and walking harness. The level of weight support being provided was adjusted to maximise bilateral lower limb weight bearing whilst also facilitating ease of foot clearance during the swing phase of gait. Each set comprised of facilitated stepping (2 minutes) followed by independent stepping (30 seconds). During the 2 minutes of facilitated stepping, initial body weight support was provided at 60% of the child's body weight at a speed that matched the child's 10MWT. Facilitation was provided by a therapist on either side of the child, adopting standardised hand positioning during the swing and stance phase. Speed was increased by 0.1.km/hr increments at a time. If the child was able to maintain foot clearance during the swing phase of gait, speed was increased by 0.1 km/hr at a time. If the walking speed is limited to 0.8km/hr (the lowest speed for most commercial treadmills), body weight support was increased by 10% at a time to enable foot clearance during the swing phase of gait. After the 2 minutes of facilitated stepping, the child had an opportunity to step without facilitation for 30 second intervals with the treadmill speed set to match their overground walking speed (measured on their 10mWT) with body weight support remaining the same as the proceeding 2-minute interval. During the 30 second independent stepping interval, verbal prompts and props will be used to encourage consistent stepping and timing of steps. The aim in this interval is to reduce body weight support by 10% at a time whilst maintaining the set speed. If the child was able to maintain stepping

	with only 10% body weight support, the speed was then be increased by 0.1km/hr. During the rest break between 8-minute sets, children will be encouraged to stand as actively as possible while engaged in a play activity. The overground walking followed immediately after the partial body weight supported treadmill training session with children being placed in a gait trainer or walking frame. The walking frame provided trunk and/or head support if required. Children were encouraged to actively step, explore and play (e.g., going around obstacles, play ball games or read and interact with a book). The progression of movement within the gait trainer was dependent on individual goals and as much as possible, a hands-off approach was 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 was for unassisted indoor walking and to negotiate obstacles. **3.** During the table top activities section (30 minutes), goal-directed upper limb skills were the focus by promoting purposeful and task-specific movements. This session was dependent on individual goals which included 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 were seated at a table and supported as required or as directed by the goals (e.g., chair with postural support, kindergarten style school chair with feet supported or sitting on a bench without back support).
Who Provided Expertise providing intervention	Individual intervention with a ratio of 2:1 – A combination of two therapists for each child working within an interdisciplinary model. The therapists include physiotherapists, occupational therapists, speech pathologists and allied health assistants.
How Modes of delivery	Group-based program
Where Location	In a community-based therapy centre – an open plan area where all children in the group had the opportunity to interact with each other.
When and how much Dosage of intervention	Training duration: 4 weeks; Frequency of training: three times per week; Length of session: 2 hours; Total number of hours: 24 hours.
Tailoring Personalisation of intervention	Toys, activities, treadmill training and overground training were individualised depending on each child's abilities. The progression of skills with increasing difficulty was implemented according to each child's ability.
Modifications	The intervention was not modified during the study.
How Well Fidelity	Each morning, a stand-up meeting with all treating therapists occurred to review participant goals and plan for the session. The lead Physiotherapist attended each of these sessions to monitor fidelity and ensure that the treatment was being implemented as planned. Progress notes were completed at the end of each session, noting adherence to treatment plan, reasons for non-attendance, and any adverse events.