BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (http://bmjopen.bmj.com).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Kindy Moves: The feasibility of an intensive interdisciplinary program on goal and motor outcomes for preschool aged children with non-progressive neurodisabilities.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-068816
Article Type:	Original research
Date Submitted by the Author:	30-Sep-2022
Complete List of Authors:	Haddon, Matthew; The Healthy Strides Foundation, West, Loren; The Healthy Strides Foundation Elliott, Catherine; Curtin University, School of Allied Health; Telethon Kids Institute Walmsley, Corrin; The Healthy Strides Foundation Valentine, Jane; Perth Children's Hospital, Paediatric Rehabilitation; Telethon Kids Institute Bear, Natasha; Child and Adolescent Health Service Healthy Strides Research Advisory Council, .; The Healthy Strides Foundation Pool, Dayna; Curtin University, School of Occupational Therapy Social Work and Speech Pathology; The Healthy Strides Foundation,
Keywords:	Developmental neurology & neurodisability < PAEDIATRICS, Neuromuscular disease < NEUROLOGY, Neurological injury < NEUROLOGY, Clinical trials < THERAPEUTICS

SCHOLARONE™
Manuscripts

Kindy Moves: The feasibility of an intensive interdisciplinary program on goal and motor outcomes for preschool aged children with non-progressive neurodisabilities.

Authors: Haddon M[1], West L[1], Elliott C PhD[2&3], Walmsley CP PhD[1], Valentine J FRACP PhD[3&4], Bear N[5], Healthy Strides Research Advisory Council[1], Pool D PhD[1&2]

1. The Healthy Strides Foundation, Perth, Western Australia, 6101
2. School of Allied Health, Curtin University, Perth, Western Australia, 6027
3. Telethon Kids Institute, Perth, Western Australia, Western Australia, 6009
4. Perth Children's Hospital, Child and Adolescent Health Service, Perth, Western Australia, 6009
5. Child and Adolescent Health Service, Perth, Western Australia, 6009

Corresponding author details:
Mr Matthew Haddon – matthew.haddon@health.wa.gov.au
Contact number – +8 0404315015
ORCID ID – 0000-0003-2795-902X
Postal address – Suite 23/954 Albany Hwy, East Victoria Park WA 6101.

Word length for main text excluding reference, abstract and tables: 5008
Word length for abstract: 300
Number of references: 81
Number of tables: 3
Number of figures: 2

Abstract

Objectives: To determine the feasibility of an intensive interdisciplinary program for goal and motor outcomes in preschool aged children with non-progressive neurodisabilities. The primary hypothesis was that limited efficacy would be demonstrated.

Design: A single group feasibility study.

Setting: An Australian paediatric community therapy provider.

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

Intervention: A goal-directed program of three two-hour sessions per week for four 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 pre-intervention (T1) to post-intervention (T2) and four-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 statistically significant improvements at T2 compared with T1 for all limited-efficacy measures. The GAS improved at T2 (MD 27.7, 95%CI 25.8-29.5, p<0.001) as well as COPM performance (MD 3.2, 95%CI 2.8-3.6, p<0.001) and satisfaction (MD 3.3, 95%CI 2.8-3.8, p<0.001). The GMFM-66 (MD 2.3, 95%CI 1.0-3.5, p=0.001) and 10MWT (median difference -2.3, 95%CI -28.8-0.0, p=0.007) 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 program is feasible in improving goal and motor outcomes for preschool children with neurodisabilities (GMFCS III-V). A randomised controlled trial is warranted to establish efficacy.

Trial registration: Australian New Zealand Clinical Trials Registry (ACTRN12619000064101).

Key terms: Developmental Disabilities; Early Goal-Directed Therapy; Child, Preschool.

Strengths and limitations of this study

- To our knowledge, this is the first trial evaluating the feasibility of an intensive, goal-directed, and interdisciplinary program 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 program makes it difficult to differentiate the effects of individual elements of the program.
- 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, intellectual impairment, autism, and epilepsy.[6] Cerebral palsy 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] Cerebral palsy 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 levels in CP, with approximately 40% of children with CP in Australia functioning within GMFCS levels III-V, indicating a dependence on physical assistance and equipment for mobility.[11] Although the GMFCS was developed specifically for children with CP, descriptors of functional mobility apply to the broader neurodisability population.[10] This group of children have a greater reduction in physical activity and participation levels than their more mobile peers,[12-15] contributing to a greater risk of adverse long-term health outcomes.[16] There is a scarcity of exercise-based interventions in those with lower functional mobility[17] despite this being a highly ranked research priority.[18]

Early intervention is of paramount importance to optimise a time of peak neuroplasticity while establishing a foundation for a physically active future.[2, 3, 19-21] Early intervention also yields higher rates of economic return when compared to intervening later in childhood.[22, 23] Children with CP classified within GMFCS III-V reach 90% of their gross motor function potential before the age of 5 years[24] and experience a functionally relevant decline into adolescence.[25] 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, 26] Neurodisability predisposes vulnerabilities in school preparedness with the rapid introduction of new cognitive, gross motor, social, and upper limb challenges in a foreign environment.[27] 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.[27] 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, 28]

Walking-related goals are common in children with neurodisability, with locomotor treadmill training (LTT) being increasingly used as a targeted approach to address these.[29-31] Locomotor treadmill training involves a combination of partial body weight supported treadmill training with overground walking to allow for safe, intense, and repetitious practice.[32] 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.[33] There is a substantial variation in dosages delivered for LTT, often ranging from four weeks[26] to three months,[20] with the optimal frequency and duration yet to be defined.[33] Although, intensive blocks and higher doses of therapy are recommended over lower doses and regular distributed therapy.[1] Improvements in motor function have been shown following 18 hours of LTT over six weeks in 5 to 12 year old children with CP (GMFCS III-V),[32] and following 14 hours of treadmill training in 1 to 5 year old pre-ambulatory children 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, 31, 35] and those under the age of 5 years.[26, 36] 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, 25]

Therefore, an LTT-focused intensive program 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, 33, 34] To date, no studies have explored LTT delivered within an interdisciplinary framework for preschool aged children with neurodisabilities. 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, 37] a group-based environment to encourage play while addressing socialisation goals is warranted. As such, this study aims to determine if LTT embedded within an interdisciplinary framework is feasible in improving goal attainment, caregiver-reported goal performance and satisfaction, gross motor function, and walking speed in preschool aged children with non-progressive neurodisabilities (GMFCS levels III-V or equivalent). The primary hypothesis was that limited-efficacy testing[38] would be demonstrated by outcome measures statistically and clinically improving after the four-week intervention. The secondary hypothesis was that the intervention would be feasible as determined by acceptability, demand, implementation, and practicality.

METHODS

This study aimed to determine the feasibility of the Kindy Moves intervention[39] for young children with non-progressive neurodisability. 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 immediately after intervention (T2) and at follow-up four weeks post-intervention (T3) with baseline (T1). Acceptability was measured according to attendance rates and adverse events. Demand was determined through the ease and extent of recruitment during a two-year timeframe. Implementation was assessed by comparing the delivered intervention to the planned protocol and practicality was determined by attendance rates and an intervention dosage evaluation. Exploration of patient and caregiver perspectives will be reported in a future qualitative paper. This single group feasibility study was reported according to the CONSORT 2010 statement: extension to randomised pilot and feasibility trials.[40, 41] Approval for this study was obtained by the Human Research Ethics Committee of Curtin University (Approval number: HRE2019-0073) and written informed consent was received by the participants' primary caregivers.

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 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)[42] and Manual Ability Classification System (MACS)[43] levels I-V (or equivalent). Children were not included in the study if they had orthopaedic surgery within six months of the study, unstable hip subluxation, uncontrolled seizure disorder, or engagement in LTT in the month prior to the study. A semi-structured interview was used for caregivers to answer open-ended questions to state diagnoses, medical conditions, and co-occurring impairments. A sample size of 34 participants predicted a large effect size (d=1.0) based on the Goal Attainment Scaling (GAS) t-score (80% power; two-sided test at $p<0.05$). Additional children were recruited to account for attrition.

Intervention

A standardised protocol of the Kindy Moves intervention was followed.[39] Kindy Moves is an intensive program that incorporates treatment approaches consistent with the best available evidence for non-progressive paediatric neurodisabilities.[1-4] The intervention incorporates goal-directed and task-specific practice in an enriched environment where the child initiates movement at a high intensity. Children attended three two-hour sessions per week for four weeks (24 hours of therapy). Locomotor treadmill training was a large focus of the program, but this was incorporated into an interdisciplinary framework with dedicated time to address communication, socialisation, and upper limb function goals. 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 two-hour intervention was separated into 30 minutes of floor time as a group to practice gross motor, socialisation, and play skills. This was followed by one hour of LTT, separated into 30 minutes of partial body weight supported treadmill training (Figure 1) and 30 minutes of overground walking in a mobility device. Lastly, participants engaged in 30 minutes of tabletop activities to address upper limb function goals. 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.

Figure 1. Treadmill Training.

Setting

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.

Canadian Occupational Performance Measure

The Canadian Occupational Performance Measure (COPM)[44] 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 two or more points on the scale were considered clinically meaningful.[44] The COPM is valid, reliable, and has been used extensively in CP and broader populations.[45]

Goal Attainment Scaling

The GAS[46] 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).[47] The fPRC conceptualises a health condition and the interplay of various constructs based on the World Health Organization's International Classification of Functioning, Disability, and Health.[48] The GAS is valid and reliable,[49] and has detected change across a variety of paediatric populations.[50] The GAS produces a t-score for analysis, with a t-score of 50 or more indicating clinical meaningfulness.[51]

Gross Motor Function Measure

The Gross Motor Function Measure (GMFM-66) is a valid and reliable[52] 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.[53] The Gross Motor Function Evolution Ratio (GMFER) was used, with a ratio of greater than one indicating improvement greater than what was expected from natural maturation.[54] 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.[26, 30, 55] Participants walked as fast as possible in a mobility device across a 10-metre distance. Facilitation of one step was provided for children who did not initiate stepping after 30 seconds.[32] If a child did not complete the 10-metre distance in six minutes, this time was recorded as the maximal result.[32]

Statistical Analysis

Intention to treat analysis was applied. Data were presented as means and standard deviations for continuous data, or medians and interquartile ranges when the data were skewed. 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% confidence intervals. The Smithers-Sheedy et al[8] list of disorders was used to define which participant's aetiologies were consistent with CP and which were not. The percentage of GAS and individual mean COPM performance and satisfaction scores that reached clinical meaningfulness at T2 and T3 were reported. It was also determined if the group mean differences for these measures were clinically meaningful. 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 sub-domains were also used to categorise these goals.[44, 56]

RESULTS

A total of 42 participants were assessed for eligibility with two being excluded due to having a progressive neurodisability (Figure 2). There was one participant drop-out due to hospitalisation for respiratory illness, with 39 participants completing the intervention as per the protocol (Figure 2). The participant demographics are outlined in Table 1. Caregiver-reported co-occurring epilepsy was present in 72.5% of participants, visual impairment in 22.5%, and hearing impairment in 10.0%. On average, participants attended 21.9 out of 24 hours of intervention and the main reason for non-attendance was illness. 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 2). Most GAS were categorised as activity-based (93.3%). There were no adverse events to report.

Figure 2. CONSORT Flow Diagram.

Table 1. Demographic Data.

Male: Female, n	20:20
Age, mean (SD)	3 years 4 months (11 months)
Age range	2 years 0 months-5 years 6 months
Cerebral palsy description, n (%)	34 (85.0)
Other neurodisability, n (%)	6 (15.0)
GMFCS, n	
II	2*
III	14
IV	14
V	10
MACS, n	
II	2
III	5

IV	14
V	19
CFCS, n	
I	1
III	4
IV	11
V	24

Abbreviations: GMFCS, Gross Motor Function Classification System[10]; MACS, Manual Ability Classification System[43]; CFCS, Communication Function Classification System.[42]
*These two participants (aged 4 years 8 months and 3 years 8 months) were able to walk short distances indoors independently but often required constant physical assistance or securing in a stroller for safety. Consequently, distinguishing between GMFCS levels II and III was unclear for these participants.

Table 2. Baseline Characteristics.

Total COPM goals set	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)

Abbreviations: COPM, Canadian Occupational Performance Measure[44]; GAS, Goal Attainment Scaling.[46]

There were statistically significant improvements for all outcome measures from baseline to post-intervention and follow-up other than the 10MWT at T3 (Table 3). All outcome measures remained stable from T2 to T3 except for the GAS t-score which showed a statistically significant improvement. Changes in group COPM performance and satisfaction were clinically meaningful at T2 and T3 compared to baseline. The group GAS t-score change was clinically meaningful at follow-up, and it could not be determined whether the group mean GMFM-66 scores were clinically meaningful. Immediately after intervention, 58.0% of GAS had achieved clinical meaningfulness which increased to 69.2% at T3. At T2, 87.2% of participant mean COPM performance scores and 84.6% of mean COPM satisfaction scores were clinically meaningful. This remained stable at 86.8% for performance and 89.5% for satisfaction at T3. When using the GMFER, 76.5% showed GMFM-66 improvements greater than expected natural evolution at T2 which reduced to 70.3% at T3.

Table 3. Outcome Measure Changes Across All Time Points.

Outcome	n	Mean (SD)	Mean Differences (95% CI) p-value		
			T2 vs T1	T3 vs T1	T3 vs T2
GAS t-score					
T1	39	20.2 (1.4)	27.7	30.9*	3.3

Outcome	n	Mean (SD)	Mean Differences (95% CI) p-value		
			T2 vs T1	T3 vs T1	T3 vs T2
T2	39	47.9 (5.5)	(25.8 to 29.5)	(29.1 to 32.8)	(1.4 to 5.1)
T3	38	51.1 (7.0)	*p*<0.001	*p*<0.001	*p*=0.001
COPM Performance					
T1	39	2.5 (1.0)	3.2*	3.3*	0.1
T2	39	5.7 (1.7)	(2.8 to 3.6)	(2.9 to 3.7)	(-0.3 to 0.6)
T3	38	5.8 (1.6)	*p*<0.001	*p*<0.001	*p*=0.531
COPM Satisfaction					
T1	39	3.1 (1.5)	3.3*	3.3*	0.0
T2	39	6.4 (1.8)	(2.8 to 3.8)	(2.8 to 3.8)	(-0.5 to 0.5)
T3	38	6.4 (1.8)	*p*<0.001	*p*<0.001	*p*=0.901
GMFM-66					
T1	38	33.7 (16.3)	2.3**	2.1**	-0.2
T2	34	35.6 (15.3)	(1.0 to 3.5)	(0.8 to 3.3)	(-1.5 to 1.1)
T3	37	36.4 (15.9)	*p*=0.001	*p*=0.001	*p*=0.797
		Median (IQR)	Median Difference (95% CI) p-value		
10MWT Time (secs)					
T1	39	294.3 (33.2, 360.0)	-2.3	-8.3	0.0
T2	37	66.0 (32.7, 360.0)	(-28.8 to 0)	(-20.9 to 0)	(-3.2 to 2.2)
T3	37	81.6 (28.3, 336.0)	*p*=0.007	*p*=0.080	*p*=0.702

Abbreviations: GAS, Goal Attainment Scaling[46]; COPM, Canadian Occupational Performance Measure[44]; GMFM-66, 66-item Gross Motor Function Measure[52]; 10MWT, 10-Metre Walk Test.[55]
*Clinically meaningful group mean change.
**Between the clinically meaningful cut-offs for GMFCS III and GMFCS IV-V.

DISCUSSION

This study aimed to determine if implementing Kindy Moves, a four-week intensive LTT program delivered within an interdisciplinary framework, was feasible for preschool aged children with non-progressive neurodisabilities. Following this intervention, there were statistically significant improvements in the GAS, COPM performance and satisfaction, GMFM-66, and 10MWT. These improvements were largely maintained four weeks after program completion other than GAS t-scores further improving and the 10MWT change no longer being statistically significant. Clinically meaningful improvements were seen post-intervention and follow-up for goal performance and satisfaction, and follow-up for goal attainment. This demonstrated limited efficacy of the feasibility study. Attendance rates were high with no adverse events to report (indicating acceptability and practicality), recruitment was successful and exceeded the power calculation sample size (reflecting demand), and the intervention accurately followed protocol (supporting implementation). These results indicate the feasibility of Kindy Moves as an intensive goal-directed program in 2 to 5 year old children 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.[57-60] Two of these studies investigated goal-directed therapy in children with CP who were 4 to 5 years old and classified across most GMFCS levels.[57, 59] 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.[57, 59] 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.[60-63] Although, research in this area often includes school aged children[60, 61, 63] or infants,[62] with trials involving children aged 2 to 5 years being less frequently completed.[64] Data exploring the retention of outcomes in a period after program completion is important in establishing the extent of real-life skill application. Goal performance and satisfaction remained high and clinically meaningful four 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 programs throughout a child's lifespan.

Although the GAS t-score improvement following intervention was statistically significant, this did not reach clinical meaningfulness. Goal attainment then showed a statistically significant improvement from T2 to T3, indicating clinically meaningful improvements during the follow-up phase. This is an encouraging result that has several possible explanations. Firstly, a hands-off approach in practicing real-life tasks facilitates more active child involvement that can continue in the home.[2-4] A fun, motivating, and enriched environment further encourages a child to spontaneously practice these tasks.[2-4] Caregivers also possibly had a role in home practice after observing their child's new capacity and learning familiar and inexpensive activities or songs that could be used to support further goal attainment. For other participants, perhaps the boost in goal attainment was sufficient to allow for regular use and subsequent practice of new skills in their daily life. For example, we observed participants developing steering using their walking frame during Kindy Moves, allowing them to spend time generalising this skill and repeatedly practice navigating around their home after program completion.

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.[18] 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, with the sample size exceeding what was required according to the power calculation. 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.[65] 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. 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 co-morbidities.

Over a 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 learned.[47]

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.[47] 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 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,[27] 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 program. 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 co-morbidities and functional ability levels. 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.[47] 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.[66] Assessment tools such as the Child Engagement in Daily Life[67] or the Young Children's Participation and Environment Measure[68] can be used to evaluate these participation interventions. Participation-focused interventions have emerged in recent years and initial results show great promise.[60, 69]

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[70-72] and younger[26, 36, 73] children with neurodisabilities. For CP populations, there is 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.[33] 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 to 2.3 years who completed 40 to 50 hours of therapy over four months.[74] Despite being a promising pilot study,[74] it is probable that natural maturation affected the results in the four-month intervention, particularly at an age of rapid motor development. To account for this in Kindy Moves, a shorter intervention timeframe was implemented alongside the GMFER to evaluate change.[54] At post-intervention assessment, 76.5% of participants improved their gross motor function more than what was expected due to natural maturation as estimated by reference curves.[54] This provides greater certainty that the changes observed were due to the intervention itself and not maturation. Although it was not certain without sub-group analysis if group mean GMFM-66 scores were clinically meaningful, the changes at T2 and T3 approached the higher GMFCS IV-V clinically meaningful cut-off score of 2.88. This, alongside positive GMFER findings, shows great promise that a larger trial of Kindy Moves with sub-group analysis may demonstrate clinically 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.[75, 76] With participants in this study having more severe functional limitations, a ceiling effect was noted in the 10MWT which skewed the data. This was particularly evident in children functioning within GMFCS levels IV-V (or equivalent). Although community ambulation may not be an achievable goal for all participants in Kindy Moves, newly learned 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.[77] A statistically significant improvement in walking speed post-intervention 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 programs for sedentary populations are diverse and yet to be fully understood. Expanding beyond goals and motor capacity, benefits may relate to chronic disease,[77] bone mineral density,[78] sleep,[77] contractures,[2, 4] and hip displacement.[2] Parents of children with CP (GMFCS III-V) have reported similar desired health outcomes beyond motor function from a locomotor training intervention,[79] further warranting activity-based interventions irrespective of motor ability. Important research in this field of health and wellbeing 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,[80] 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 four weeks (12 hours total),[26] whereas others have explored up to three months of 1-hour sessions four times per week (48 hours total).[20] 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.[61] A similar protocol of HABIT-ILE in children with unilateral CP aged 1 to 4 years resulted in goal and gross motor improvements after 50 hours of therapy over two weeks.[64] The outcomes of Kindy Moves highlight improvements in goals and motor function after 24 hours of therapy across four 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 outcomes needs to be determined.[80] 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 to 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.[81] 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. Due to the lack of sub-group analysis in this feasibility study, it was not possible to confirm whether group GMFM-66 improvements were clinically meaningful. The GMFER 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 program 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. Additionally, 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 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.

CONCLUSION

Kindy Moves has highlighted that an intensive LTT-focused program delivered within an interdisciplinary framework is potentially efficacious in improving goal attainment, caregiver-reported goal performance and satisfaction, gross motor function, and walking speed in preschool aged children with non-progressive neurodisabilities. The intervention was feasible according to limited-efficacy testing, acceptability, demand, practicality, and implementation. 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 use of additional programs to specifically target participation should be considered to achieve a child's goals that are based at the participation level. 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 program highlights promising preliminary evidence for improving goal-driven outcomes and motor capacity in this population, warranting a well-powered randomised controlled trial to establish its efficacy.

Acknowledgements: The authors acknowledge the Healthy Strides Research Advisory Council for consulting and providing guidance on the development of the intervention.

Collaborators: The Healthy Strides Research Advisory Council comprises of the Healthy Strides clinical team: Dr Dayna Pool, Loren West, Dr Corrin Walmsley, Georgia Hoffman, Marissa Smith, Eddie Pool, Meagan Smith, Georgina Jones, Matthew Haddon, Jordan Dinh and Bridget Chapman. Research Advisors: Dr Ashleigh Thornton, Dr Sue McCabe and Dr Claire Willis. Consumer Advisors: Ben O'Rourke, Noraishah Naim.

Author Contributions: 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 co-developed 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 conceptualised, planned, developed, and wrote the study protocol.

Funding Statement: This work has been supported by the Telethon7 Trust 2019 and 2020.

Competing Interests Statements: None declared.

Patient Consent: Consent was provided for the inclusion of Figure 1 in the paper through the BMJ Patient Consent Form.

Data Sharing: Data can be made available for research purposes upon request.

Reporting Checklist Flow Diagram: The CONSORT 2010 statement: extension to randomised pilot and feasibility studies.[40]

REFERENCES

1. Jackman M, Sakzewski L, Morgan C, et al. Interventions to improve physical function for children and young people with cerebral palsy: International clinical practice guideline. *Dev Med Child Neurol*2021; 64(5):536-549. doi:10.1111/dmcn.15055.
2. Morgan C, Fetters L, Adde L, et al. Early intervention for children aged 0 to 2 years with or at high risk of cerebral palsy: International clinical practice guideline based on systematic reviews. *JAMA Pediatr*2021; 175(8):846-858. doi:10.1001/jamapediatrics.2021.0878.
3. Damiano DL, Longo E. Early intervention evidence for infants with or at risk for cerebral palsy: An overview of systematic reviews. *Dev Med Child Neurol*2021; 63(7):771-784. doi:10.1111/dmcn.14855.
4. Novak I, Morgan C, Fahey M, et al. State of the evidence traffic lights 2019: Systematic review of interventions for preventing and treating children with cerebral palsy. *Curr Neurol Neurosci Rep*2020; 20(2):3. doi:10.1007/s11910-020-1022-z.
5. Novak I, Honan I. Effectiveness of paediatric occupational therapy for children with disabilities: A systematic review. *Aust Occup Ther J*2019; 66(3):258-273. doi:10.1111/1440-1630.12573.
6. Morris C, Janssens A, Tomlinson R, Williams J, Logan S. Towards a definition of neurodisability: A delphi survey. *Dev Med Child Neurol*2013; 55(12):1103-1108. doi:10.1111/dmcn.12218.
7. Cans C. Surveillance of cerebral palsy in Europe: A collaboration of cerebral palsy surveys and registers. *Dev Med Child Neurol*2000; 42(12):816-824. doi:10.1017/s0012162200001511.
8. Smithers-Sheedy H, Badawi N, Blair E, et al. What constitutes cerebral palsy in the twenty-first century? *Dev Med Child Neurol*2014; 56(4):323-328. doi:10.1111/dmcn.12262.
9. Novak I, Hines M, Goldsmith S, Barclay R. Clinical prognostic messages from a systematic review on cerebral palsy. *Pediatrics*2012; 130(5):e1285-1312. doi:10.1542/peds.2012-0924.
10.Palisano R, Rosenbaum P, Walter S, et al. Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Dev Med Child Neurol*1997; 39(4):214-223. doi:10.1111/j.1469-8749.1997.tb07414.x.
11. Australian Cerebral Palsy Register Group. Australia and the Australian cerebral palsy register for the birth cohort 1993 to 2006. *Dev Med Child Neurol*2016; 58 Suppl 2:3-4. doi:10.1111/dmcn.13002.
12. Aviram R, Harries N, Shkedy Rabani A, et al. Comparison of habitual physical activity and sedentary behavior in adolescents and young adults with and without cerebral palsy. *Pediatr Exerc Sci*2019; 31(1):60-66. doi:10.1123/pes.2017-0285.
13. Shkedy Rabani A, Harries N, Namoora I, et al. Duration and patterns of habitual physical activity in adolescents and young adults with cerebral palsy. *Dev Med Child Neurol*2014; 56(7):673-680. doi:10.1111/dmcn.12394.
14. Fauconnier J, Dickinson HO, Beckung E, et al. Participation in life situations of 8-12 year old children with cerebral palsy: Cross sectional European study. *BMJ*2009; 338:b1458. doi:10.1136/bmj.b1458.
15. Imms C. Children with cerebral palsy participate: A review of the literature. *Disabil Rehabil*2008; 30(24):1867-1884. doi:10.1080/09638280701673542.
16. Peterson MD, Gordon PM, Hurvitz EA. Chronic disease risk among adults with cerebral palsy: The role of premature sarcopoenia, obesity and sedentary behaviour. *Obes Rev*2013; 14(2):171-182. doi:10.1111/j.1467-789X.2012.01052.x.
17. Ryan JM, Cassidy EE, Noorduyn SG, O'Connell NE. Exercise interventions for cerebral palsy. *Cochrane Database Syst Rev*2017; 6:CD011660. doi:10.1002/14651858.CD011660.pub2.
18. Gross PH, Bailes AF, Horn SD, et al. Setting a patient-centered research agenda for cerebral palsy: A participatory action research initiative. *Dev Med Child Neurol*2018; 60(12):1278-1284. doi:10.1111/dmcn.13984.
19. Byrne R, Noritz G, Maitre NL, NCH Early Developmental Group. Implementation of early diagnosis and intervention guidelines for cerebral palsy in a high-risk infant follow-up clinic. *Pediatr Neurol*2017; 76:66-71. doi:10.1016/j.pediatrneurol.2017.08.002.
20. Yang JF, Livingstone D, Brunton K, et al. Training to enhance walking in children with cerebral palsy: Are we missing the window of opportunity? *Semin Pediatr Neurol*2013; 20(2):106-115. doi:10.1016/j.spen.2013.06.011.
21. Johnston MV, Ishida A, Ishida WN, et al. Plasticity and injury in the developing brain. *Brain Dev*2009; 31(1):1-10. doi:10.1016/j.braindev.2008.03.014.

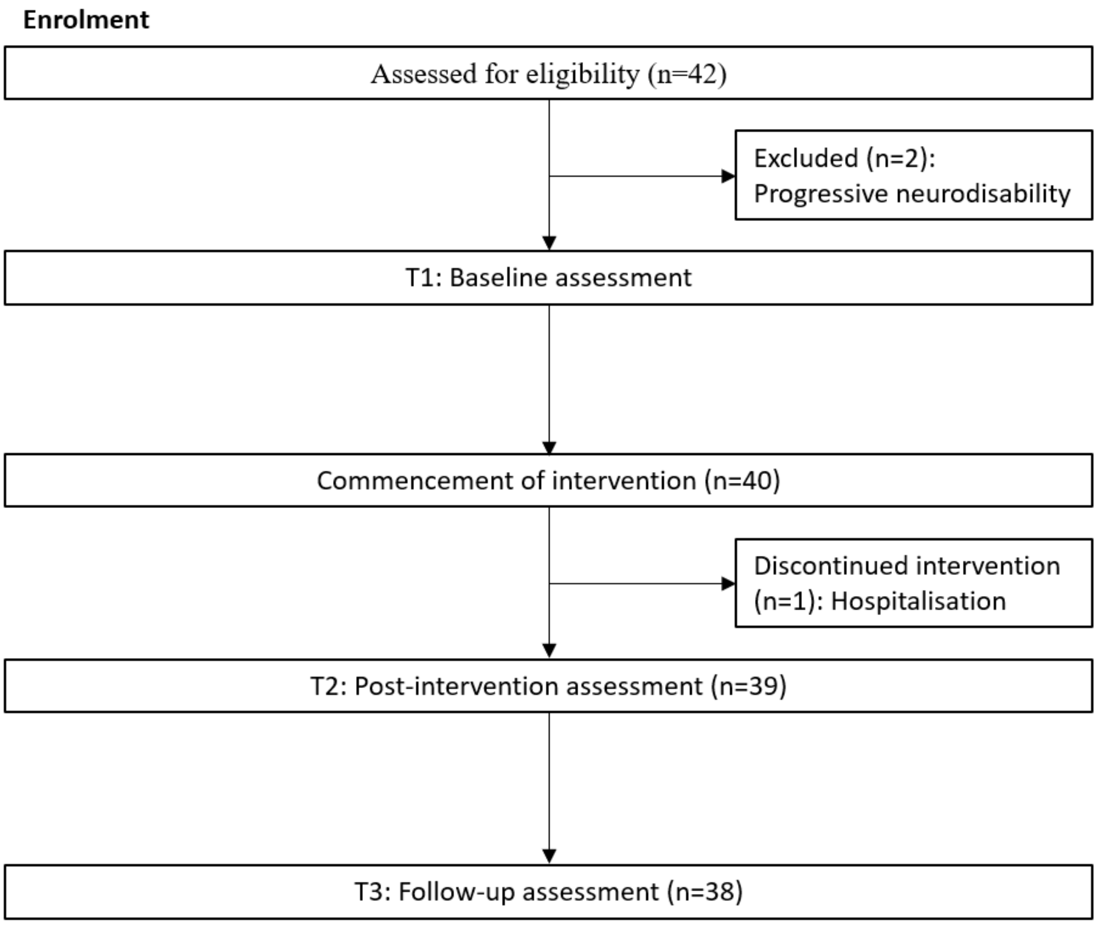
22. Daelmans B, Darmstadt GL, Lombardi J, et al. Early childhood development: The foundation of sustainable development. *Lancet*2017; 389(10064):9-11. doi:10.1016/S0140-6736(16)31659-2.
23. Richter LM, Daelmans B, Lombardi J, et al. Investing in the foundation of sustainable development: Pathways to scale up for early childhood development. *Lancet*2017; 389(10064):103-118. doi:10.1016/S0140-6736(16)31698-1.
24. Rosenbaum PL, Walter SD, Hanna SE, et al. Prognosis for gross motor function in cerebral palsy: Creation of motor development curves. *JAMA*2002; 288(11):1357-1363. doi:10.1001/jama.288.11.1357.
25. Hanna SE, Bartlett DJ, Rivard LM, Russell DJ. Reference curves for the gross motor function measure: Percentiles for clinical description and tracking over time among children with cerebral palsy. *Phys Ther*2008; 88(5):596-607. doi:10.2522/ptj.20070314.
26. Mattern-Baxter K, Bellamy S, Mansoor JK. Effects of intensive locomotor treadmill training on young children with cerebral palsy. *Pediatr Phys Ther*2009; 21(4):308-318. doi:10.1097/PEP.0b013e3181bf53d9.
27. Gehrmann FE, Coleman A, Weir KA, Ware RS, Boyd RN. School readiness of children with cerebral palsy. *Dev Med Child Neurol*2014; 56(8):786-793. doi:10.1111/dmcn.12377.
28. Choi BC, Pak AW. Multidisciplinarity, interdisciplinarity and transdisciplinarity in health research, services, education and policy: 1. Definitions, objectives, and evidence of effectiveness. *Clin Invest Med*2006; 29(6):351-364. Available from: https://www.ncbi.nlm.nih.gov/pubmed/17330451.
29. Mattern-Baxter K. Locomotor treadmill training for children with cerebral palsy. *Orthop Nurs*2010; 29(3):169-173; quiz 174-165. doi:10.1097/NOR.0b013e3181db5441.
30. Willoughby KL, Dodd KJ, Shields N. A systematic review of the effectiveness of treadmill training for children with cerebral palsy. *Disabil Rehabil*2009; 31(24):1971-1979. doi:10.3109/09638280902874204.
31. Dodd KJ, Foley S. Partial body-weight-supported treadmill training can improve walking in children with cerebral palsy: A clinical controlled trial. *Dev Med Child Neurol*2007; 49(2):101-105. doi:10.1111/j.1469-8749.2007.00101.x.
32. Pool D, Valentine J, Taylor NF, Bear N, Elliott C. Locomotor and robotic assistive gait training for children with cerebral palsy. *Dev Med Child Neurol*2021; 63(3):328-335. doi:10.1111/dmcn.14746.
33. Valentin-Gudiol M, Mattern-Baxter K, Girabent-Farres M, et al. Treadmill interventions in children under six years of age at risk of neuromotor delay. *Cochrane Database Syst Rev*2017; 7:CD009242. doi:10.1002/14651858.CD009242.pub3.
34. Mattern-Baxter K. Analysis of a group-based treadmill program for children with neuromotor delay who are pre-ambulatory. *Phys Occup Ther Pediatr*2021; 41(3):271-283. doi:10.1080/01942638.2020.1834055.
35. Bryant E, Pountney T, Williams H, Edelman N. Can a six-week exercise intervention improve gross motor function for non-ambulant children with cerebral palsy? A pilot randomized controlled trial. *Clin Rehabil*2013; 27(2):150-159. doi:10.1177/0269215512453061.
36. Mattern-Baxter K, McNeil S, Mansoor JK. Effects of home-based locomotor treadmill training on gross motor function in young children with cerebral palsy: A quasi-randomized controlled trial. *Arch Phys Med Rehabil*2013; 94(11):2061-2067. doi:10.1016/j.apmr.2013.05.012.
37. Kleim JA, Jones TA. Principles of experience-dependent neural plasticity: Implications for rehabilitation after brain damage. *J Speech Lang Hear Res*2008; 51(1):S225-239. doi:10.1044/1092-4388(2008/018).
38. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med*2009; 36(5):452-457. doi:10.1016/j.amepre.2009.02.002.
39. Pool D, Elliott C, Healthy Strides Research Advisory Council. 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. *BMJ Open*2021; 11(8):e046831. doi:10.1136/bmjopen-2020-046831.
40. Eldridge SM, Chan CL, Campbell MJ, et al. Consort 2010 statement: Extension to randomised pilot and feasibility trials. *BMJ*2016; 355:i5239. doi:10.1136/bmj.i5239.
41. Lancaster GA, Thabane L. Guidelines for reporting non-randomised pilot and feasibility studies. *Pilot Feasibility Stud*2019; 5:114. doi:10.1186/s40814-019-0499-1.

42. Hidecker MJ, Cunningham BJ, Thomas-Stonell N, Oddson B, Rosenbaum P. Validity of the communication function classification system for use with preschool children with communication disorders. *Dev Med Child Neurol*2017; 59(5):526-530. doi:10.1111/dmcn.13373.
43. Eliasson AC, Krumlinde-Sundholm L, Rosblad B, et al. The manual ability classification system (MACS) for children with cerebral palsy: Scale development and evidence of validity and reliability. *Dev Med Child Neurol*2006; 48(7):549-554. doi:10.1017/S0012162206001162.
44. Law M, Baptiste S, McColl M, et al. The canadian occupational performance measure: An outcome measure for occupational therapy. *Can J Occup Ther*1990; 57(2):82-87. doi:10.1177/000841749005700207.
45. Cusick A, Lannin NA, Lowe K. Adapting the canadian occupational performance measure for use in a paediatric clinical trial. *Disabil Rehabil*2007; 29(10):761-766. doi:10.1080/09638280600929201.
46. Kiresuk TJ, Sherman RE. Goal attainment scaling: A general method for evaluating comprehensive community mental health programs. *Community Ment Health J*1968; 4(6):443-453. doi:10.1007/BF01530764.
47. Imms C, Granlund M, Wilson PH, et al. Participation, both a means and an end: A conceptual analysis of processes and outcomes in childhood disability. *Dev Med Child Neurol*2017; 59(1):16-25. doi:10.1111/dmcn.13237.
48. World Health Organization. International classification of functioning, disability and health: ICF. Geneva, Switzerland; 2001.
49. Livingstone R, Paleg G. Measuring outcomes for children with cerebral palsy who use gait trainers. *Technologies*2016; 4:1-19. doi:10.3390/technologies4030022.
50. Cusick A, McIntyre S, Novak I, Lannin N, Lowe K. A comparison of goal attainment scaling and the canadian occupational performance measure for paediatric rehabilitation research. *Pediatr Rehabil*2006; 9(2):149-157. doi:10.1080/13638490500235581.
51. Harpster K, Sheehan A, Foster EA, et al. The methodological application of goal attainment scaling in pediatric rehabilitation research: A systematic review. *Disabil Rehabil*2019; 41(24):2855-2864. doi:10.1080/09638288.2018.1474952.
52. Russell DJ, Avery LM, Rosenbaum PL, et al. Improved scaling of the gross motor function measure for children with cerebral palsy: Evidence of reliability and validity. *Phys Ther*2000; 80(9):873-885. Available from: https://www.ncbi.nlm.nih.gov/pubmed/10960935.
53. Ko J. Sensitivity to functional improvements of GMFM-88, GMFM-66, and PEDI mobility scores in young children with cerebral palsy. *Percept Mot Skills*2014; 119(1):305-319. doi:10.2466/03.25.PMS.119c14z1.
54. Marois P, Marois M, Pouliot-Laforte A, et al. Gross motor function measure evolution ratio: Use as a control for natural progression in cerebral palsy. *Arch Phys Med Rehabil*2016; 97(5):807-814 e802. doi:10.1016/j.apmr.2015.07.024.
55. Graser JV, Letsch C, van Hedel HJA. Reliability of timed walking tests and temporo-spatial gait parameters in youths with neurological gait disorders. *BMC Neurol*2016; 16:15. doi:10.1186/s12883-016-0538-y.
56. Ostensjo S, Oien I, Fallang B. Goal-oriented rehabilitation of preschoolers with cerebral palsy--a multi-case study of combined use of the canadian occupational performance measure (COPM) and the goal attainment scaling (GAS). *Dev Neurorehabil*2008; 11(4):252-259. doi:10.1080/17518420802525500.
57. Lowing K, Bexelius A, Brogren Carlberg E. Activity focused and goal directed therapy for children with cerebral palsy--do goals make a difference? *Disabil Rehabil*2009; 31(22):1808-1816. doi:10.1080/09638280902822278.
58. Lowing K, Thews K, Haglund-Akerlind Y, Gutierrez-Farewik EM. Effects of botulinum toxin-a and goal-directed physiotherapy in children with cerebral palsy GMFCS levels I & II. *Phys Occup Ther Pediatr*2017; 37(3):268-282. doi:10.3109/01942638.2016.1150384.
59. Sorsdahl AB, Moe-Nilssen R, Kaale HK, Rieber J, Strand LI. Change in basic motor abilities, quality of movement and everyday activities following intensive, goal-directed, activity-focused physiotherapy in a group setting for children with cerebral palsy. *BMC Pediatr*2010; 10:26. doi:10.1186/1471-2431-10-26.

60. Willis C, Nyquist A, Jahnsen R, Elliott C, Ullenhag A. Enabling physical activity participation for children and youth with disabilities following a goal-directed, family-centred intervention. *Res Dev Disabil*2018; 77:30-39. doi:10.1016/j.ridd.2018.03.010.
61. Bleyenheuft Y, Ebner-Karestinos D, Surana B, et al. Intensive upper- and lower-extremity training for children with bilateral cerebral palsy: A quasi-randomized trial. *Dev Med Child Neurol*2017; 59(6):625-633. doi:10.1111/dmcn.13379.
62. Morgan C, Novak I, Dale RC, Guzzetta A, Badawi N. Single blind randomised controlled trial of GAME (goals - activity - motor enrichment) in infants at high risk of cerebral palsy. *Res Dev Disabil*2016; 55:256-267. doi:10.1016/j.ridd.2016.04.005.
63. Armstrong EL, Boyd RN, Horan SA, et al. Functional electrical stimulation cycling, goal-directed training, and adapted cycling for children with cerebral palsy: A randomized controlled trial. *Dev Med Child Neurol*2020; 62(12):1406-1413. doi:10.1111/dmcn.14648.
64. Araneda R, Klocker A, Ebner-Karestinos D, et al. Feasibility and effectiveness of HABIT-ILE in children aged 1 to 4 years with cerebral palsy: A pilot study. *Ann Phys Rehabil Med*2021; 64(3):101381. doi:10.1016/j.rehab.2020.03.006.
65. Novak I, Smithers-Sheedy H, Morgan C. Predicting equipment needs of children with cerebral palsy using the gross motor function classification system: A cross-sectional study. *Disabil Rehabil Assist Technol*2012; 7(1):30-36. doi:10.3109/17483107.2011.556210.
66. Shields N, Synnot A. Perceived barriers and facilitators to participation in physical activity for children with disability: A qualitative study. *BMC Pediatr*2016; 16:9. doi:10.1186/s12887-016-0544-7.
67. Chiarello LA, Palisano RJ, McCoy SW, et al. Child engagement in daily life: A measure of participation for young children with cerebral palsy. *Disabil Rehabil*2014; 36(21):1804-1816. doi:10.3109/09638288.2014.882417.
68. Khetani MA. Validation of environmental content in the young children's participation and environment measure. *Arch Phys Med Rehabil*2015; 96(2):317-322. doi:10.1016/j.apmr.2014.11.016.
69. Reedman SE, Boyd RN, Trost SG, Elliott C, Sakzewski L. Efficacy of participation-focused therapy on performance of physical activity participation goals and habitual physical activity in children with cerebral palsy: A randomized controlled trial. *Arch Phys Med Rehabil*2019; 100(4):676-686. doi:10.1016/j.apmr.2018.11.012.
70. Chrysagis N, Skordilis EK, Stavrou N, Grammatopoulou E, Koutsouki D. The effect of treadmill training on gross motor function and walking speed in ambulatory adolescents with cerebral palsy: A randomized controlled trial. *Am J Phys Med Rehabil*2012; 91(9):747-760. doi:10.1097/PHM.0b013e3182643eba.
71. Schindl MR, Forstner C, Kern H, Hesse S. Treadmill training with partial body weight support in nonambulatory patients with cerebral palsy. *Arch Phys Med Rehabil*2000; 81(3):301-306. doi:10.1016/s0003-9993(00)90075-3.
72. Swe NN, Sendhilnnathan S, van Den Berg M, Barr C. Over ground walking and body weight supported walking improve mobility equally in cerebral palsy: A randomised controlled trial. *Clin Rehabil*2015; 29(11):1108-1116. doi:10.1177/0269215514566249.
73. Cherng RJ, Liu CF, Lau TW, Hong RB. Effect of treadmill training with body weight support on gait and gross motor function in children with spastic cerebral palsy. *Am J Phys Med Rehabil*2007; 86(7):548-555. doi:10.1097/PHM.0b013e31806dc302.
74. Richards C, Malouin F, Dumas F, et al. Early and intensive treadmill locomotor training for young children with cerebral palsy: A feasibility study. *Pediatr Phys Ther*1997; 9(4):158-165.
75. MacCarthy M, Heyn P, Tagawa A, Carollo J. Walking speed and patient-reported outcomes in young adults with cerebral palsy. *Dev Med Child Neurol*2022; doi:10.1111/dmcn.15225.
76. Pirpiris M, Gates PE, McCarthy JJ, et al. Function and well-being in ambulatory children with cerebral palsy. *J Pediatr Orthop*2006; 26(1):119-124. doi:10.1097/01.bpo.0000191553.26574.27.
77. Verschuren O, Hulst RY, Voorman J, et al. 24-hour activity for children with cerebral palsy: A clinical practice guide. *Dev Med Child Neurol*2021; 63(1):54-59. doi:10.1111/dmcn.14654.
78. Gannotti ME, Liquori BM, Thorpe DE, Fuchs RK. Designing exercise to improve bone health among individuals with cerebral palsy. *Pediatr Phys Ther*2021; 33(1):50-56. doi:10.1097/PEP.0000000000000765.

79. Pool D, Elliott C, Willis C, Thornton A. The experience of locomotor training from the perspectives of therapists and parents of children with cerebral palsy. *Frontiers in Rehabilitation Sciences*2021; 2. doi:10.3389/fresc.2021.740426.
80. Jackman M, Lannin N, Galea C, et al. What is the threshold dose of upper limb training for children with cerebral palsy to improve function? A systematic review. *Aust Occup Ther J*2020; 67(3):269-280. doi:10.1111/1440-1630.12666.
81. Romeiser-Logan L, Slaughter R, Hickman R. Single-subject research designs in pediatric rehabilitation: A valuable step towards knowledge translation. *Dev Med Child Neurol*2017; 59(6):574-580. doi:10.1111/dmcn.13405.

Supplementary file: The Kindy Moves protocol paper.[39]


Enrolment
Assessed for eligibility (n=42)
Excluded (n=2):
Progressive neurodisability
T1: Baseline assessment
Commencement of intervention (n=40)
Discontinued intervention
(n=1): Hospitalisation
T2: Post-intervention assessment (n=39)
T3: Follow-up assessment (n=38)

Open access

Protocol

BMJ Open

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

Dayna Pool ,[1,2] Catherine Elliott,[1,3] Healthy Strides Research Advisory Council

To cite: Pool D, Elliott C, Healthy Strides Research Advisory Council. 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. *BMJ Open* 2021;**11**:e046831. doi:10.1136/bmjopen-2020-046831

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-046831).

Received 10 November 2020
Accepted 03 August 2021

For numbered affiliations see end of article.

Correspondence to
Dr Dayna Pool;
Dayna.Pool@curtin.edu.au

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.

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

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.

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

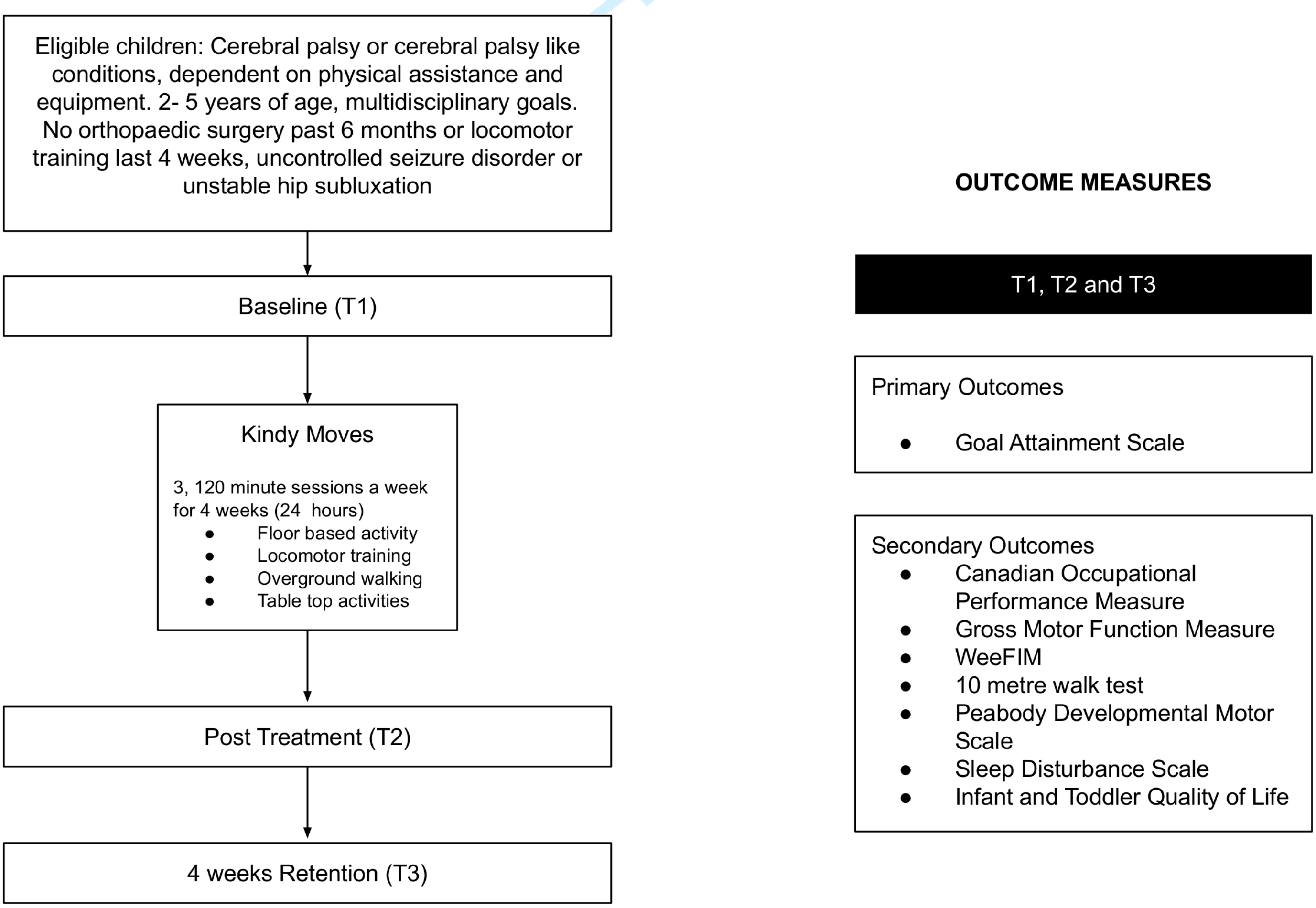


Figure 1 Study design and outcome measures. WeeFIM, Functional Independence Measure.

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

Topic	Prompts: Parents	Prompts: 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.

Author affiliations
[1]School of Allied Health, Curtin University, Perth, Western Australia, Australia
[2]The Healthy Strides Foundation, Perth, Western Australia, Australia
[3]Telethon Institute for Child Health Research, Nedlands, Western Australia, Australia

Twitter Dayna Pool @daynapool

Acknowledgements The authors acknowledge the Healthy Strides Research Advisory Council for consulting and providing guidance on the development of the intervention.

Collaborators The Healthy Strides Research Advisory Council comprises of the Healthy Strides clinical team: Loren West, Corrin Walmsley, Georgia Hoffman, Marissa Smith, Eddie Pool, Meagan Smith, Georgina Jones, Matthew Haddon, Jordan Dinh and Bridget Chapman. Research Advisors: Dr Ashleigh Thornton, Dr Sue McCabe and Dr Claire Willis. Consumer Advisors: Ben O'Rourke, Noraishah Naim, Alishum Osman Ali.

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.

Funding This research was supported by the Telethon7 Trust 2019 and 2020.

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.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD
Dayna Pool http://orcid.org/0000-0001-8313-5661

REFERENCES

1. Human Early Learning Partnership & Commission on Social Determinants of Health. *Early child development : a powerful equalizer: final report for the World Health Organization's Commission on the Social Determinants of Health. / Prepared by Arjumand Siddiqi, Lori G. Irwin, Dr. Clyde Hertzman*. Vancouver: Human Early Learning Partnership, 2007.
2. Heckman JJ, Masterov DV. The productivity argument for investing in young children. *Rev Agri Econom* 2007;29:446–93.
3. Nores M, Barnett WS. Benefits of early childhood interventions across the world: (under) investing in the very young. *Econ Educ Rev* 2010;29:271–82.
4. Richter LM, Daelmans B, Lombardi J, *et al*. Investing in the foundation of sustainable development: pathways to scale up for early childhood development. *Lancet* 2017;389:103–18.
5. Goldfeld S, O'Connor E, O'Connor M, *et al*. The role of preschool in promoting children's healthy development: Evidence from an Australian population cohort. *Early Child Res Q* 2016;35:40–8.
6. Roberts G, Lim J, Doyle LW, *et al*. High rates of school readiness difficulties at 5 years of age in very preterm infants compared with term controls. *J Dev Behav Pediatr* 2011;32:117–24.
7. Gehrmann FE, Coleman A, Weir KA, *et al*. School readiness of children with cerebral palsy. *Dev Med Child Neurol* 2014;56:786–93.
8. Cairney J, Hay JA, Faught BE, *et al*. Developmental coordination disorder, generalized self-efficacy toward physical activity, and participation in organized and free play activities. *J Pediatr* 2005;147:515–20.
9. Van Hus JW, Potharst ES, Jeukens-Visser M, *et al*. Motor impairment in very preterm-born children: links with other developmental deficits at 5 years of age. *Dev Med Child Neurol* 2014;56:587–94.
10. Report of the Australian cerebral palsy register, birth years 1993-2009, 2016.
11. Palisano R, Rosenbaum P, Walter S, *et al*. Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Dev Med Child Neurol* 1997;39:214–23.
12. Palisano RJ, Hanna SE, Rosenbaum PL, *et al*. Validation of a model of gross motor function for children with cerebral palsy. *Phys Ther* 2000;80:974–85.
13. World Health Organization. Neurological disorders: public health challenges, 2006. Available: https://www.who.int/mental_health/neurology/neurological_disorders_report_web.pdf [Accessed 9 Nov 2020].
14. Smithers-Sheedy H, Badawi N, Blair E, *et al*. What constitutes cerebral palsy in the twenty-first century? *Dev Med Child Neurol* 2014;56:323–8.
15. Novak I, Honan I. Effectiveness of paediatric occupational therapy for children with disabilities: a systematic review. *Aust Occup Ther J* 2019;66:258–73.
16. Ostensjø S, Carlberg EB, Vøllestad NK. Everyday functioning in young children with cerebral palsy: functional skills, caregiver

assistance, and modifications of the environment. *Dev Med Child Neurol* 2003;45:603–12.
17 Cope S, Mohn-Johnsen S. The effects of dosage time and frequency on motor outcomes in children with cerebral palsy: a systematic review. *Dev Neurorehabil* 2017;20:376–87.
18 Bleyenheuft Y, Gordon AM. Hand-arm bimanual intensive therapy including lower extremities (HABIT-ILE) for children with cerebral palsy. *Phys Occup Ther Pediatr* 2014;34:390–403.
19 Størvold GV, Jahnsen RB, Evensen KAI, *et al*. Factors associated with enhanced gross motor progress in children with cerebral palsy: a register-based study. *Phys Occup Ther Pediatr* 2018;38:548–61.
20 Jackman M, Lannin N, Galea C, *et al*. What is the threshold dose of upper limb training for children with cerebral palsy to improve function? A systematic review. *Aust Occup Ther J* 2020;67:269–80.
21 Pool D, Valentine J, Taylor NF, *et al*. Locomotor and robotic assistive gait training for children with cerebral palsy. *Dev Med Child Neurol* 2021;63:328–35.
22 Geijen M, Ketelaar M, Sakzewski L, *et al*. Defining functional therapy in research involving children with cerebral palsy: a systematic review. *Phys Occup Ther Pediatr* 2020;40:231–46.
23 Novak I, Morgan C, Fahey M, *et al*. State of the evidence traffic lights 2019: systematic review of interventions for preventing and treating children with cerebral palsy. *Curr Neurol Neurosci Rep* 2020;20:3.
24 Jeglinsky I, Salminen A-L, Carlberg EB, *et al*. Rehabilitation planning for children and adolescents with cerebral palsy. *J Pediatr Rehabil Med* 2012;5:203–15.
25 Choi BCK, Pak AWP. Multidisciplinarity, interdisciplinarity and transdisciplinarity in health research, services, education and policy: 1. definitions, objectives, and evidence of effectiveness. *Clin Invest Med* 2006;29:351–64.
26 Soper AK, Cross A, Rosenbaum P, *et al*. Knowledge translation strategies to support service providers' implementation of the "F-words in Childhood Disability". *Disabil Rehabil* 2020;45:1–7.
27 Jan MMS. Cerebral palsy: comprehensive review and update. *Ann Saudi Med* 2006;26:123–32.
28 Trabacca A, Russo L, Losito L, *et al*. The ICF-CY perspective on the neurorehabilitation of cerebral palsy: a single case study. *J Child Neurol* 2012;27:183–90.
29 Glader L, Plews-Ogan J, Agrawal R. Children with medical complexity: creating a framework for care based on the International classification of functioning, disability and health. *Dev Med Child Neurol* 2016;58:1116–23.
30 Morgan C, Novak I, Dale RC, *et al*. Single blind randomised controlled trial of GAME (Goals - Activity - Motor Enrichment) in infants at high risk of cerebral palsy. *Res Dev Disabil* 2016;55:256–67.
31 Danger S, Landreth G. Child-centered group play therapy with children with speech difficulties. *Int J Play Ther* 2005;14:81–102.
32 Astramovich RL, Lyons C, Hamilton NJ. Play therapy for children with intellectual disabilities. *J Child Adolesc Couns* 2015;1:27–36.
33 Fauconnier J, Dickinson HO, Beckung E, *et al*. Participation in life situations of 8-12 year old children with cerebral palsy: cross sectional European study. *BMJ* 2009;338:b1458.
34 Michelsen SI, Flachs EM, Uldall P, *et al*. Frequency of participation of 8-12-year-old children with cerebral palsy: a multi-centre cross-sectional European study. *Eur J Paediatr Neurol* 2009;13:165–77.
35 Imms C. Children with cerebral palsy participate: a review of the literature. *Disabil Rehabil* 2008;30:1867–84.
36 Bleyenheuft Y, Arnould C, Brandao MB, *et al*. Hand and arm bimanual intensive therapy including lower extremity (HABIT-ILE) in children with unilateral spastic cerebral palsy: a randomized trial. *Neurorehabil Neural Repair* 2015;29:645–57.
37 Mutlu A, Krosschell K, Spira DG. Treadmill training with partial body-weight support in children with cerebral palsy: a systematic review. *Dev Med Child Neurol* 2009;51:268–75.
38 Peterson MD, Gordon PM, Hurvitz EA. Chronic disease risk among adults with cerebral palsy: the role of premature sarcopoenia, obesity and sedentary behaviour. *Obes Rev* 2013;14:171–82.
39 Willoughby KL, Dodd KJ, Shields N. A systematic review of the effectiveness of treadmill training for children with cerebral palsy. *Disabil Rehabil* 2009;31:1971–9.
40 Anderson DI, Campos JJ, Witherington DC, *et al*. The role of locomotion in psychological development. *Front Psychol* 2013;4:440.
41 Huang H-H, Chen C-L. The use of modified ride-on cars to maximize mobility and improve socialization-a group design. *Res Dev Disabil* 2017;61:172–80.
42 Ryan JM, Cassidy EE, Noorduyn SG, *et al*. Exercise interventions for cerebral palsy. *Cochrane Database Syst Rev* 2017;2017.
43 Fonzo M, Sirico F, Corrado B. Evidence-Based physical therapy for individuals with Rett syndrome: a systematic review. *Brain Sci* 2020;10:410.
44 Wheeler AC, Sacco P, Cabo R. Unmet clinical needs and burden in Angelman syndrome: a review of the literature. *Orphanet J Rare Dis* 2017;12:164.
45 Willoughby KL, Dodd KJ, Shields N, *et al*. Efficacy of partial body weight-supported treadmill training compared with overground walking practice for children with cerebral palsy: a randomized controlled trial. *Arch Phys Med Rehabil* 2010;91:333–9.
46 Dodd KJ, Foley S. Partial body-weight-supported treadmill training can improve walking in children with cerebral palsy: a clinical controlled trial. *Dev Med Child Neurol* 2007;49:101–5.
47 Day JA, Fox EJ, Lowe J, *et al*. Locomotor training with partial body weight support on a treadmill in a nonambulatory child with spastic tetraplegic cerebral palsy: a case report. *Pediatr Phys Ther* 2004;16:106–13.
48 Schindl MR, Forstner C, Kern H, *et al*. Treadmill training with partial body weight support in nonambulatory patients with cerebral palsy. *Arch Phys Med Rehabil* 2000;81:301–6.
49 Verschuren O, Helders PJM, Mattern-Baxter K. Effects of intensive locomotor treadmill training on young children with cerebral palsy. *Pediatr Phys Ther* 2009;21:319–19.
50 Valentín-Gudiol M, Mattern-Baxter K, Girabent-Farrés M, *et al*. Treadmill interventions in children under six years of age at risk of neuromotor delay. *Cochrane Database Syst Rev* 2017;7:Cd009242.
51 Ginsburg KR, American Academy of Pediatrics Committee on Communications, American Academy of Pediatrics Committee on Psychosocial Aspects of Child and Family Health. The importance of play in promoting healthy child development and maintaining strong parent-child bonds. *Pediatrics* 2007;119:182–91.
52 Novak I, McIntyre S, Morgan C, *et al*. A systematic review of interventions for children with cerebral palsy: state of the evidence. *Dev Med Child Neurol* 2013;55:885–910.
53 Patel DR. Therapeutic interventions in cerebral palsy. *Indian J Pediatr* 2005;72:979–83.
54 Mickan SM. Evaluating the effectiveness of health care teams. *Aust Health Rev* 2005;29:211–7.
55 Damiano DL, DeJong SL. A systematic review of the effectiveness of treadmill training and body weight support in pediatric rehabilitation. *J Neurol Phys Ther* 2009;33:27–44.
56 Bowen DJ, Kreuter M, Spring B, *et al*. How we design feasibility studies. *Am J Prev Med* 2009;36:452–7.
57 Rosenbaum P, Gorter JW. The 'F-words' in childhood disability: I swear this is how we should think! *Child Care Health Dev* 2012;38:457–63.
58 Turner-Stokes L. Goal attainment scaling (GAS) in rehabilitation: a practical guide. *Clin Rehabil* 2009;23:362–70.
59 Carswell A, McColl MA, Baptiste S, *et al*. The Canadian occupational performance measure: a research and clinical literature review. *Can J Occup Ther* 2004;71:210–22.
60 Booth ATC, Buizer AI, Meyns P, *et al*. The efficacy of functional gait training in children and young adults with cerebral palsy: a systematic review and meta-analysis. *Dev Med Child Neurol* 2018;60:866–83.
61 Ottenbacher KJ, Msall ME, Lyon N, *et al*. The WeeFIM instrument: its utility in detecting change in children with developmental disabilities. *Arch Phys Med Rehabil* 2000;81:1317–26.
62 Wang H-H, Liao H-F, Hsieh C-L. Reliability, sensitivity to change, and responsiveness of the peabody developmental motor scales-second edition for children with cerebral palsy. *Phys Ther* 2006;86:1351–9.
63 Romeo DM, Brogna C, Musto E, *et al*. Sleep disturbances in preschool age children with cerebral palsy: a questionnaire study. *Sleep Med* 2014;15:1089–93.
64 Spuijbroek AT, Oostenbrink R, Landgraf JM, *et al*. Health-related quality of life in preschool children in five health conditions. *Qual Life Res* 2011;20:779–86.
65 Bleyenheuft Y, Ebner-Karestinos D, Surana B, *et al*. Intensive upper- and lower-extremity training for children with bilateral cerebral palsy: a quasi-randomized trial. *Dev Med Child Neurol* 2017;59:625–33.
66 Palisano RJ, Rosenbaum P, Bartlett D, *et al*. Content validity of the expanded and revised gross motor function classification system. *Dev Med Child Neurol* 2008;50:744–50.
67 Eliasson A-C, Krumlinde-Sundholm L, Rösblad B, *et al*. The manual ability classification system (MACS) for children with cerebral palsy: scale development and evidence of validity and reliability. *Dev Med Child Neurol* 2006;48:549–54.
68 Hidecker MJC, Cunningham BJ, Thomas-Stonell N, *et al*. Validity of the communication function classification system for use with preschool children with communication disorders. *Dev Med Child Neurol* 2017;59:526–30.
69 Graham HK, Harvey A, Rodda J, *et al*. The functional mobility scale (FMS). *J Pediatr Orthop* 2004;24:514–20.

70 Livingstone R, Paleg G. Measuring outcomes for children with cerebral palsy who use gait trainers. *Technology* 2016;4:1–19.
71 Cusick A, McIntyre S, Novak I, *et al*. A comparison of goal attainment scaling and the Canadian occupational performance measure for paediatric rehabilitation research. *Pediatr Rehabil* 2006;9:149–57.
72 Novak I, Cusick A, Lannin N. Occupational therapy home programs for cerebral palsy: double-blind, randomized, controlled trial. *Pediatrics* 2009;124:e606–14.
73 Meyer-Heim A, Borggraefe I, Ammann-Reiffer C, *et al*. Feasibility of robotic-assisted locomotor training in children with central gait impairment. *Dev Med Child Neurol* 2007;49:900–6.
74 Mattern-Baxter K. Effects of partial body weight supported treadmill training on children with cerebral palsy. *Pediatr Phys Ther* 2009;21:12–22.
75 Romeo DM, Bruni O, Brogna C, *et al*. Application of the sleep disturbance scale for children (SDSC) in preschool age. *Eur J Paediatr Neurol* 2013;17:374–82.
76 Russell DJ, Avery LM, Rosenbaum PL, *et al*. Improved scaling of the gross motor function measure for children with cerebral palsy: evidence of reliability and validity. *Phys Ther* 2000;80:873–85.
77 Wang H-Y, Yang YH. Evaluating the responsiveness of 2 versions of the gross motor function measure for children with cerebral palsy. *Arch Phys Med Rehabil* 2006;87:51–6.
78 Ko J. Sensitivity to functional improvements of GMFM-88, GMFM-66, and PEDI mobility scores in young children with cerebral palsy. *Percept Mot Skills* 2014;119:305–19.
79 Behrman AL, Harkema SJ. Spinal Cord Injury Special Series Locomotor Training After Human Spinal Cord Injury : A Series of Case Studies. *Physical Therapy* 2000;80:688–700.
80 Imms C, Granlund M, Wilson PH, *et al*. Participation, both a means and an end: a conceptual analysis of processes and outcomes in childhood disability. *Dev Med Child Neurol* 2017;59:16–25.
81 Guba EG. Criteria for assessing the trustworthiness of naturalistic inquiries. *Educ Comm Technol J* 1981;29:75–91.
82 Smith B, McGannon KR. Developing rigor in qualitative research: problems and opportunities within sport and exercise psychology. *Int Rev Sport Exerc Psychol* 2018;11:101–21.
83 Portney LG, Watkins MP. *Foundations of clinical research: applications to practice*. 3rd edn. New Jersey: Person Prentice Hall, 2009.
84 Barwick M. Building scientist capacity in knowledge translation: development of the knowledge translation planning template. *Technol Innov Manage Rev* 2016;6:9–15.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of study as randomised pilot or feasibility trial	p1 line 1
Authors *	Contact details for the corresponding author	P1 line 14-18
Trial design	Description of pilot trial design (eg, parallel, cluster)	5
Methods		
Participants	Eligibility criteria for participants and the settings where the pilot trial was conducted	6-11
Interventions	Interventions intended for each group	12-14
Objective	Specific objectives of the pilot trial	2-4
Outcome	Prespecified assessment or measurement to address the pilot trial objectives**	15-19
Randomization	How participants were allocated to interventions	N/A
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	N/A
Results		
Numbers randomized	Number of participants screened and randomised to each group for the pilot trial objectives**	7
Recruitment	Trial status†	
Numbers analysed	Number of participants analysed in each group for the pilot objectives**	7
Outcome	Results for the pilot objectives, including any expressions of uncertainty**	20-25
Harms	Important adverse events or side effects	25
Conclusions	General interpretation of the results of pilot trial and their implications for the future definitive trial	26-28
Trial registration	Registration number for pilot trial and name of trial register	29
Funding	Source of funding for pilot trial	P12 line 42

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

**this item is specific to conference abstracts*

***Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those that are a priori agreed as the most important to the decision to proceed with the future definitive RCT.*

†For conference abstracts.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3-4
	2b	Specific objectives or research questions for pilot trial	4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	5
	4c	How participants were identified and consented	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	4-6
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	4-6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	6
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4, 6
	14b	Why the pilot trial ended or was stopped	4, 5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6-7
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	7-8
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	7-8
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	6-8
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	6
	19a	If relevant, other important unintended consequences	6
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	11-12
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	10-14
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	10-13
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	8-12
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	2
Protocol	24	Where the pilot trial protocol can be accessed, if available	14, 17
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	12
	26	Ethical approval or approval by research review committee, confirmed with reference number	4

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-068816.R1
Article Type:	Original research
Date Submitted by the Author:	23-Jan-2023
Complete List of Authors:	Haddon, Matthew; The Healthy Strides Foundation, West, Loren; The Healthy Strides Foundation Elliott, Catherine; Curtin University, School of Allied Health; Telethon Kids Institute Walmsley, Corrin; The Healthy Strides Foundation Valentine, Jane; Perth Children's Hospital, Paediatric Rehabilitation; Telethon Kids Institute Bear, Natasha; Child and Adolescent Health Service Healthy Strides Research Advisory Council, .; The Healthy Strides Foundation Pool, Dayna; Curtin University, School of Occupational Therapy Social Work and Speech Pathology; The Healthy Strides Foundation,
Primary Subject Heading:	Paediatrics
Secondary Subject Heading:	Rehabilitation medicine, Sports and exercise medicine, Evidence based practice
Keywords:	Developmental neurology & neurodisability < PAEDIATRICS, Neurological injury < NEUROLOGY, Clinical trials < THERAPEUTICS

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

Authors: Haddon M[1], West L[1], Elliott C PhD[2&3], Walmsley CP PhD[1], Valentine J FRACP PhD[3&4], Bear N[5], Healthy Strides Research Advisory Council[1], Pool D PhD[1&2]

1. The Healthy Strides Foundation, Perth, Western Australia, 6101
2. School of Allied Health, Curtin University, Perth, Western Australia, 6027
3. Telethon Kids Institute, Perth, Western Australia, Western Australia, 6009
4. Perth Children's Hospital, Child and Adolescent Health Service, Perth, Western Australia, 6009
5. Child and Adolescent Health Service, Perth, Western Australia, 6009

Corresponding author details:
Mr Matthew Haddon – matthew.haddon@health.wa.gov.au
Contact number – +8 0404315015
ORCID ID – 0000-0003-2795-902X
Postal address – Suite 23/954 Albany Hwy, East Victoria Park WA 6101.

Word length for main text excluding reference, abstract and tables: 5704
Word length for abstract: 300
Number of references: 84
Number of tables: 2
Number of figures: 2

Abstract

Objectives: To determine the feasibility of an intensive interdisciplinary program for goal and motor outcomes in preschool aged children with non-progressive neurodisabilities. The primary hypothesis was that limited efficacy would be demonstrated.

Design: A single group feasibility study.

Setting: An Australian paediatric community therapy provider.

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

Intervention: A goal-directed program of three two-hour sessions per week for four 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 pre-intervention (T1) to post-intervention (T2) and four-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 statistically significant improvements at T2 compared with T1 for all limited-efficacy measures. The GAS improved at T2 (MD 27.7, 95%CI 25.8-29.5, p<0.001) as well as COPM performance (MD 3.2, 95%CI 2.8-3.6, p<0.001) and satisfaction (MD 3.3, 95%CI 2.8-3.8, p<0.001). The GMFM-66 (MD 2.3, 95%CI 1.0-3.5, p=0.001) and 10MWT (median difference -2.3, 95%CI -28.8-0.0, p=0.007) 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 program is feasible in improving goal and motor outcomes for preschool children with neurodisabilities (GMFCS III-V). A randomised controlled trial is warranted to establish efficacy.

Trial registration: Australian New Zealand Clinical Trials Registry (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 program 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 program makes it difficult to differentiate the effects of individual elements of the program.
- 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 syndrome.[6] Cerebral palsy 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] Cerebral palsy 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 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 to 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] Locomotor treadmill training 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 four weeks[27] to three 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 six weeks in 5 to 12 year old children with CP (GMFCS III-V),[33] and following 14 hours of treadmill training in 1 to 5 year old pre-ambulatory children 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 program 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. 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 feasibility study aims to determine the potential efficacy[41] of LTT embedded within an interdisciplinary framework in improving goal attainment, caregiver-reported goal performance and satisfaction, gross motor function, and walking speed in preschool aged children with non-progressive neurodisabilities requiring daily equipment and physical assistance (i.e. GMFCS levels III-V or equivalent). The secondary aim of the study is to determine the feasibility of the intervention as measured by limited-efficacy testing, acceptability, demand, implementation, and practicality. The primary hypothesis was that limited-efficacy testing[41] would be demonstrated by outcome measures statistically and clinically improving after the four-week intervention. The secondary hypothesis was that the intervention would be feasible as determined 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 to 5 years were recruited. Participants undertook four weeks of intervention, completing a two-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 two weeks before the intervention (T1) to the week following intervention completion (T2) and at follow-up four weeks post-intervention (T3). The shorter four-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 two-year timeframe. 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 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 will be reported in a future qualitative paper. This study was reported according to the CONSORT 2010 statement: extension to randomised pilot and feasibility trials.[43, 44] Approval for this study was obtained by the Human Research Ethics Committee of Curtin University (Approval number: HRE2019-0073) and written informed consent was received by the participants' primary caregivers.

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 six months of the study, unstable hip subluxation, uncontrolled seizure disorder, or engagement in LTT in the month prior to the study. A semi-structured interview was used for caregivers to answer open-ended questions to state diagnoses, medical conditions, and co-occurring impairments. A sample size of 34 participants predicted a large effect size (d=1.0) based on the Goal Attainment Scaling (GAS) t-score (80% power; two-sided t-test at an alpha of 0.05). Participant drop-out was anticipated to be 15% in the context of this population's young age, medical complexity, and frequency of hospital admissions. As a result of this, 40 children were recruited to account for attrition.

Intervention

A standardised protocol of the Kindy Moves intervention was followed (Supplementary Material 1).[42] Kindy Moves is an intensive program 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 two-hour sessions per week for four weeks (24 hours of therapy). Locomotor treadmill training was a large focus of the program, but this was incorporated into an interdisciplinary framework with dedicated time to address communication, socialisation, and upper limb function goals. 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 two-hour intervention was separated into 30 minutes of floor time as a group to practice gross motor, socialisation and play skills through games, songs, and book reading. This was followed by one hour of LTT, separated into 30 minutes of partial body weight supported treadmill training (Figure 1) and 30 minutes of overground walking in a mobility device which was designed based upon 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 minutes 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 the supplementary materials (Supplementary Material 2).

Figure 1. Treadmill Training.

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 two 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 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 World Health Organization'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] Participants walked as fast as possible in a mobility device across a 10-metre distance. Facilitation of one step was provided for children who did not initiate stepping after 30 seconds.[33] If a child did not complete the 10-metre distance in six minutes, this time was recorded as the maximal result.[33] The clinically meaningful change in 10MWT speed is 0.1m/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 5 to 12 year old children 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 standard deviations for continuous data, or medians and interquartile ranges 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% confidence intervals. The Smithers-Sheedy et al[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 sub-domains 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. Upon review of their pre-intervention 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. There was one participant drop-out due to hospitalisation for respiratory illness, with 39 participants completing the intervention as per the protocol. 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 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%. On average, participants attended 21.9 out of 24 hours of intervention and the main reason for non-attendance was illness. 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%). There were no adverse events to report.

Figure 2. 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-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)

Abbreviations: GMFCS, Gross Motor Function Classification System[10]; MACS, Manual Ability Classification System[46]; CFCS, Communication Function Classification System[45]; COPM, Canadian Occupational Performance Measure[47]; GAS, Goal Attainment Scaling.[49]

There were statistically significant improvements for all outcome measures from baseline to post-intervention and follow-up other than the 10MWT at T3 (Table 2). All outcome measures remained stable from T2 to T3 except for the GAS t-score which showed a statistically significant 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 post-intervention 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.

Table 2. Outcome Measure Changes Across All Time Points.

Outcome	Assessment Time Point			Outcome Measure Changes		
	Mean (SD)			Mean Difference (95% CI) p-value		
	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) p<0.001	30.9 (29.1 to 32.8) p<0.001	3.3 (1.4 to 5.1) p=0.001
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) p<0.001	3.3 (2.9 to 3.7) p<0.001	0.1 (-0.3 to 0.6) p=0.531
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) p<0.001	3.3 (2.8 to 3.8) p<0.001	0.0 (-0.5 to 0.5) p=0.901
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) p=0.001	2.1 (0.8 to 3.3) p=0.001	-0.2 (-1.5 to 1.1) p=0.797
	Median (IQR)			Median Difference (95% CI) p-value		

Skewed Data	T1	T2	T3	T2 vs T1	T3 vs T1	T3 vs T2
10MWT Time (secs)	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) p=0.007	-8.3 (-20.9 to 0) p=0.080	0.0 (-3.2 to 2.2) p=0.702

Abbreviations: GAS, Goal Attainment Scaling[49]; COPM, Canadian Occupational Performance Measure[47]; GMFM-66, 66-item Gross Motor Function Measure[54]; 10MWT, 10-Metre Walk Test.[57]

DISCUSSION

This study aimed to determine if implementing Kindy Moves, a four-week intensive LTT program delivered within an interdisciplinary framework, was feasible for preschool aged children with non-progressive neurodisabilities. Following this intervention, there were statistically significant improvements in the GAS, COPM performance and satisfaction, GMFM-66, and 10MWT. These improvements were largely maintained four weeks after program completion other than GAS t-scores further improving and the 10MWT change no longer being statistically significant. Clinically meaningful improvements were seen post-intervention and follow-up across all outcome measures, particularly in goal performance and satisfaction. 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 exceeded the power calculation sample size (reflecting demand), and the intervention accurately followed protocol (supporting implementation). These results indicate the feasibility of Kindy Moves as an intensive goal-directed program in 2 to 5 year old children 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 to 5 years old 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 to 5 years being less frequently completed.[67] Data exploring the retention of outcomes in a period after program completion is important in establishing the extent of real-life skill application. Goal performance and satisfaction remained high four 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 programs throughout a child's lifespan.

Goal attainment showed a statistically significant improvement from T2 to T3, with an increased proportion of clinically meaningful changes during the follow-up phase. This is an encouraging result that has several possible explanations. Firstly, a hands-off approach in practicing real-life tasks facilitates more active child involvement that can continue in the home.[2-4] A fun, motivating, and enriched environment further encourages a child to spontaneously practice these tasks. [2-4] Caregivers also possibly had a role in home practice after observing their child's new capacity and learning familiar and inexpensive activities or songs that could be used to support further goal attainment. For other participants, perhaps the boost in goal attainment was sufficient to allow for regular use and subsequent practice of new skills in their daily life. For example, we observed participants developing steering using their walking frame during Kindy Moves, allowing them to spend time generalising this skill and repeatedly practice navigating around their home after program completion.

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, with the sample size exceeding what was required according to the power calculation. 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. 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 co-morbidities.

Over a 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 learned.[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 learned 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 program. 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 co-morbidities and functional ability levels. 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 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 to 2.3 years who completed 40 to 50 hours of therapy over four months.[77] Despite being a promising pilot study,[77] it is probable that natural maturation affected the results in the four-month intervention, particularly at an age of rapid motor development. To account for this in Kindy Moves, a shorter intervention timeframe and only a four-week follow-up period were selected. Although longer follow-up periods beyond three 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. Additionally, 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 post-intervention 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] This 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 was noted in the 10MWT which skewed the data. This was particularly evident in children functioning within GMFCS levels IV-V (or equivalent). Although community ambulation may not be an achievable goal for all participants in Kindy Moves, newly learned 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 post-intervention 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 programs 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 wellbeing 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 four weeks (12 hours total),[27] whereas others have explored up to three 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 to 4 years resulted in goal and gross motor improvements after 50 hours of therapy over two weeks.[67] The outcomes of Kindy Moves highlight improvements in goals and motor function after 24 hours of therapy across four 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 to 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. Firstly, 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. 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 program 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. Additionally, 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.

CONCLUSION

Kindy Moves has highlighted that an intensive LTT-focused program delivered within an interdisciplinary framework is potentially efficacious in improving goal attainment, caregiver-reported goal performance and satisfaction, gross motor function, and walking speed in preschool aged children with non-progressive neurodisabilities. The intervention was feasible according to limited-efficacy testing, acceptability, demand, practicality, and implementation. 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 use of additional programs to specifically target participation should be considered to achieve a child's goals that are based at the participation level. 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 program highlights promising preliminary evidence for improving goal-driven outcomes and motor capacity in this population, warranting a well-powered randomised controlled trial to establish its efficacy.

Acknowledgements: The authors acknowledge the Healthy Strides Research Advisory Council for consulting and providing guidance on the development of the intervention.

Collaborators: The Healthy Strides Research Advisory Council comprises of the Healthy Strides clinical team: Dr Dayna Pool, Loren West, Dr Corrin Walmsley, Georgia Hoffman, Marissa Smith, Eddie Pool, Meagan Smith, Georgina Jones, Matthew Haddon, Jordan Dinh and Bridget Chapman. Research Advisors: Dr Ashleigh Thornton, Dr Sue McCabe and Dr Claire Willis. Consumer Advisors: Ben O'Rourke, Noraishah Naim.

Author Contributions: 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 co-developed 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 conceptualised, planned, developed, and wrote the study protocol.

Funding Statement: This work has been supported by the Telethon7 Trust 2019 and 2020. Award/Grant number is not applicable.

Competing Interests Statements: None declared.

Patient Consent: Consent was provided for the inclusion of Figure 1 in the paper through the BMJ Patient Consent Form.

Data Sharing: Data can be made available for research purposes upon request.

Reporting Checklist Flow Diagram: The CONSORT 2010 statement: extension to randomised pilot and feasibility studies.[40]

Ethics Approval: Approval for this study was obtained by the Human Research Ethics Committee of Curtin University (Approval number: HRE2019-0073) and written informed consent was received by the participants' primary caregivers.

REFERENCES

1. Jackman M, Sakzewski L, Morgan C, et al. Interventions to improve physical function for children and young people with cerebral palsy: International clinical practice guideline. *Dev Med Child Neurol*2021; 64(5):536-549. doi:10.1111/dmcn.15055.
2. Morgan C, Fetters L, Adde L, et al. Early intervention for children aged 0 to 2 years with or at high risk of cerebral palsy: International clinical practice guideline based on systematic reviews. *JAMA Pediatr*2021; 175(8):846-858. doi:10.1001/jamapediatrics.2021.0878.
3. Damiano DL, Longo E. Early intervention evidence for infants with or at risk for cerebral palsy: An overview of systematic reviews. *Dev Med Child Neurol*2021; 63(7):771-784. doi:10.1111/dmcn.14855.
4. Novak I, Morgan C, Fahey M, et al. State of the evidence traffic lights 2019: Systematic review of interventions for preventing and treating children with cerebral palsy. *Curr Neurol Neurosci Rep*2020; 20(2):3. doi:10.1007/s11910-020-1022-z.
5. Novak I, Honan I. Effectiveness of paediatric occupational therapy for children with disabilities: A systematic review. *Aust Occup Ther J*2019; 66(3):258-273. doi:10.1111/1440-1630.12573.

6. Morris C, Janssens A, Tomlinson R, Williams J, Logan S. Towards a definition of neurodisability: A delphi survey. *Dev Med Child Neurol*2013; 55(12):1103-1108. doi:10.1111/dmcn.12218.
7. Cans C. Surveillance of cerebral palsy in Europe: A collaboration of cerebral palsy surveys and registers. *Dev Med Child Neurol*2000; 42(12):816-824. doi:10.1017/s0012162200001511.
8. Smithers-Sheedy H, Badawi N, Blair E, et al. What constitutes cerebral palsy in the twenty-first century? *Dev Med Child Neurol*2014; 56(4):323-328. doi:10.1111/dmcn.12262.
9. Novak I, Hines M, Goldsmith S, Barclay R. Clinical prognostic messages from a systematic review on cerebral palsy. *Pediatrics*2012; 130(5):e1285-1312. doi:10.1542/peds.2012-0924.
10. Palisano R, Rosenbaum P, Walter S, et al. Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Dev Med Child Neurol*1997; 39(4):214-223. doi:10.1111/j.1469-8749.1997.tb07414.x.
11. Australian Cerebral Palsy Register Group. Australia and the Australian cerebral palsy register for the birth cohort 1993 to 2006. *Dev Med Child Neurol*2016; 58 Suppl 2:3-4. doi:10.1111/dmcn.13002.
12. Imms C, Granlund M, Wilson PH, et al. Participation, both a means and an end: A conceptual analysis of processes and outcomes in childhood disability. *Dev Med Child Neurol*2017; 59(1):16-25. doi:10.1111/dmcn.13237.
13. Aviram R, Harries N, Shkedy Rabani A, et al. Comparison of habitual physical activity and sedentary behavior in adolescents and young adults with and without cerebral palsy. *Pediatr Exerc Sci*2019; 31(1):60-66. doi:10.1123/pes.2017-0285.
14. Fauconnier J, Dickinson HO, Beckung E, et al. Participation in life situations of 8-12 year old children with cerebral palsy: Cross sectional European study. *BMJ*2009; 338:b1458. doi:10.1136/bmj.b1458.
15. Imms C. Children with cerebral palsy participate: A review of the literature. *Disabil Rehabil*2008; 30(24):1867-1884. doi:10.1080/09638280701673542.
16. Shkedy Rabani A, Harries N, Namoora I, et al. Duration and patterns of habitual physical activity in adolescents and young adults with cerebral palsy. *Dev Med Child Neurol*2014; 56(7):673-680. doi:10.1111/dmcn.12394.
17. Peterson MD, Gordon PM, Hurvitz EA. Chronic disease risk among adults with cerebral palsy: The role of premature sarcopoenia, obesity and sedentary behaviour. *Obes Rev*2013; 14(2):171-182. doi:10.1111/j.1467-789X.2012.01052.x.
18. Ryan JM, Cassidy EE, Noorduyn SG, O'Connell NE. Exercise interventions for cerebral palsy. *Cochrane Database Syst Rev*2017; 6:CD011660. doi:10.1002/14651858.CD011660.pub2.
19. Gross PH, Bailes AF, Horn SD, et al. Setting a patient-centered research agenda for cerebral palsy: A participatory action research initiative. *Dev Med Child Neurol*2018; 60(12):1278-1284. doi:10.1111/dmcn.13984.
20. Byrne R, Noritz G, Maitre NL, NCH Early Developmental Group. Implementation of early diagnosis and intervention guidelines for cerebral palsy in a high-risk infant follow-up clinic. *Pediatr Neurol*2017; 76:66-71. doi:10.1016/j.pediatrneurol.2017.08.002.
21. Johnston MV, Ishida A, Ishida WN, et al. Plasticity and injury in the developing brain. *Brain Dev*2009; 31(1):1-10. doi:10.1016/j.braindev.2008.03.014.
22. Yang JF, Livingstone D, Brunton K, et al. Training to enhance walking in children with cerebral palsy: Are we missing the window of opportunity? *Semin Pediatr Neurol*2013; 20(2):106-115. doi:10.1016/j.spen.2013.06.011.
23. Daelmans B, Darmstadt GL, Lombardi J, et al. Early childhood development: The foundation of sustainable development. *Lancet*2017; 389(10064):9-11. doi:10.1016/S0140-6736(16)31659-2.
24. Richter LM, Daelmans B, Lombardi J, et al. Investing in the foundation of sustainable development: Pathways to scale up for early childhood development. *Lancet*2017; 389(10064):103-118. doi:10.1016/S0140-6736(16)31698-1.
25. Rosenbaum PL, Walter SD, Hanna SE, et al. Prognosis for gross motor function in cerebral palsy: Creation of motor development curves. *JAMA*2002; 288(11):1357-1363. doi:10.1001/jama.288.11.1357.
26. Hanna SE, Bartlett DJ, Rivard LM, Russell DJ. Reference curves for the gross motor function measure: Percentiles for clinical description and tracking over time among children with cerebral palsy. *Phys Ther*2008; 88(5):596-607. doi:10.2522/ptj.20070314.

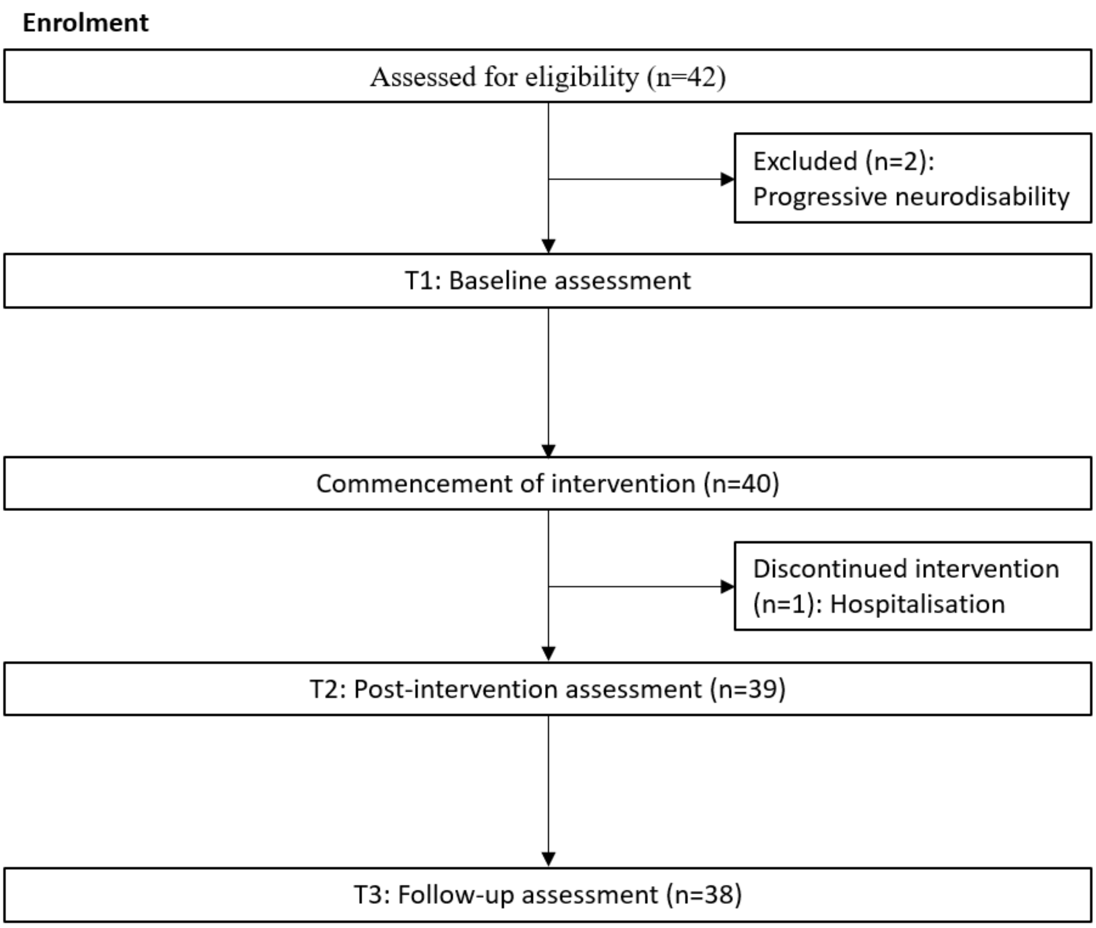
27. Mattern-Baxter K, Bellamy S, Mansoor JK. Effects of intensive locomotor treadmill training on young children with cerebral palsy. *Pediatr Phys Ther*2009; 21(4):308-318. doi:10.1097/PEP.0b013e3181bf53d9.
28. Gehrmann FE, Coleman A, Weir KA, Ware RS, Boyd RN. School readiness of children with cerebral palsy. *Dev Med Child Neurol*2014; 56(8):786-793. doi:10.1111/dmcn.12377.
29. Choi BC, Pak AW. Multidisciplinarity, interdisciplinarity and transdisciplinarity in health research, services, education and policy: 1. Definitions, objectives, and evidence of effectiveness. *Clin Invest Med*2006; 29(6):351-364. Available from: https://www.ncbi.nlm.nih.gov/pubmed/17330451.
30. Dodd KJ, Foley S. Partial body-weight-supported treadmill training can improve walking in children with cerebral palsy: A clinical controlled trial. *Dev Med Child Neurol*2007; 49(2):101-105. doi:10.1111/j.1469-8749.2007.00101.x.
31. Mattern-Baxter K. Locomotor treadmill training for children with cerebral palsy. *Orthop Nurs*2010; 29(3):169-173; quiz 174-165. doi:10.1097/NOR.0b013e3181db5441.
32. Willoughby KL, Dodd KJ, Shields N. A systematic review of the effectiveness of treadmill training for children with cerebral palsy. *Disabil Rehabil*2009; 31(24):1971-1979. doi:10.3109/09638280902874204.
33. Pool D, Valentine J, Taylor NF, Bear N, Elliott C. Locomotor and robotic assistive gait training for children with cerebral palsy. *Dev Med Child Neurol*2021; 63(3):328-335. doi:10.1111/dmcn.14746.
34. Valentin-Gudiol M, Mattern-Baxter K, Girabent-Farres M, et al. Treadmill interventions in children under six years of age at risk of neuromotor delay. *Cochrane Database Syst Rev*2017; 7:CD009242. doi:10.1002/14651858.CD009242.pub3.
35. Tinderholt Myrhaug H, Ostensjo S, Larun L, Odgaard-Jensen J, Jahnsen R. Intensive training of motor function and functional skills among young children with cerebral palsy: A systematic review and meta-analysis. *BMC Pediatr*2014; 14:292. doi:10.1186/s12887-014-0292-5.
36. Jackman M, Lannin N, Galea C, et al. What is the threshold dose of upper limb training for children with cerebral palsy to improve function? A systematic review. *Aust Occup Ther J*2020; 67(3):269-280. doi:10.1111/1440-1630.12666.
37. Bryant E, Pountney T, Williams H, Edelman N. Can a six-week exercise intervention improve gross motor function for non-ambulant children with cerebral palsy? A pilot randomized controlled trial. *Clin Rehabil*2013; 27(2):150-159. doi:10.1177/0269215512453061.
38. Mattern-Baxter K, McNeil S, Mansoor JK. Effects of home-based locomotor treadmill training on gross motor function in young children with cerebral palsy: A quasi-randomized controlled trial. *Arch Phys Med Rehabil*2013; 94(11):2061-2067. doi:10.1016/j.apmr.2013.05.012.
39. Mattern-Baxter K. Analysis of a group-based treadmill program for children with neuromotor delay who are pre-ambulatory. *Phys Occup Ther Pediatr*2021; 41(3):271-283. doi:10.1080/01942638.2020.1834055.
40. Kleim JA, Jones TA. Principles of experience-dependent neural plasticity: Implications for rehabilitation after brain damage. *J Speech Lang Hear Res*2008; 51(1):S225-239. doi:10.1044/1092-4388(2008/018).
41. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med*2009; 36(5):452-457. doi:10.1016/j.amepre.2009.02.002.
42. Pool D, Elliott C, Healthy Strides Research Advisory Council. 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. *BMJ Open*2021; 11(8):e046831. doi:10.1136/bmjopen-2020-046831.
43. Eldridge SM, Chan CL, Campbell MJ, et al. Consort 2010 statement: Extension to randomised pilot and feasibility trials. *BMJ*2016; 355:i5239. doi:10.1136/bmj.i5239.
44. Lancaster GA, Thabane L. Guidelines for reporting non-randomised pilot and feasibility studies. *Pilot Feasibility Stud*2019; 5:114. doi:10.1186/s40814-019-0499-1.
45. Hidecker MJ, Cunningham BJ, Thomas-Stonell N, Oddson B, Rosenbaum P. Validity of the communication function classification system for use with preschool children with communication disorders. *Dev Med Child Neurol*2017; 59(5):526-530. doi:10.1111/dmcn.13373.

46. Eliasson AC, Krumlinde-Sundholm L, Rosblad B, et al. The manual ability classification system (MACS) for children with cerebral palsy: Scale development and evidence of validity and reliability. *Dev Med Child Neurol*2006; 48(7):549-554. doi:10.1017/S0012162206001162.
47. Law M, Baptiste S, McColl M, et al. The canadian occupational performance measure: An outcome measure for occupational therapy. *Can J Occup Ther*1990; 57(2):82-87. doi:10.1177/000841749005700207.
48. Cusick A, Lannin NA, Lowe K. Adapting the canadian occupational performance measure for use in a paediatric clinical trial. *Disabil Rehabil*2007; 29(10):761-766. doi:10.1080/09638280600929201.
49. Kiresuk TJ, Sherman RE. Goal attainment scaling: A general method for evaluating comprehensive community mental health programs. *Community Ment Health J*1968; 4(6):443-453. doi:10.1007/BF01530764.
50. World Health Organization. International classification of functioning, disability and health: ICF. Geneva, Switzerland; 2001. p.
51. Livingstone R, Paleg G. Measuring outcomes for children with cerebral palsy who use gait trainers. *Technologies*2016; 4:1-19. doi:10.3390/technologies4030022.
52. Cusick A, McIntyre S, Novak I, Lannin N, Lowe K. A comparison of goal attainment scaling and the canadian occupational performance measure for paediatric rehabilitation research. *Pediatr Rehabil*2006; 9(2):149-157. doi:10.1080/13638490500235581.
53. Harpster K, Sheehan A, Foster EA, et al. The methodological application of goal attainment scaling in pediatric rehabilitation research: A systematic review. *Disabil Rehabil*2019; 41(24):2855-2864. doi:10.1080/09638288.2018.1474952.
54. Russell DJ, Avery LM, Rosenbaum PL, et al. Improved scaling of the gross motor function measure for children with cerebral palsy: Evidence of reliability and validity. *Phys Ther*2000; 80(9):873-885. Available from: https://www.ncbi.nlm.nih.gov/pubmed/10960935.
55. Ko J. Sensitivity to functional improvements of GMFM-88, GMFM-66, and PEDI mobility scores in young children with cerebral palsy. *Percept Mot Skills*2014; 119(1):305-319. doi:10.2466/03.25.PMS.119c14z1.
56. Marois P, Marois M, Pouliot-Laforte A, et al. Gross motor function measure evolution ratio: Use as a control for natural progression in cerebral palsy. *Arch Phys Med Rehabil*2016; 97(5):807-814 e802. doi:10.1016/j.apmr.2015.07.024.
57. Graser JV, Letsch C, van Hedel HJA. Reliability of timed walking tests and temporo-spatial gait parameters in youths with neurological gait disorders. *BMC Neurol*2016; 16:15. doi:10.1186/s12883-016-0538-y.
58. Oeffinger D, Bagley A, Rogers S, et al. Outcome tools used for ambulatory children with cerebral palsy: Responsiveness and minimum clinically important differences. *Dev Med Child Neurol*2008; 50(12):918-925. doi:10.1111/j.1469-8749.2008.03150.x.
59. Ostensjo S, Oien I, Fallang B. Goal-oriented rehabilitation of preschoolers with cerebral palsy--a multi-case study of combined use of the canadian occupational performance measure (COPM) and the goal attainment scaling (GAS). *Dev Neurorehabil*2008; 11(4):252-259. doi:10.1080/17518420802525500.
60. Lowing K, Bexelius A, Brogren Carlberg E. Activity focused and goal directed therapy for children with cerebral palsy--do goals make a difference? *Disabil Rehabil*2009; 31(22):1808-1816. doi:10.1080/09638280902822278.
61. Lowing K, Thews K, Haglund-Akerlind Y, Gutierrez-Farewik EM. Effects of botulinum toxin-a and goal-directed physiotherapy in children with cerebral palsy GMFCS levels I & II. *Phys Occup Ther Pediatr*2017; 37(3):268-282. doi:10.3109/01942638.2016.1150384.
62. Sorsdahl AB, Moe-Nilssen R, Kaale HK, Rieber J, Strand LI. Change in basic motor abilities, quality of movement and everyday activities following intensive, goal-directed, activity-focused physiotherapy in a group setting for children with cerebral palsy. *BMC Pediatr*2010; 10:26. doi:10.1186/1471-2431-10-26.
63. Willis C, Nyquist A, Jahnsen R, Elliott C, Ullenhag A. Enabling physical activity participation for children and youth with disabilities following a goal-directed, family-centred intervention. *Res Dev Disabil*2018; 77:30-39. doi:10.1016/j.ridd.2018.03.010.

64. Bleyenheuft Y, Ebner-Karestinos D, Surana B, et al. Intensive upper- and lower-extremity training for children with bilateral cerebral palsy: A quasi-randomized trial. *Dev Med Child Neurol*2017; 59(6):625-633. doi:10.1111/dmcn.13379.
65. Morgan C, Novak I, Dale RC, Guzzetta A, Badawi N. Single blind randomised controlled trial of GAME (goals - activity - motor enrichment) in infants at high risk of cerebral palsy. *Res Dev Disabil*2016; 55:256-267. doi:10.1016/j.ridd.2016.04.005.
66. Armstrong EL, Boyd RN, Horan SA, et al. Functional electrical stimulation cycling, goal-directed training, and adapted cycling for children with cerebral palsy: A randomized controlled trial. *Dev Med Child Neurol*2020; 62(12):1406-1413. doi:10.1111/dmcn.14648.
67. Araneda R, Klocker A, Ebner-Karestinos D, et al. Feasibility and effectiveness of HABIT-ILE in children aged 1 to 4 years with cerebral palsy: A pilot study. *Ann Phys Rehabil Med*2021; 64(3):101381. doi:10.1016/j.rehab.2020.03.006.
68. Novak I, Smithers-Sheedy H, Morgan C. Predicting equipment needs of children with cerebral palsy using the gross motor function classification system: A cross-sectional study. *Disabil Rehabil Assist Technol*2012; 7(1):30-36. doi:10.3109/17483107.2011.556210.
69. Shields N, Synnot A. Perceived barriers and facilitators to participation in physical activity for children with disability: A qualitative study. *BMC Pediatr*2016; 16:9. doi:10.1186/s12887-016-0544-7.
70. Chiarello LA, Palisano RJ, McCoy SW, et al. Child engagement in daily life: A measure of participation for young children with cerebral palsy. *Disabil Rehabil*2014; 36(21):1804-1816. doi:10.3109/09638288.2014.882417.
71. Khetani MA. Validation of environmental content in the young children's participation and environment measure. *Arch Phys Med Rehabil*2015; 96(2):317-322. doi:10.1016/j.apmr.2014.11.016.
72. Reedman SE, Boyd RN, Trost SG, Elliott C, Sakzewski L. Efficacy of participation-focused therapy on performance of physical activity participation goals and habitual physical activity in children with cerebral palsy: A randomized controlled trial. *Arch Phys Med Rehabil*2019; 100(4):676-686. doi:10.1016/j.apmr.2018.11.012.
73. Chrysagis N, Skordilis EK, Stavrou N, Grammatopoulou E, Koutsouki D. The effect of treadmill training on gross motor function and walking speed in ambulatory adolescents with cerebral palsy: A randomized controlled trial. *Am J Phys Med Rehabil*2012; 91(9):747-760. doi:10.1097/PHM.0b013e3182643eba.
74. Schindl MR, Forstner C, Kern H, Hesse S. Treadmill training with partial body weight support in nonambulatory patients with cerebral palsy. *Arch Phys Med Rehabil*2000; 81(3):301-306. doi:10.1016/s0003-9993(00)90075-3.
75. Swe NN, Sendhilnnathan S, van Den Berg M, Barr C. Over ground walking and body weight supported walking improve mobility equally in cerebral palsy: A randomised controlled trial. *Clin Rehabil*2015; 29(11):1108-1116. doi:10.1177/0269215514566249.
76. Cherng RJ, Liu CF, Lau TW, Hong RB. Effect of treadmill training with body weight support on gait and gross motor function in children with spastic cerebral palsy. *Am J Phys Med Rehabil*2007; 86(7):548-555. doi:10.1097/PHM.0b013e31806dc302.
77. Richards C, Malouin F, Dumas F, et al. Early and intensive treadmill locomotor training for young children with cerebral palsy: A feasibility study. *Pediatr Phys Ther*1997; 9(4):158-165.
78. MacCarthy M, Heyn P, Tagawa A, Carollo J. Walking speed and patient-reported outcomes in young adults with cerebral palsy. *Dev Med Child Neurol*2022; doi:10.1111/dmcn.15225.
79. Pirpiris M, Gates PE, McCarthy JJ, et al. Function and well-being in ambulatory children with cerebral palsy. *J Pediatr Orthop*2006; 26(1):119-124. doi:10.1097/01.bpo.0000191553.26574.27.
80. Verschuren O, Hulst RY, Voorman J, et al. 24-hour activity for children with cerebral palsy: A clinical practice guide. *Dev Med Child Neurol*2021; 63(1):54-59. doi:10.1111/dmcn.14654.
81. McLean LJ, Paleg GS, Livingstone RW. Supported-standing interventions for children and young adults with non-ambulant cerebral palsy: A scoping review. *Dev Med Child Neurol*2022; doi:10.1111/dmcn.15435.
82. Gannotti ME, Liquori BM, Thorpe DE, Fuchs RK. Designing exercise to improve bone health among individuals with cerebral palsy. *Pediatr Phys Ther*2021; 33(1):50-56. doi:10.1097/PEP.0000000000000765.

83. Pool D, Elliott C, Willis C, Thornton A. The experience of locomotor training from the perspectives of therapists and parents of children with cerebral palsy. *Frontiers in Rehabilitation Sciences*2021; 2. doi:10.3389/fresc.2021.740426.
84. Romeiser-Logan L, Slaughter R, Hickman R. Single-subject research designs in pediatric rehabilitation: A valuable step towards knowledge translation. *Dev Med Child Neurol*2017; 59(6):574-580. doi:10.1111/dmcn.13405.

Supplementary Materials: The Kindy Moves protocol paper,[42] Template for Intervention Description and Replication.


Enrolment
Assessed for eligibility (n=42)
Excluded (n=2):
Progressive neurodisability
T1: Baseline assessment
Commencement of intervention (n=40)
Discontinued intervention
(n=1): Hospitalisation
T2: Post-intervention assessment (n=39)
T3: Follow-up assessment (n=38)

Open access Protocol

BMJ Open

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

Dayna Pool ,[1,2] Catherine Elliott,[1,3] Healthy Strides Research Advisory Council

To cite: Pool D, Elliott C, Healthy Strides Research Advisory Council. 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. *BMJ Open* 2021;**11**:e046831. doi:10.1136/bmjopen-2020-046831

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-046831).

Received 10 November 2020
Accepted 03 August 2021

For numbered affiliations see end of article.

Correspondence to
Dr Dayna Pool;
Dayna.Pool@curtin.edu.au

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.

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

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.

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

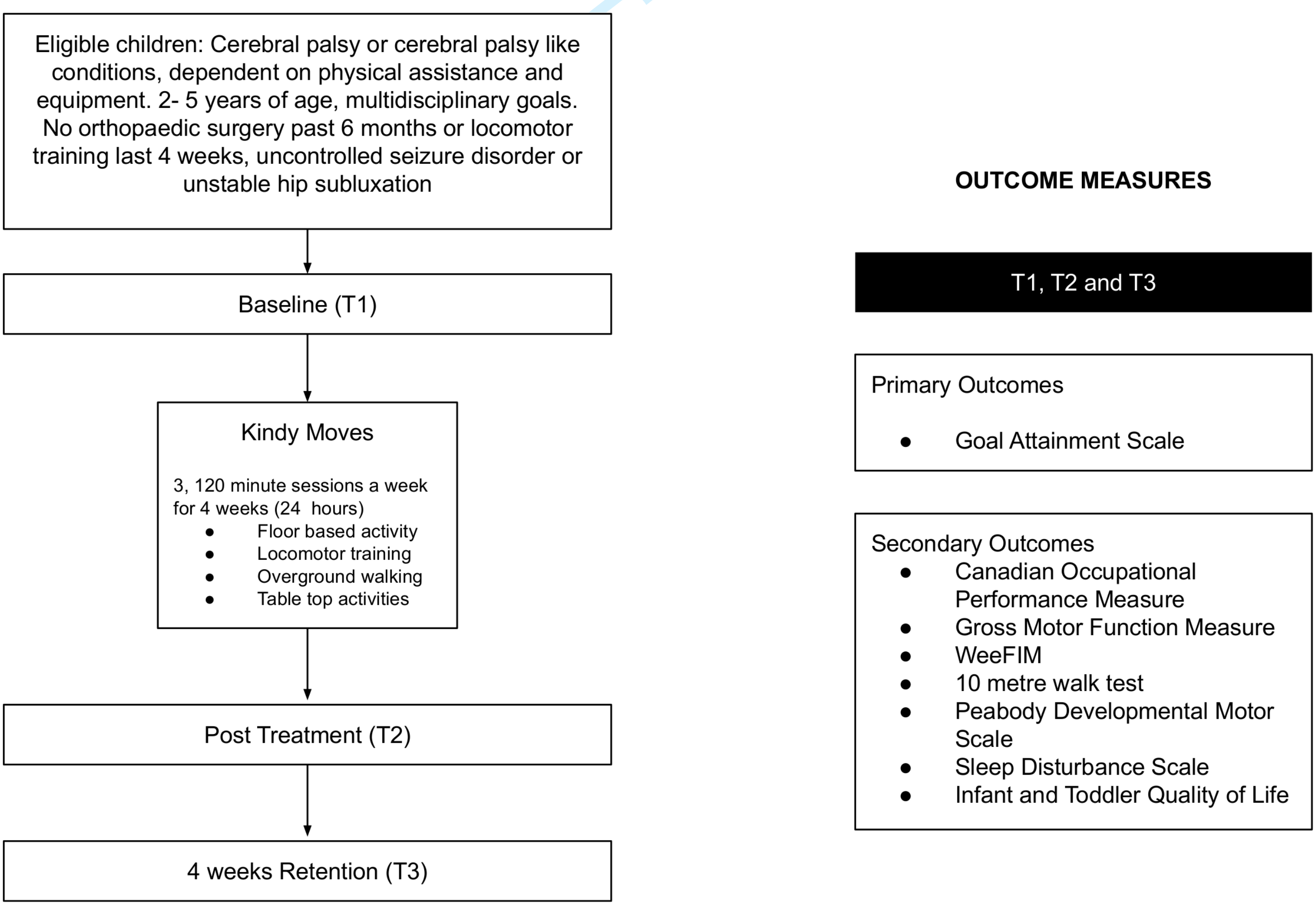


Figure 1 Study design and outcome measures. WeeFIM, Functional Independence Measure.

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.

Author affiliations
[1]School of Allied Health, Curtin University, Perth, Western Australia, Australia
[2]The Healthy Strides Foundation, Perth, Western Australia, Australia
[3]Telethon Institute for Child Health Research, Nedlands, Western Australia, Australia

Twitter Dayna Pool @daynapool

Acknowledgements The authors acknowledge the Healthy Strides Research Advisory Council for consulting and providing guidance on the development of the intervention.

Collaborators The Healthy Strides Research Advisory Council comprises of the Healthy Strides clinical team: Loren West, Corrin Walmsley, Georgia Hoffman, Marissa Smith, Eddie Pool, Meagan Smith, Georgina Jones, Matthew Haddon, Jordan Dinh and Bridget Chapman. Research Advisors: Dr Ashleigh Thornton, Dr Sue McCabe and Dr Claire Willis. Consumer Advisors: Ben O'Rourke, Noraishah Naim, Alishum Osman Ali.

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.

Funding This research was supported by the Telethon7 Trust 2019 and 2020.

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.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD
Dayna Pool http://orcid.org/0000-0001-8313-5661

REFERENCES

1 Human Early Learning Partnership & Commission on Social Determinants of Health. *Early child development : a powerful equalizer: final report for the World Health Organization's Commission on the Social Determinants of Health. / Prepared by Arjumand Siddiqi, Lori G. Irwin, Dr. Clyde Hertzman*. Vancouver: Human Early Learning Partnership, 2007.
2 Heckman JJ, Masterov DV. The productivity argument for investing in young children. *Rev Agri Econom* 2007;29:446–93.
3 Nores M, Barnett WS. Benefits of early childhood interventions across the world: (under) investing in the very young. *Econ Educ Rev* 2010;29:271–82.
4 Richter LM, Daelmans B, Lombardi J, *et al*. Investing in the foundation of sustainable development: pathways to scale up for early childhood development. *Lancet* 2017;389:103–18.
5 Goldfeld S, O'Connor E, O'Connor M, *et al*. The role of preschool in promoting children's healthy development: Evidence from an Australian population cohort. *Early Child Res Q* 2016;35:40–8.
6 Roberts G, Lim J, Doyle LW, *et al*. High rates of school readiness difficulties at 5 years of age in very preterm infants compared with term controls. *J Dev Behav Pediatr* 2011;32:117–24.
7 Gehrmann FE, Coleman A, Weir KA, *et al*. School readiness of children with cerebral palsy. *Dev Med Child Neurol* 2014;56:786–93.
8 Cairney J, Hay JA, Faught BE, *et al*. Developmental coordination disorder, generalized self-efficacy toward physical activity, and participation in organized and free play activities. *J Pediatr* 2005;147:515–20.
9 Van Hus JW, Potharst ES, Jeukens-Visser M, *et al*. Motor impairment in very preterm-born children: links with other developmental deficits at 5 years of age. *Dev Med Child Neurol* 2014;56:587–94.
10 Report of the Australian cerebral palsy register, birth years 1993-2009, 2016.
11 Palisano R, Rosenbaum P, Walter S, *et al*. Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Dev Med Child Neurol* 1997;39:214–23.
12 Palisano RJ, Hanna SE, Rosenbaum PL, *et al*. Validation of a model of gross motor function for children with cerebral palsy. *Phys Ther* 2000;80:974–85.
13 World Health Organization. Neurological disorders: public health challenges, 2006. Available: https://www.who.int/mental_health/neurology/neurological_disorders_report_web.pdf [Accessed 9 Nov 2020].
14 Smithers-Sheedy H, Badawi N, Blair E, *et al*. What constitutes cerebral palsy in the twenty-first century? *Dev Med Child Neurol* 2014;56:323–8.
15 Novak I, Honan I. Effectiveness of paediatric occupational therapy for children with disabilities: a systematic review. *Aust Occup Ther J* 2019;66:258–73.
16 Ostensjø S, Carlberg EB, Vøllestad NK. Everyday functioning in young children with cerebral palsy: functional skills, caregiver

assistance, and modifications of the environment. *Dev Med Child Neurol* 2003;45:603–12.
17 Cope S, Mohn-Johnsen S. The effects of dosage time and frequency on motor outcomes in children with cerebral palsy: a systematic review. *Dev Neurorehabil* 2017;20:376–87.
18 Bleyenheuft Y, Gordon AM. Hand-arm bimanual intensive therapy including lower extremities (HABIT-ILE) for children with cerebral palsy. *Phys Occup Ther Pediatr* 2014;34:390–403.
19 Størvold GV, Jahnsen RB, Evensen KAI, *et al*. Factors associated with enhanced gross motor progress in children with cerebral palsy: a register-based study. *Phys Occup Ther Pediatr* 2018;38:548–61.
20 Jackman M, Lannin N, Galea C, *et al*. What is the threshold dose of upper limb training for children with cerebral palsy to improve function? A systematic review. *Aust Occup Ther J* 2020;67:269–80.
21 Pool D, Valentine J, Taylor NF, *et al*. Locomotor and robotic assistive gait training for children with cerebral palsy. *Dev Med Child Neurol* 2021;63:328–35.
22 Geijen M, Ketelaar M, Sakzewski L, *et al*. Defining functional therapy in research involving children with cerebral palsy: a systematic review. *Phys Occup Ther Pediatr* 2020;40:231–46.
23 Novak I, Morgan C, Fahey M, *et al*. State of the evidence traffic lights 2019: systematic review of interventions for preventing and treating children with cerebral palsy. *Curr Neurol Neurosci Rep* 2020;20:3.
24 Jeglinsky I, Salminen A-L, Carlberg EB, *et al*. Rehabilitation planning for children and adolescents with cerebral palsy. *J Pediatr Rehabil Med* 2012;5:203–15.
25 Choi BCK, Pak AWP. Multidisciplinarity, interdisciplinarity and transdisciplinarity in health research, services, education and policy: 1. definitions, objectives, and evidence of effectiveness. *Clin Invest Med* 2006;29:351–64.
26 Soper AK, Cross A, Rosenbaum P, *et al*. Knowledge translation strategies to support service providers' implementation of the "F-words in Childhood Disability". *Disabil Rehabil* 2020;45:1–7.
27 Jan MMS. Cerebral palsy: comprehensive review and update. *Ann Saudi Med* 2006;26:123–32.
28 Trabacca A, Russo L, Losito L, *et al*. The ICF-CY perspective on the neurorehabilitation of cerebral palsy: a single case study. *J Child Neurol* 2012;27:183–90.
29 Glader L, Plews-Ogan J, Agrawal R. Children with medical complexity: creating a framework for care based on the International classification of functioning, disability and health. *Dev Med Child Neurol* 2016;58:1116–23.
30 Morgan C, Novak I, Dale RC, *et al*. Single blind randomised controlled trial of GAME (Goals - Activity - Motor Enrichment) in infants at high risk of cerebral palsy. *Res Dev Disabil* 2016;55:256–67.
31 Danger S, Landreth G. Child-centered group play therapy with children with speech difficulties. *Int J Play Ther* 2005;14:81–102.
32 Astramovich RL, Lyons C, Hamilton NJ. Play therapy for children with intellectual disabilities. *J Child Adolesc Couns* 2015;1:27–36.
33 Fauconnier J, Dickinson HO, Beckung E, *et al*. Participation in life situations of 8-12 year old children with cerebral palsy: cross sectional European study. *BMJ* 2009;338:b1458.
34 Michelsen SI, Flachs EM, Uldall P, *et al*. Frequency of participation of 8-12-year-old children with cerebral palsy: a multi-centre cross-sectional European study. *Eur J Paediatr Neurol* 2009;13:165–77.
35 Imms C. Children with cerebral palsy participate: a review of the literature. *Disabil Rehabil* 2008;30:1867–84.
36 Bleyenheuft Y, Arnould C, Brandao MB, *et al*. Hand and arm bimanual intensive therapy including lower extremity (HABIT-ILE) in children with unilateral spastic cerebral palsy: a randomized trial. *Neurorehabil Neural Repair* 2015;29:645–57.
37 Mutlu A, Krosschell K, Spira DG. Treadmill training with partial body-weight support in children with cerebral palsy: a systematic review. *Dev Med Child Neurol* 2009;51:268–75.
38 Peterson MD, Gordon PM, Hurvitz EA. Chronic disease risk among adults with cerebral palsy: the role of premature sarcopoenia, obesity and sedentary behaviour. *Obes Rev* 2013;14:171–82.
39 Willoughby KL, Dodd KJ, Shields N. A systematic review of the effectiveness of treadmill training for children with cerebral palsy. *Disabil Rehabil* 2009;31:1971–9.
40 Anderson DI, Campos JJ, Witherington DC, *et al*. The role of locomotion in psychological development. *Front Psychol* 2013;4:440.
41 Huang H-H, Chen C-L. The use of modified ride-on cars to maximize mobility and improve socialization-a group design. *Res Dev Disabil* 2017;61:172–80.
42 Ryan JM, Cassidy EE, Noorduyn SG, *et al*. Exercise interventions for cerebral palsy. *Cochrane Database Syst Rev* 2017;2017.
43 Fonzo M, Sirico F, Corrado B. Evidence-Based physical therapy for individuals with Rett syndrome: a systematic review. *Brain Sci* 2020;10:410.
44 Wheeler AC, Sacco P, Cabo R. Unmet clinical needs and burden in Angelman syndrome: a review of the literature. *Orphanet J Rare Dis* 2017;12:164.
45 Willoughby KL, Dodd KJ, Shields N, *et al*. Efficacy of partial body weight-supported treadmill training compared with overground walking practice for children with cerebral palsy: a randomized controlled trial. *Arch Phys Med Rehabil* 2010;91:333–9.
46 Dodd KJ, Foley S. Partial body-weight-supported treadmill training can improve walking in children with cerebral palsy: a clinical controlled trial. *Dev Med Child Neurol* 2007;49:101–5.
47 Day JA, Fox EJ, Lowe J, *et al*. Locomotor training with partial body weight support on a treadmill in a nonambulatory child with spastic tetraplegic cerebral palsy: a case report. *Pediatr Phys Ther* 2004;16:106–13.
48 Schindl MR, Forstner C, Kern H, *et al*. Treadmill training with partial body weight support in nonambulatory patients with cerebral palsy. *Arch Phys Med Rehabil* 2000;81:301–6.
49 Verschuren O, Helders PJM, Mattern-Baxter K. Effects of intensive locomotor treadmill training on young children with cerebral palsy. *Pediatr Phys Ther* 2009;21:319–19.
50 Valentín-Gudiol M, Mattern-Baxter K, Girabent-Farrés M, *et al*. Treadmill interventions in children under six years of age at risk of neuromotor delay. *Cochrane Database Syst Rev* 2017;7:Cd009242.
51 Ginsburg KR, American Academy of Pediatrics Committee on Communications, American Academy of Pediatrics Committee on Psychosocial Aspects of Child and Family Health. The importance of play in promoting healthy child development and maintaining strong parent-child bonds. *Pediatrics* 2007;119:182–91.
52 Novak I, McIntyre S, Morgan C, *et al*. A systematic review of interventions for children with cerebral palsy: state of the evidence. *Dev Med Child Neurol* 2013;55:885–910.
53 Patel DR. Therapeutic interventions in cerebral palsy. *Indian J Pediatr* 2005;72:979–83.
54 Mickan SM. Evaluating the effectiveness of health care teams. *Aust Health Rev* 2005;29:211–7.
55 Damiano DL, DeJong SL. A systematic review of the effectiveness of treadmill training and body weight support in pediatric rehabilitation. *J Neurol Phys Ther* 2009;33:27–44.
56 Bowen DJ, Kreuter M, Spring B, *et al*. How we design feasibility studies. *Am J Prev Med* 2009;36:452–7.
57 Rosenbaum P, Gorter JW. The 'F-words' in childhood disability: I swear this is how we should think! *Child Care Health Dev* 2012;38:457–63.
58 Turner-Stokes L. Goal attainment scaling (GAS) in rehabilitation: a practical guide. *Clin Rehabil* 2009;23:362–70.
59 Carswell A, McColl MA, Baptiste S, *et al*. The Canadian occupational performance measure: a research and clinical literature review. *Can J Occup Ther* 2004;71:210–22.
60 Booth ATC, Buizer AI, Meyns P, *et al*. The efficacy of functional gait training in children and young adults with cerebral palsy: a systematic review and meta-analysis. *Dev Med Child Neurol* 2018;60:866–83.
61 Ottenbacher KJ, Msall ME, Lyon N, *et al*. The WeeFIM instrument: its utility in detecting change in children with developmental disabilities. *Arch Phys Med Rehabil* 2000;81:1317–26.
62 Wang H-H, Liao H-F, Hsieh C-L. Reliability, sensitivity to change, and responsiveness of the peabody developmental motor scales-second edition for children with cerebral palsy. *Phys Ther* 2006;86:1351–9.
63 Romeo DM, Brogna C, Musto E, *et al*. Sleep disturbances in preschool age children with cerebral palsy: a questionnaire study. *Sleep Med* 2014;15:1089–93.
64 Spuijbroek AT, Oostenbrink R, Landgraf JM, *et al*. Health-related quality of life in preschool children in five health conditions. *Qual Life Res* 2011;20:779–86.
65 Bleyenheuft Y, Ebner-Karestinos D, Surana B, *et al*. Intensive upper- and lower-extremity training for children with bilateral cerebral palsy: a quasi-randomized trial. *Dev Med Child Neurol* 2017;59:625–33.
66 Palisano RJ, Rosenbaum P, Bartlett D, *et al*. Content validity of the expanded and revised gross motor function classification system. *Dev Med Child Neurol* 2008;50:744–50.
67 Eliasson A-C, Krumlinde-Sundholm L, Rösblad B, *et al*. The manual ability classification system (MACS) for children with cerebral palsy: scale development and evidence of validity and reliability. *Dev Med Child Neurol* 2006;48:549–54.
68 Hidecker MJC, Cunningham BJ, Thomas-Stonell N, *et al*. Validity of the communication function classification system for use with preschool children with communication disorders. *Dev Med Child Neurol* 2017;59:526–30.
69 Graham HK, Harvey A, Rodda J, *et al*. The functional mobility scale (FMS). *J Pediatr Orthop* 2004;24:514–20.

70 Livingstone R, Paleg G. Measuring outcomes for children with cerebral palsy who use gait trainers. *Technology* 2016;4:1–19.
71 Cusick A, McIntyre S, Novak I, *et al*. A comparison of goal attainment scaling and the Canadian occupational performance measure for paediatric rehabilitation research. *Pediatr Rehabil* 2006;9:149–57.
72 Novak I, Cusick A, Lannin N. Occupational therapy home programs for cerebral palsy: double-blind, randomized, controlled trial. *Pediatrics* 2009;124:e606–14.
73 Meyer-Heim A, Borggraefe I, Ammann-Reiffer C, *et al*. Feasibility of robotic-assisted locomotor training in children with central gait impairment. *Dev Med Child Neurol* 2007;49:900–6.
74 Mattern-Baxter K. Effects of partial body weight supported treadmill training on children with cerebral palsy. *Pediatr Phys Ther* 2009;21:12–22.
75 Romeo DM, Bruni O, Brogna C, *et al*. Application of the sleep disturbance scale for children (SDSC) in preschool age. *Eur J Paediatr Neurol* 2013;17:374–82.
76 Russell DJ, Avery LM, Rosenbaum PL, *et al*. Improved scaling of the gross motor function measure for children with cerebral palsy: evidence of reliability and validity. *Phys Ther* 2000;80:873–85.
77 Wang H-Y, Yang YH. Evaluating the responsiveness of 2 versions of the gross motor function measure for children with cerebral palsy. *Arch Phys Med Rehabil* 2006;87:51–6.
78 Ko J. Sensitivity to functional improvements of GMFM-88, GMFM-66, and PEDI mobility scores in young children with cerebral palsy. *Percept Mot Skills* 2014;119:305–19.
79 Behrman AL, Harkema SJ. Spinal Cord Injury Special Series Locomotor Training After Human Spinal Cord Injury : A Series of Case Studies. *Physical Therapy* 2000;80:688–700.
80 Imms C, Granlund M, Wilson PH, *et al*. Participation, both a means and an end: a conceptual analysis of processes and outcomes in childhood disability. *Dev Med Child Neurol* 2017;59:16–25.
81 Guba EG. Criteria for assessing the trustworthiness of naturalistic inquiries. *Educ Comm Technol J* 1981;29:75–91.
82 Smith B, McGannon KR. Developing rigor in qualitative research: problems and opportunities within sport and exercise psychology. *Int Rev Sport Exerc Psychol* 2018;11:101–21.
83 Portney LG, Watkins MP. *Foundations of clinical research: applications to practice*. 3rd edn. New Jersey: Person Prentice Hall, 2009.
84 Barwick M. Building scientist capacity in knowledge translation: development of the knowledge translation planning template. *Technol Innov Manage Rev* 2016;6:9–15.

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.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3-4
	2b	Specific objectives or research questions for pilot trial	4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	5
	4c	How participants were identified and consented	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	4-6
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	4-6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	6
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4, 6
	14b	Why the pilot trial ended or was stopped	4, 5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6-7
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	7-8
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	7-8
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	6-8
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	6
	19a	If relevant, other important unintended consequences	6
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	11-12
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	10-14
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	10-13
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	8-12
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	2
Protocol	24	Where the pilot trial protocol can be accessed, if available	14, 17
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	12
	26	Ethical approval or approval by research review committee, confirmed with reference number	4

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of study as randomised pilot or feasibility trial	p1 line 1
Authors *	Contact details for the corresponding author	P1 line 14-18
Trial design	Description of pilot trial design (eg, parallel, cluster)	5
Methods		
Participants	Eligibility criteria for participants and the settings where the pilot trial was conducted	6-11
Interventions	Interventions intended for each group	12-14
Objective	Specific objectives of the pilot trial	2-4
Outcome	Prespecified assessment or measurement to address the pilot trial objectives**	15-19
Randomization	How participants were allocated to interventions	N/A
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	N/A
Results		
Numbers randomized	Number of participants screened and randomised to each group for the pilot trial objectives**	7
Recruitment	Trial status†	
Numbers analysed	Number of participants analysed in each group for the pilot objectives**	7
Outcome	Results for the pilot objectives, including any expressions of uncertainty**	20-25
Harms	Important adverse events or side effects	25
Conclusions	General interpretation of the results of pilot trial and their implications for the future definitive trial	26-28
Trial registration	Registration number for pilot trial and name of trial register	29
Funding	Source of funding for pilot trial	P12 line 42

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

**this item is specific to conference abstracts*

***Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those that are a priori agreed as the most important to the decision to proceed with the future definitive RCT.*

†For conference abstracts.

BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-068816.R2
Article Type:	Original research
Date Submitted by the Author:	31-Mar-2023
Complete List of Authors:	Haddon, Matthew; The Healthy Strides Foundation, West, Loren; The Healthy Strides Foundation Elliott, Catherine; Curtin University, School of Allied Health; Telethon Kids Institute Walmsley, Corrin; The Healthy Strides Foundation Valentine, Jane; Perth Children's Hospital, Paediatric Rehabilitation; Telethon Kids Institute Bear, Natasha; Child and Adolescent Health Service Healthy Strides Research Advisory Council, .; The Healthy Strides Foundation Pool, Dayna; Curtin University, School of Occupational Therapy Social Work and Speech Pathology; The Healthy Strides Foundation,
Primary Subject Heading:	Paediatrics
Secondary Subject Heading:	Rehabilitation medicine, Sports and exercise medicine, Evidence based practice
Keywords:	Developmental neurology & neurodisability < PAEDIATRICS, Neurological injury < NEUROLOGY, Clinical trials < THERAPEUTICS

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

Authors: Haddon M[1], West L[1], Elliott C PhD[2&3], Walmsley CP PhD[1], Valentine J FRACP PhD[3&4], Bear N[5], Healthy Strides Research Advisory Council[1], Pool D PhD[1&2]

1. The Healthy Strides Foundation, Perth, Western Australia, 6101
2. School of Allied Health, Curtin University, Perth, Western Australia, 6027
3. Telethon Kids Institute, Perth, Western Australia, Western Australia, 6009
4. Perth Children's Hospital, Child and Adolescent Health Service, Perth, Western Australia, 6009
5. Child and Adolescent Health Service, Perth, Western Australia, 6009

Corresponding author details:
Mr Matthew Haddon – matthew.haddon@health.wa.gov.au
Contact number – +8 0404315015
ORCID ID – 0000-0003-2795-902X
Postal address – Suite 23/954 Albany Hwy, East Victoria Park WA 6101.

Word length for main text excluding reference, abstract and tables: 6132
Word length for abstract: 300
Number of references: 84
Number of tables: 2
Number of figures: 2

Abstract

Objectives: To determine the feasibility of an intensive interdisciplinary program 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 to 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 six months, unstable hip subluxation, uncontrolled seizure disorder, or treadmill training in the past month.

Intervention: A goal-directed program of three two-hour sessions per week for four 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 pre-intervention (T1) to post-intervention (T2) and four-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 (MD 27.7, 95% CI 25.8-29.5) as well as COPM performance (MD 3.2, 95% CI 2.8-3.6) and satisfaction (MD 3.3, 95% CI 2.8-3.8). The GMFM-66 (MD 2.3, 95% CI 1.0-3.5) and 10MWT (median difference -2.3, 95% CI -28.8-0.0) 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 program is feasible in improving goal and motor outcomes for preschool children with neurodisabilities (GMFCS III-V). A randomised controlled trial is warranted to establish efficacy.

Trial registration: Australian New Zealand Clinical Trials Registry (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 program 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 program makes it difficult to differentiate the effects of individual elements of the program.
- 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 syndrome.[6] Cerebral palsy 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] Cerebral palsy 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 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 to 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] Locomotor treadmill training 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 four weeks[27] to three 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 six weeks in 5 to 12 year old children with CP (GMFCS III-V),[33] and following 14 hours of treadmill training in 1 to 5 year old pre-ambulatory children 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 program 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 (i.e. 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 to 5 years were recruited. Participants undertook four weeks of intervention, completing a two-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 two weeks before the intervention (T1) to the week following intervention completion (T2) and at follow-up four weeks post-intervention (T3). The shorter four-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 two-year timeframe. 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 upon 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 CONSORT 2010 statement: extension to randomised pilot and feasibility trials.[43, 44] Approval for this study was obtained by the Human Research Ethics Committee of Curtin University (Approval number: HRE2019-0073) and written informed consent was received by the participants' primary caregivers.

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 six months of the study, unstable hip subluxation, uncontrolled seizure disorder, or engagement in LTT in the month prior to the study. A semi-structured 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 two-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 (Supplementary Material 1).[42] Kindy Moves is an intensive program 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 two-hour sessions per week for four weeks (24 hours of therapy). Locomotor treadmill training was a large focus of the program, 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 practiced 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 two-hour intervention was separated into 30 minutes of floor time as a group to practice gross motor, socialisation and play skills through games, songs, and book reading. This was followed by one hour of LTT, separated into 30 minutes of partial body weight supported treadmill training (Figure 1) and 30 minutes of overground walking in a mobility device which was designed based upon 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 minutes 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 the supplementary materials (Supplementary Material 2).

Figure 1. Treadmill Training.

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 two 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 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 World Health Organization'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-metre distance. Facilitation of one step was provided for children who did not initiate stepping after 30 seconds.[33] If a child did not complete the 10-metre distance in 360 seconds, this time was recorded as the maximal result.[33] The clinically meaningful change in 10MWT speed is 0.1m/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 5 to 12 year old children 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 standard deviations for continuous data, or medians and interquartile ranges 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% confidence intervals (CI). The Smithers-Sheedy et al[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 sub-domains 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. Upon review of their pre-intervention 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 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%).

Figure 2. 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-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)

Abbreviations: GMFCS, Gross Motor Function Classification System[10]; MACS, Manual Ability Classification System[46]; CFCS, Communication Function Classification System[45]; COPM, Canadian Occupational Performance Measure[47]; GAS, Goal Attainment Scaling.[49]

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 two-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 eight hours. All outcomes measured were assessed as per the study protocol, however, 18 participants could not complete the 10MWT within the designated 360 seconds 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 post-intervention 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 post-intervention 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.

Table 2. Outcome Measure Changes Across All Time Points.

Outcome	Assessment Time Point Mean (SD)			Outcome Measure Changes Mean Difference (95% CI)		
	T1	T2	T3	T2 vs T1	T3 vs T1	T3 vs T2
GAS t-score	20.2	47.9	51.1	27.7	30.9	3.3

	(1.4) n=39	(5.5) n=39	(7.0) n=38	(25.8 to 29.5)	(29.1 to 32.8)	(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 (secs)	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)

Abbreviations: T1, Baseline; T2, Post-Intervention; T3, Follow-up; GAS, Goal Attainment Scaling[49]; COPM, Canadian Occupational Performance Measure[47]; GMFM-66, 66-item Gross Motor Function Measure[54]; 10MWT, 10-Metre Walk Test.[57]

DISCUSSION

Feasibility

This study aimed to determine if implementing Kindy Moves, a four-week intensive LTT program 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, GMFM-66, and 10MWT. These improvements were largely maintained four weeks after program 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 program in 2 to 5 year old children 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 to 5 years old 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 to 5 years being less frequently completed.[67] Data exploring the retention of outcomes in a period after program completion is important in establishing the extent of real-life skill application. Goal performance and satisfaction remained high four 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 programs 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 post-intervention (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 co-morbidities while bringing to light assessment considerations that may reduce the burden of time on families.

Over a 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 learned.[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 learned 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 program. 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 co-morbidities 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 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 to 2.3 years who completed 40 to 50 hours of therapy over four months.[77] Despite being a promising pilot study,[77] it is probable that natural maturation affected the results in the four-month intervention, particularly at an age of rapid motor development. To account for this in Kindy Moves, a shorter intervention timeframe and only a four-week follow-up period were selected. Although longer follow-up periods beyond three 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. Additionally, 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 post-intervention 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 seconds. This was particularly evident in children functioning within GMFCS levels IV-V (or equivalent). The 6-Minute 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 learned 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 post-intervention 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 programs 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 wellbeing 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 four weeks (12 hours total),[27] whereas others have explored up to three 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 to 4 years resulted in goal and gross motor improvements after 50 hours of therapy over two weeks.[67] The outcomes of Kindy Moves highlight improvements in goals and motor function after 24 hours of therapy across four 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 to 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. Firstly, 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 program 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. Additionally, 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. Firstly, 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 post-intervention 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 program satisfaction and acceptability. To reduce the possibility of a ceiling effect, the 6-Minute 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 semi-structured 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 co-morbidities 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 program 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 program 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.

Acknowledgements: The authors acknowledge the Healthy Strides Research Advisory Council for consulting and providing guidance on the development of the intervention.

Collaborators: The Healthy Strides Research Advisory Council comprises of the Healthy Strides clinical team: Dr Dayna Pool, Loren West, Dr Corrin Walmsley, Georgia Hoffman, Marissa Smith, Eddie Pool, Meagan Smith, Georgina Jones, Matthew Haddon, Jordan Dinh and Bridget Chapman. Research Advisors: Dr Ashleigh Thornton, Dr Sue McCabe, and Dr Claire Willis. Consumer Advisors: Ben O'Rourke, Noraishah Naim.

Author Contributions: 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 co-developed 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 conceptualised, planned, developed, and wrote the study protocol.

Funding Statement: This work has been supported by the Telethon7 Trust 2019 and 2020. Award/Grant number is not applicable.

Competing Interests Statements: None declared.

Patient Consent: Consent was provided for the inclusion of Figure 1 in the paper through the BMJ Patient Consent Form.

Data Sharing: Data can be made available for research purposes upon request.

Reporting Checklist Flow Diagram: The CONSORT 2010 statement: extension to randomised pilot and feasibility studies.[40]

Ethics Approval: Approval for this study was obtained by the Human Research Ethics Committee of Curtin University (Approval number: HRE2019-0073) and written informed consent was received by the participants' primary caregivers.

REFERENCES

1. Jackman M, Sakzewski L, Morgan C, et al. Interventions to improve physical function for children and young people with cerebral palsy: International clinical practice guideline. *Dev Med Child Neurol*2021; 64(5):536-549. doi:10.1111/dmcn.15055.
2. Morgan C, Fetters L, Adde L, et al. Early intervention for children aged 0 to 2 years with or at high risk of cerebral palsy: International clinical practice guideline based on systematic reviews. *JAMA Pediatr*2021; 175(8):846-858. doi:10.1001/jamapediatrics.2021.0878.
3. Damiano DL, Longo E. Early intervention evidence for infants with or at risk for cerebral palsy: An overview of systematic reviews. *Dev Med Child Neurol*2021; 63(7):771-784. doi:10.1111/dmcn.14855.
4. Novak I, Morgan C, Fahey M, et al. State of the evidence traffic lights 2019: Systematic review of interventions for preventing and treating children with cerebral palsy. *Curr Neurol Neurosci Rep*2020; 20(2):3. doi:10.1007/s11910-020-1022-z.
5. Novak I, Honan I. Effectiveness of paediatric occupational therapy for children with disabilities: A systematic review. *Aust Occup Ther J*2019; 66(3):258-273. doi:10.1111/1440-1630.12573.
6. Morris C, Janssens A, Tomlinson R, Williams J, Logan S. Towards a definition of neurodisability: A delphi survey. *Dev Med Child Neurol*2013; 55(12):1103-1108. doi:10.1111/dmcn.12218.
7. Cans C. Surveillance of cerebral palsy in Europe: A collaboration of cerebral palsy surveys and registers. *Dev Med Child Neurol*2000; 42(12):816-824. doi:10.1017/s0012162200001511.
8. Smithers-Sheedy H, Badawi N, Blair E, et al. What constitutes cerebral palsy in the twenty-first century? *Dev Med Child Neurol*2014; 56(4):323-328. doi:10.1111/dmcn.12262.
9. Novak I, Hines M, Goldsmith S, Barclay R. Clinical prognostic messages from a systematic review on cerebral palsy. *Pediatrics*2012; 130(5):e1285-1312. doi:10.1542/peds.2012-0924.
10. Palisano R, Rosenbaum P, Walter S, et al. Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Dev Med Child Neurol*1997; 39(4):214-223. doi:10.1111/j.1469-8749.1997.tb07414.x.
11. Australian Cerebral Palsy Register Group. Australia and the Australian cerebral palsy register for the birth cohort 1993 to 2006. *Dev Med Child Neurol*2016; 58 Suppl 2:3-4. doi:10.1111/dmcn.13002.
12. Imms C, Granlund M, Wilson PH, et al. Participation, both a means and an end: A conceptual analysis of processes and outcomes in childhood disability. *Dev Med Child Neurol*2017; 59(1):16-25. doi:10.1111/dmcn.13237.
13. Aviram R, Harries N, Shkedy Rabani A, et al. Comparison of habitual physical activity and sedentary behavior in adolescents and young adults with and without cerebral palsy. *Pediatr Exerc Sci*2019; 31(1):60-66. doi:10.1123/pes.2017-0285.
14. Fauconnier J, Dickinson HO, Beckung E, et al. Participation in life situations of 8-12 year old children with cerebral palsy: Cross sectional European study. *BMJ*2009; 338:b1458. doi:10.1136/bmj.b1458.

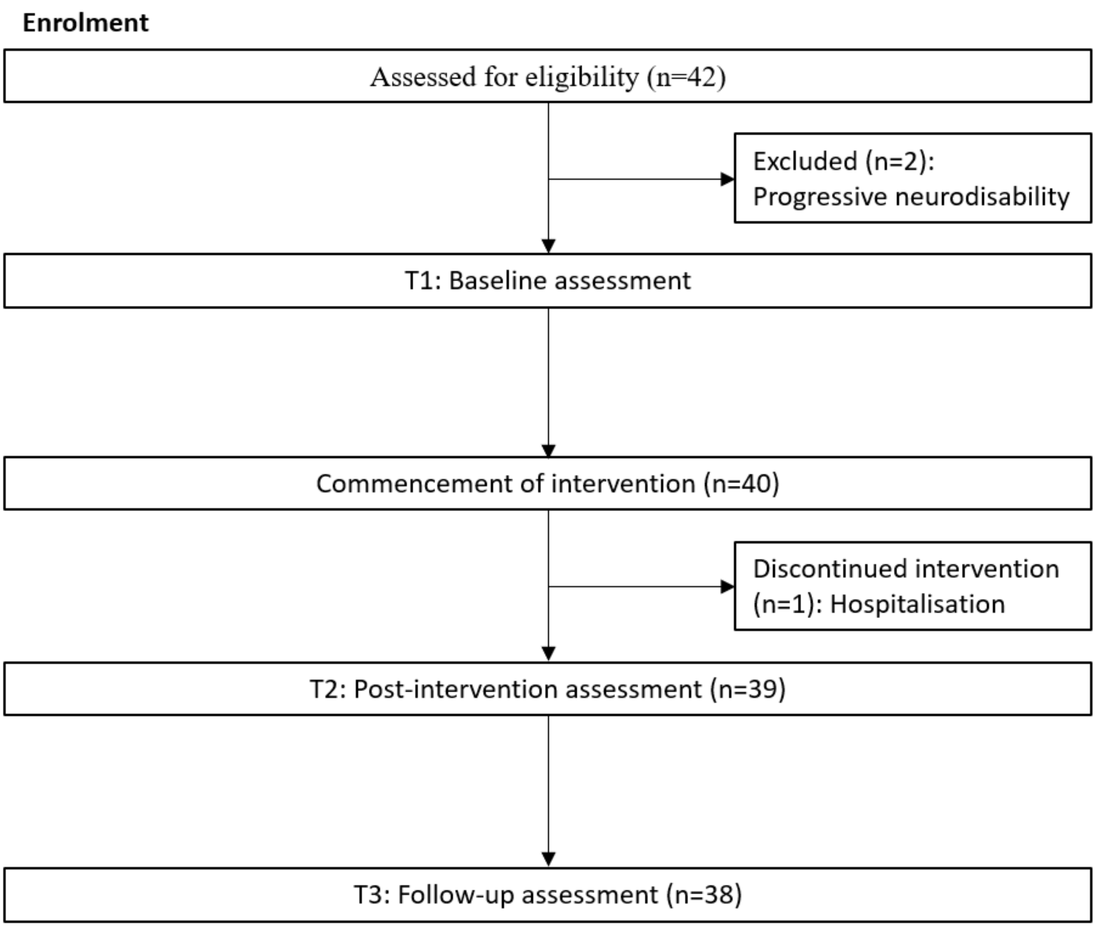
15. Imms C. Children with cerebral palsy participate: A review of the literature. *Disabil Rehabil*2008; 30(24):1867-1884. doi:10.1080/09638280701673542.
16. Shkedy Rabani A, Harries N, Namoora I, et al. Duration and patterns of habitual physical activity in adolescents and young adults with cerebral palsy. *Dev Med Child Neurol*2014; 56(7):673-680. doi:10.1111/dmcn.12394.
17. Peterson MD, Gordon PM, Hurvitz EA. Chronic disease risk among adults with cerebral palsy: The role of premature sarcopoenia, obesity and sedentary behaviour. *Obes Rev*2013; 14(2):171-182. doi:10.1111/j.1467-789X.2012.01052.x.
18. Ryan JM, Cassidy EE, Noorduyn SG, O'Connell NE. Exercise interventions for cerebral palsy. *Cochrane Database Syst Rev*2017; 6:CD011660. doi:10.1002/14651858.CD011660.pub2.
19. Gross PH, Bailes AF, Horn SD, et al. Setting a patient-centered research agenda for cerebral palsy: A participatory action research initiative. *Dev Med Child Neurol*2018; 60(12):1278-1284. doi:10.1111/dmcn.13984.
20. Byrne R, Noritz G, Maitre NL, NCH Early Developmental Group. Implementation of early diagnosis and intervention guidelines for cerebral palsy in a high-risk infant follow-up clinic. *Pediatr Neurol*2017; 76:66-71. doi:10.1016/j.pediatrneurol.2017.08.002.
21. Johnston MV, Ishida A, Ishida WN, et al. Plasticity and injury in the developing brain. *Brain Dev*2009; 31(1):1-10. doi:10.1016/j.braindev.2008.03.014.
22. Yang JF, Livingstone D, Brunton K, et al. Training to enhance walking in children with cerebral palsy: Are we missing the window of opportunity? *Semin Pediatr Neurol*2013; 20(2):106-115. doi:10.1016/j.spen.2013.06.011.
23. Daelmans B, Darmstadt GL, Lombardi J, et al. Early childhood development: The foundation of sustainable development. *Lancet*2017; 389(10064):9-11. doi:10.1016/S0140-6736(16)31659-2.
24. Richter LM, Daelmans B, Lombardi J, et al. Investing in the foundation of sustainable development: Pathways to scale up for early childhood development. *Lancet*2017; 389(10064):103-118. doi:10.1016/S0140-6736(16)31698-1.
25. Rosenbaum PL, Walter SD, Hanna SE, et al. Prognosis for gross motor function in cerebral palsy: Creation of motor development curves. *JAMA*2002; 288(11):1357-1363. doi:10.1001/jama.288.11.1357.
26. Hanna SE, Bartlett DJ, Rivard LM, Russell DJ. Reference curves for the gross motor function measure: Percentiles for clinical description and tracking over time among children with cerebral palsy. *Phys Ther*2008; 88(5):596-607. doi:10.2522/ptj.20070314.
27. Mattern-Baxter K, Bellamy S, Mansoor JK. Effects of intensive locomotor treadmill training on young children with cerebral palsy. *Pediatr Phys Ther*2009; 21(4):308-318. doi:10.1097/PEP.0b013e3181bf53d9.
28. Gehrmann FE, Coleman A, Weir KA, Ware RS, Boyd RN. School readiness of children with cerebral palsy. *Dev Med Child Neurol*2014; 56(8):786-793. doi:10.1111/dmcn.12377.
29. Choi BC, Pak AW. Multidisciplinarity, interdisciplinarity and transdisciplinarity in health research, services, education and policy: 1. Definitions, objectives, and evidence of effectiveness. *Clin Invest Med*2006; 29(6):351-364. Available from: https://www.ncbi.nlm.nih.gov/pubmed/17330451.
30. Dodd KJ, Foley S. Partial body-weight-supported treadmill training can improve walking in children with cerebral palsy: A clinical controlled trial. *Dev Med Child Neurol*2007; 49(2):101-105. doi:10.1111/j.1469-8749.2007.00101.x.
31. Mattern-Baxter K. Locomotor treadmill training for children with cerebral palsy. *Orthop Nurs*2010; 29(3):169-173; quiz 174-165. doi:10.1097/NOR.0b013e3181db5441.
32. Willoughby KL, Dodd KJ, Shields N. A systematic review of the effectiveness of treadmill training for children with cerebral palsy. *Disabil Rehabil*2009; 31(24):1971-1979. doi:10.3109/09638280902874204.
33. Pool D, Valentine J, Taylor NF, Bear N, Elliott C. Locomotor and robotic assistive gait training for children with cerebral palsy. *Dev Med Child Neurol*2021; 63(3):328-335. doi:10.1111/dmcn.14746.
34. Valentin-Gudiol M, Mattern-Baxter K, Girabent-Farres M, et al. Treadmill interventions in children under six years of age at risk of neuromotor delay. *Cochrane Database Syst Rev*2017; 7:CD009242. doi:10.1002/14651858.CD009242.pub3.

35. Tinderholt Myrhaug H, Ostensjo S, Larun L, Odgaard-Jensen J, Jahnsen R. Intensive training of motor function and functional skills among young children with cerebral palsy: A systematic review and meta-analysis. *BMC Pediatr*2014; 14:292. doi:10.1186/s12887-014-0292-5.
36. Jackman M, Lannin N, Galea C, et al. What is the threshold dose of upper limb training for children with cerebral palsy to improve function? A systematic review. *Aust Occup Ther J*2020; 67(3):269-280. doi:10.1111/1440-1630.12666.
37. Bryant E, Pountney T, Williams H, Edelman N. Can a six-week exercise intervention improve gross motor function for non-ambulant children with cerebral palsy? A pilot randomized controlled trial. *Clin Rehabil*2013; 27(2):150-159. doi:10.1177/0269215512453061.
38. Mattern-Baxter K, McNeil S, Mansoor JK. Effects of home-based locomotor treadmill training on gross motor function in young children with cerebral palsy: A quasi-randomized controlled trial. *Arch Phys Med Rehabil*2013; 94(11):2061-2067. doi:10.1016/j.apmr.2013.05.012.
39. Mattern-Baxter K. Analysis of a group-based treadmill program for children with neuromotor delay who are pre-ambulatory. *Phys Occup Ther Pediatr*2021; 41(3):271-283. doi:10.1080/01942638.2020.1834055.
40. Kleim JA, Jones TA. Principles of experience-dependent neural plasticity: Implications for rehabilitation after brain damage. *J Speech Lang Hear Res*2008; 51(1):S225-239. doi:10.1044/1092-4388(2008/018).
41. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med*2009; 36(5):452-457. doi:10.1016/j.amepre.2009.02.002.
42. Pool D, Elliott C, Healthy Strides Research Advisory Council. 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. *BMJ Open*2021; 11(8):e046831. doi:10.1136/bmjopen-2020-046831.
43. Eldridge SM, Chan CL, Campbell MJ, et al. Consort 2010 statement: Extension to randomised pilot and feasibility trials. *BMJ*2016; 355:i5239. doi:10.1136/bmj.i5239.
44. Lancaster GA, Thabane L. Guidelines for reporting non-randomised pilot and feasibility studies. *Pilot Feasibility Stud*2019; 5:114. doi:10.1186/s40814-019-0499-1.
45. Hidecker MJ, Cunningham BJ, Thomas-Stonell N, Oddson B, Rosenbaum P. Validity of the communication function classification system for use with preschool children with communication disorders. *Dev Med Child Neurol*2017; 59(5):526-530. doi:10.1111/dmcn.13373.
46. Eliasson AC, Krumlinde-Sundholm L, Rosblad B, et al. The manual ability classification system (MACS) for children with cerebral palsy: Scale development and evidence of validity and reliability. *Dev Med Child Neurol*2006; 48(7):549-554. doi:10.1017/S0012162206001162.
47. Law M, Baptiste S, McColl M, et al. The canadian occupational performance measure: An outcome measure for occupational therapy. *Can J Occup Ther*1990; 57(2):82-87. doi:10.1177/000841749005700207.
48. Cusick A, Lannin NA, Lowe K. Adapting the canadian occupational performance measure for use in a paediatric clinical trial. *Disabil Rehabil*2007; 29(10):761-766. doi:10.1080/09638280600929201.
49. Kiresuk TJ, Sherman RE. Goal attainment scaling: A general method for evaluating comprehensive community mental health programs. *Community Ment Health J*1968; 4(6):443-453. doi:10.1007/BF01530764.
50. World Health Organization. International classification of functioning, disability and health: ICF. Geneva, Switzerland; 2001. p.
51. Livingstone R, Paleg G. Measuring outcomes for children with cerebral palsy who use gait trainers. *Technologies*2016; 4:1-19. doi:10.3390/technologies4030022.
52. Cusick A, McIntyre S, Novak I, Lannin N, Lowe K. A comparison of goal attainment scaling and the canadian occupational performance measure for paediatric rehabilitation research. *Pediatr Rehabil*2006; 9(2):149-157. doi:10.1080/13638490500235581.
53. Harpster K, Sheehan A, Foster EA, et al. The methodological application of goal attainment scaling in pediatric rehabilitation research: A systematic review. *Disabil Rehabil*2019; 41(24):2855-2864. doi:10.1080/09638288.2018.1474952.
54. Russell DJ, Avery LM, Rosenbaum PL, et al. Improved scaling of the gross motor function measure for children with cerebral palsy: Evidence of reliability and validity. *Phys Ther*2000; 80(9):873-885. Available from: https://www.ncbi.nlm.nih.gov/pubmed/10960935.

55. Ko J. Sensitivity to functional improvements of GMFM-88, GMFM-66, and PEDI mobility scores in young children with cerebral palsy. *Percept Mot Skills*2014; 119(1):305-319. doi:10.2466/03.25.PMS.119c14z1.
56. Marois P, Marois M, Pouliot-Laforte A, et al. Gross motor function measure evolution ratio: Use as a control for natural progression in cerebral palsy. *Arch Phys Med Rehabil*2016; 97(5):807-814 e802. doi:10.1016/j.apmr.2015.07.024.
57. Graser JV, Letsch C, van Hedel HJA. Reliability of timed walking tests and temporo-spatial gait parameters in youths with neurological gait disorders. *BMC Neurol*2016; 16:15. doi:10.1186/s12883-016-0538-y.
58. Oeffinger D, Bagley A, Rogers S, et al. Outcome tools used for ambulatory children with cerebral palsy: Responsiveness and minimum clinically important differences. *Dev Med Child Neurol*2008; 50(12):918-925. doi:10.1111/j.1469-8749.2008.03150.x.
59. Ostensjo S, Oien I, Fallang B. Goal-oriented rehabilitation of preschoolers with cerebral palsy--a multi-case study of combined use of the canadian occupational performance measure (COPM) and the goal attainment scaling (GAS). *Dev Neurorehabil*2008; 11(4):252-259. doi:10.1080/17518420802525500.
60. Lowing K, Bexelius A, Brogren Carlberg E. Activity focused and goal directed therapy for children with cerebral palsy--do goals make a difference? *Disabil Rehabil*2009; 31(22):1808-1816. doi:10.1080/09638280902822278.
61. Lowing K, Thews K, Haglund-Akerlind Y, Gutierrez-Farewik EM. Effects of botulinum toxin-a and goal-directed physiotherapy in children with cerebral palsy GMFCS levels I & II. *Phys Occup Ther Pediatr*2017; 37(3):268-282. doi:10.3109/01942638.2016.1150384.
62. Sorsdahl AB, Moe-Nilssen R, Kaale HK, Rieber J, Strand LI. Change in basic motor abilities, quality of movement and everyday activities following intensive, goal-directed, activity-focused physiotherapy in a group setting for children with cerebral palsy. *BMC Pediatr*2010; 10:26. doi:10.1186/1471-2431-10-26.
63. Willis C, Nyquist A, Jahnsen R, Elliott C, Ullenhag A. Enabling physical activity participation for children and youth with disabilities following a goal-directed, family-centred intervention. *Res Dev Disabil*2018; 77:30-39. doi:10.1016/j.ridd.2018.03.010.
64. Bleyenheuft Y, Ebner-Karestinos D, Surana B, et al. Intensive upper- and lower-extremity training for children with bilateral cerebral palsy: A quasi-randomized trial. *Dev Med Child Neurol*2017; 59(6):625-633. doi:10.1111/dmcn.13379.
65. Morgan C, Novak I, Dale RC, Guzzetta A, Badawi N. Single blind randomised controlled trial of GAME (goals - activity - motor enrichment) in infants at high risk of cerebral palsy. *Res Dev Disabil*2016; 55:256-267. doi:10.1016/j.ridd.2016.04.005.
66. Armstrong EL, Boyd RN, Horan SA, et al. Functional electrical stimulation cycling, goal-directed training, and adapted cycling for children with cerebral palsy: A randomized controlled trial. *Dev Med Child Neurol*2020; 62(12):1406-1413. doi:10.1111/dmcn.14648.
67. Araneda R, Klocker A, Ebner-Karestinos D, et al. Feasibility and effectiveness of HABIT-ILE in children aged 1 to 4 years with cerebral palsy: A pilot study. *Ann Phys Rehabil Med*2021; 64(3):101381. doi:10.1016/j.rehab.2020.03.006.
68. Novak I, Smithers-Sheedy H, Morgan C. Predicting equipment needs of children with cerebral palsy using the gross motor function classification system: A cross-sectional study. *Disabil Rehabil Assist Technol*2012; 7(1):30-36. doi:10.3109/17483107.2011.556210.
69. Shields N, Synnot A. Perceived barriers and facilitators to participation in physical activity for children with disability: A qualitative study. *BMC Pediatr*2016; 16:9. doi:10.1186/s12887-016-0544-7.
70. Chiarello LA, Palisano RJ, McCoy SW, et al. Child engagement in daily life: A measure of participation for young children with cerebral palsy. *Disabil Rehabil*2014; 36(21):1804-1816. doi:10.3109/09638288.2014.882417.
71. Khetani MA. Validation of environmental content in the young children's participation and environment measure. *Arch Phys Med Rehabil*2015; 96(2):317-322. doi:10.1016/j.apmr.2014.11.016.
72. Reedman SE, Boyd RN, Trost SG, Elliott C, Sakzewski L. Efficacy of participation-focused therapy on performance of physical activity participation goals and habitual physical activity in

children with cerebral palsy: A randomized controlled trial. *Arch Phys Med Rehabil*2019; 100(4):676-686. doi:10.1016/j.apmr.2018.11.012.
73. Chrysagis N, Skordilis EK, Stavrou N, Grammatopoulou E, Koutsouki D. The effect of treadmill training on gross motor function and walking speed in ambulatory adolescents with cerebral palsy: A randomized controlled trial. *Am J Phys Med Rehabil*2012; 91(9):747-760. doi:10.1097/PHM.0b013e3182643eba.
74. Schindl MR, Forstner C, Kern H, Hesse S. Treadmill training with partial body weight support in nonambulatory patients with cerebral palsy. *Arch Phys Med Rehabil*2000; 81(3):301-306. doi:10.1016/s0003-9993(00)90075-3.
75. Swe NN, Sendhilnnathan S, van Den Berg M, Barr C. Over ground walking and body weight supported walking improve mobility equally in cerebral palsy: A randomised controlled trial. *Clin Rehabil*2015; 29(11):1108-1116. doi:10.1177/0269215514566249.
76. Cherng RJ, Liu CF, Lau TW, Hong RB. Effect of treadmill training with body weight support on gait and gross motor function in children with spastic cerebral palsy. *Am J Phys Med Rehabil*2007; 86(7):548-555. doi:10.1097/PHM.0b013e31806dc302.
77. Richards C, Malouin F, Dumas F, et al. Early and intensive treadmill locomotor training for young children with cerebral palsy: A feasibility study. *Pediatr Phys Ther*1997; 9(4):158-165.
78. MacCarthy M, Heyn P, Tagawa A, Carollo J. Walking speed and patient-reported outcomes in young adults with cerebral palsy. *Dev Med Child Neurol*2022; doi:10.1111/dmcn.15225.
79. Pirpiris M, Gates PE, McCarthy JJ, et al. Function and well-being in ambulatory children with cerebral palsy. *J Pediatr Orthop*2006; 26(1):119-124. doi:10.1097/01.bpo.0000191553.26574.27.
80. Verschuren O, Hulst RY, Voorman J, et al. 24-hour activity for children with cerebral palsy: A clinical practice guide. *Dev Med Child Neurol*2021; 63(1):54-59. doi:10.1111/dmcn.14654.
81. McLean LJ, Paleg GS, Livingstone RW. Supported-standing interventions for children and young adults with non-ambulant cerebral palsy: A scoping review. *Dev Med Child Neurol*2022; doi:10.1111/dmcn.15435.
82. Gannotti ME, Liquori BM, Thorpe DE, Fuchs RK. Designing exercise to improve bone health among individuals with cerebral palsy. *Pediatr Phys Ther*2021; 33(1):50-56. doi:10.1097/PEP.0000000000000765.
83. Pool D, Elliott C, Willis C, Thornton A. The experience of locomotor training from the perspectives of therapists and parents of children with cerebral palsy. *Frontiers in Rehabilitation Sciences*2021; 2. doi:10.3389/fresc.2021.740426.
84. Romeiser-Logan L, Slaughter R, Hickman R. Single-subject research designs in pediatric rehabilitation: A valuable step towards knowledge translation. *Dev Med Child Neurol*2017; 59(6):574-580. doi:10.1111/dmcn.13405.

Supplementary Materials: The Kindy Moves protocol paper,[42] Template for Intervention Description and Replication.


Enrolment
Assessed for eligibility (n=42)
Excluded (n=2):
Progressive neurodisability
T1: Baseline assessment
Commencement of intervention (n=40)
Discontinued intervention
(n=1): Hospitalisation
T2: Post-intervention assessment (n=39)
T3: Follow-up assessment (n=38)

Open access Protocol

BMJ Open

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

Dayna Pool [ID], [1,2] Catherine Elliott,[1,3] Healthy Strides Research Advisory Council

To cite: Pool D, Elliott C, Healthy Strides Research Advisory Council. 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. *BMJ Open* 2021;**11**:e046831. doi:10.1136/bmjopen-2020-046831

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-046831).

Received 10 November 2020
Accepted 03 August 2021

Check for updates

For numbered affiliations see end of article.

Correspondence to
Dr Dayna Pool;
Dayna.Pool@curtin.edu.au

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.

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

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.

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

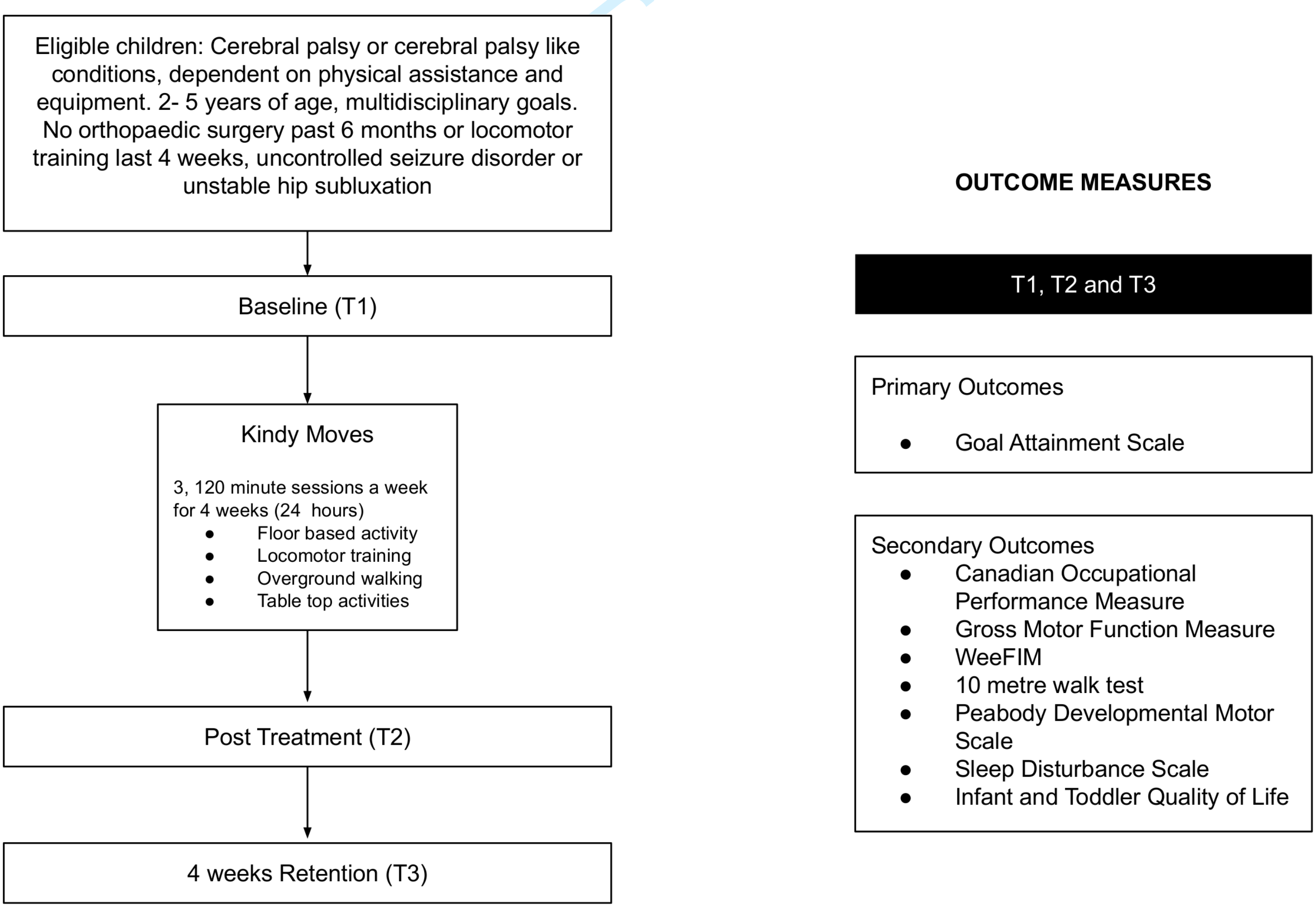


Figure 1 Study design and outcome measures. WeeFIM, Functional Independence Measure.

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.

Author affiliations
[1]School of Allied Health, Curtin University, Perth, Western Australia, Australia
[2]The Healthy Strides Foundation, Perth, Western Australia, Australia
[3]Telethon Institute for Child Health Research, Nedlands, Western Australia, Australia

Twitter Dayna Pool @daynapool

Acknowledgements The authors acknowledge the Healthy Strides Research Advisory Council for consulting and providing guidance on the development of the intervention.

Collaborators The Healthy Strides Research Advisory Council comprises of the Healthy Strides clinical team: Loren West, Corrin Walmsley, Georgia Hoffman, Marissa Smith, Eddie Pool, Meagan Smith, Georgina Jones, Matthew Haddon, Jordan Dinh and Bridget Chapman. Research Advisors: Dr Ashleigh Thornton, Dr Sue McCabe and Dr Claire Willis. Consumer Advisors: Ben O'Rourke, Noraishah Naim, Alishum Osman Ali.

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.

Funding This research was supported by the Telethon7 Trust 2019 and 2020.

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.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD
Dayna Pool http://orcid.org/0000-0001-8313-5661

REFERENCES

1 Human Early Learning Partnership & Commission on Social Determinants of Health. *Early child development : a powerful equalizer: final report for the World Health Organization's Commission on the Social Determinants of Health. / Prepared by Arjumand Siddiqi, Lori G. Irwin, Dr. Clyde Hertzman*. Vancouver: Human Early Learning Partnership, 2007.
2 Heckman JJ, Masterov DV. The productivity argument for investing in young children. *Rev Agri Econom* 2007;29:446–93.
3 Nores M, Barnett WS. Benefits of early childhood interventions across the world: (under) investing in the very young. *Econ Educ Rev* 2010;29:271–82.
4 Richter LM, Daelmans B, Lombardi J, *et al*. Investing in the foundation of sustainable development: pathways to scale up for early childhood development. *Lancet* 2017;389:103–18.
5 Goldfeld S, O'Connor E, O'Connor M, *et al*. The role of preschool in promoting children's healthy development: Evidence from an Australian population cohort. *Early Child Res Q* 2016;35:40–8.
6 Roberts G, Lim J, Doyle LW, *et al*. High rates of school readiness difficulties at 5 years of age in very preterm infants compared with term controls. *J Dev Behav Pediatr* 2011;32:117–24.
7 Gehrmann FE, Coleman A, Weir KA, *et al*. School readiness of children with cerebral palsy. *Dev Med Child Neurol* 2014;56:786–93.
8 Cairney J, Hay JA, Faught BE, *et al*. Developmental coordination disorder, generalized self-efficacy toward physical activity, and participation in organized and free play activities. *J Pediatr* 2005;147:515–20.
9 Van Hus JW, Potharst ES, Jeukens-Visser M, *et al*. Motor impairment in very preterm-born children: links with other developmental deficits at 5 years of age. *Dev Med Child Neurol* 2014;56:587–94.
10 Report of the Australian cerebral palsy register, birth years 1993-2009, 2016.
11 Palisano R, Rosenbaum P, Walter S, *et al*. Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Dev Med Child Neurol* 1997;39:214–23.
12 Palisano RJ, Hanna SE, Rosenbaum PL, *et al*. Validation of a model of gross motor function for children with cerebral palsy. *Phys Ther* 2000;80:974–85.
13 World Health Organization. Neurological disorders: public health challenges, 2006. Available: https://www.who.int/mental_health/neurology/neurological_disorders_report_web.pdf [Accessed 9 Nov 2020].
14 Smithers-Sheedy H, Badawi N, Blair E, *et al*. What constitutes cerebral palsy in the twenty-first century? *Dev Med Child Neurol* 2014;56:323–8.
15 Novak I, Honan I. Effectiveness of paediatric occupational therapy for children with disabilities: a systematic review. *Aust Occup Ther J* 2019;66:258–73.
16 Ostensjø S, Carlberg EB, Vøllestad NK. Everyday functioning in young children with cerebral palsy: functional skills, caregiver

assistance, and modifications of the environment. *Dev Med Child Neurol* 2003;45:603–12.

17 Cope S, Mohn-Johnsen S. The effects of dosage time and frequency on motor outcomes in children with cerebral palsy: a systematic review. *Dev Neurorehabil* 2017;20:376–87.

18 Bleyenheuft Y, Gordon AM. Hand-arm bimanual intensive therapy including lower extremities (HABIT-ILE) for children with cerebral palsy. *Phys Occup Ther Pediatr* 2014;34:390–403.

19 Størvold GV, Jahnsen RB, Evensen KAI, *et al*. Factors associated with enhanced gross motor progress in children with cerebral palsy: a register-based study. *Phys Occup Ther Pediatr* 2018;38:548–61.

20 Jackman M, Lannin N, Galea C, *et al*. What is the threshold dose of upper limb training for children with cerebral palsy to improve function? A systematic review. *Aust Occup Ther J* 2020;67:269–80.

21 Pool D, Valentine J, Taylor NF, *et al*. Locomotor and robotic assistive gait training for children with cerebral palsy. *Dev Med Child Neurol* 2021;63:328–35.

22 Geijen M, Ketelaar M, Sakzewski L, *et al*. Defining functional therapy in research involving children with cerebral palsy: a systematic review. *Phys Occup Ther Pediatr* 2020;40:231–46.

23 Novak I, Morgan C, Fahey M, *et al*. State of the evidence traffic lights 2019: systematic review of interventions for preventing and treating children with cerebral palsy. *Curr Neurol Neurosci Rep* 2020;20:3.

24 Jeglinsky I, Salminen A-L, Carlberg EB, *et al*. Rehabilitation planning for children and adolescents with cerebral palsy. *J Pediatr Rehabil Med* 2012;5:203–15.

25 Choi BCK, Pak AWP. Multidisciplinarity, interdisciplinarity and transdisciplinarity in health research, services, education and policy: 1. definitions, objectives, and evidence of effectiveness. *Clin Invest Med* 2006;29:351–64.

26 Soper AK, Cross A, Rosenbaum P, *et al*. Knowledge translation strategies to support service providers' implementation of the "F-words in Childhood Disability". *Disabil Rehabil* 2020;45:1–7.

27 Jan MMS. Cerebral palsy: comprehensive review and update. *Ann Saudi Med* 2006;26:123–32.

28 Trabacca A, Russo L, Losito L, *et al*. The ICF-CY perspective on the neurorehabilitation of cerebral palsy: a single case study. *J Child Neurol* 2012;27:183–90.

29 Glader L, Plews-Ogan J, Agrawal R. Children with medical complexity: creating a framework for care based on the International classification of functioning, disability and health. *Dev Med Child Neurol* 2016;58:1116–23.

30 Morgan C, Novak I, Dale RC, *et al*. Single blind randomised controlled trial of GAME (Goals - Activity - Motor Enrichment) in infants at high risk of cerebral palsy. *Res Dev Disabil* 2016;55:256–67.

31 Danger S, Landreth G. Child-centered group play therapy with children with speech difficulties. *Int J Play Ther* 2005;14:81–102.

32 Astramovich RL, Lyons C, Hamilton NJ. Play therapy for children with intellectual disabilities. *J Child Adolesc Couns* 2015;1:27–36.

33 Fauconnier J, Dickinson HO, Beckung E, *et al*. Participation in life situations of 8-12 year old children with cerebral palsy: cross sectional European study. *BMJ* 2009;338:b1458.

34 Michelsen SI, Flachs EM, Uldall P, *et al*. Frequency of participation of 8-12-year-old children with cerebral palsy: a multi-centre cross-sectional European study. *Eur J Paediatr Neurol* 2009;13:165–77.

35 Imms C. Children with cerebral palsy participate: a review of the literature. *Disabil Rehabil* 2008;30:1867–84.

36 Bleyenheuft Y, Arnould C, Brandao MB, *et al*. Hand and arm bimanual intensive therapy including lower extremity (HABIT-ILE) in children with unilateral spastic cerebral palsy: a randomized trial. *Neurorehabil Neural Repair* 2015;29:645–57.

37 Mutlu A, Krosschell K, Spira DG. Treadmill training with partial body-weight support in children with cerebral palsy: a systematic review. *Dev Med Child Neurol* 2009;51:268–75.

38 Peterson MD, Gordon PM, Hurvitz EA. Chronic disease risk among adults with cerebral palsy: the role of premature sarcopoenia, obesity and sedentary behaviour. *Obes Rev* 2013;14:171–82.

39 Willoughby KL, Dodd KJ, Shields N. A systematic review of the effectiveness of treadmill training for children with cerebral palsy. *Disabil Rehabil* 2009;31:1971–9.

40 Anderson DI, Campos JJ, Witherington DC, *et al*. The role of locomotion in psychological development. *Front Psychol* 2013;4:440.

41 Huang H-H, Chen C-L. The use of modified ride-on cars to maximize mobility and improve socialization-a group design. *Res Dev Disabil* 2017;61:172–80.

42 Ryan JM, Cassidy EE, Noorduyn SG, *et al*. Exercise interventions for cerebral palsy. *Cochrane Database Syst Rev* 2017;2017.

43 Fonzo M, Sirico F, Corrado B. Evidence-Based physical therapy for individuals with Rett syndrome: a systematic review. *Brain Sci* 2020;10:410.

44 Wheeler AC, Sacco P, Cabo R. Unmet clinical needs and burden in Angelman syndrome: a review of the literature. *Orphanet J Rare Dis* 2017;12:164.

45 Willoughby KL, Dodd KJ, Shields N, *et al*. Efficacy of partial body weight-supported treadmill training compared with overground walking practice for children with cerebral palsy: a randomized controlled trial. *Arch Phys Med Rehabil* 2010;91:333–9.

46 Dodd KJ, Foley S. Partial body-weight-supported treadmill training can improve walking in children with cerebral palsy: a clinical controlled trial. *Dev Med Child Neurol* 2007;49:101–5.

47 Day JA, Fox EJ, Lowe J, *et al*. Locomotor training with partial body weight support on a treadmill in a nonambulatory child with spastic tetraplegic cerebral palsy: a case report. *Pediatr Phys Ther* 2004;16:106–13.

48 Schindl MR, Forstner C, Kern H, *et al*. Treadmill training with partial body weight support in nonambulatory patients with cerebral palsy. *Arch Phys Med Rehabil* 2000;81:301–6.

49 Verschuren O, Helders PJM, Mattern-Baxter K. Effects of intensive locomotor treadmill training on young children with cerebral palsy. *Pediatr Phys Ther* 2009;21:319–19.

50 Valentín-Gudiol M, Mattern-Baxter K, Girabent-Farrés M, *et al*. Treadmill interventions in children under six years of age at risk of neuromotor delay. *Cochrane Database Syst Rev* 2017;7:Cd009242.

51 Ginsburg KR, American Academy of Pediatrics Committee on Communications, American Academy of Pediatrics Committee on Psychosocial Aspects of Child and Family Health. The importance of play in promoting healthy child development and maintaining strong parent-child bonds. *Pediatrics* 2007;119:182–91.

52 Novak I, McIntyre S, Morgan C, *et al*. A systematic review of interventions for children with cerebral palsy: state of the evidence. *Dev Med Child Neurol* 2013;55:885–910.

53 Patel DR. Therapeutic interventions in cerebral palsy. *Indian J Pediatr* 2005;72:979–83.

54 Mickan SM. Evaluating the effectiveness of health care teams. *Aust Health Rev* 2005;29:211–7.

55 Damiano DL, DeJong SL. A systematic review of the effectiveness of treadmill training and body weight support in pediatric rehabilitation. *J Neurol Phys Ther* 2009;33:27–44.

56 Bowen DJ, Kreuter M, Spring B, *et al*. How we design feasibility studies. *Am J Prev Med* 2009;36:452–7.

57 Rosenbaum P, Gorter JW. The 'F-words' in childhood disability: I swear this is how we should think! *Child Care Health Dev* 2012;38:457–63.

58 Turner-Stokes L. Goal attainment scaling (GAS) in rehabilitation: a practical guide. *Clin Rehabil* 2009;23:362–70.

59 Carswell A, McColl MA, Baptiste S, *et al*. The Canadian occupational performance measure: a research and clinical literature review. *Can J Occup Ther* 2004;71:210–22.

60 Booth ATC, Buizer AI, Meyns P, *et al*. The efficacy of functional gait training in children and young adults with cerebral palsy: a systematic review and meta-analysis. *Dev Med Child Neurol* 2018;60:866–83.

61 Ottenbacher KJ, Msall ME, Lyon N, *et al*. The WeeFIM instrument: its utility in detecting change in children with developmental disabilities. *Arch Phys Med Rehabil* 2000;81:1317–26.

62 Wang H-H, Liao H-F, Hsieh C-L. Reliability, sensitivity to change, and responsiveness of the peabody developmental motor scales-second edition for children with cerebral palsy. *Phys Ther* 2006;86:1351–9.

63 Romeo DM, Brogna C, Musto E, *et al*. Sleep disturbances in preschool age children with cerebral palsy: a questionnaire study. *Sleep Med* 2014;15:1089–93.

64 Spuijbroek AT, Oostenbrink R, Landgraf JM, *et al*. Health-related quality of life in preschool children in five health conditions. *Qual Life Res* 2011;20:779–86.

65 Bleyenheuft Y, Ebner-Karestinos D, Surana B, *et al*. Intensive upper- and lower-extremity training for children with bilateral cerebral palsy: a quasi-randomized trial. *Dev Med Child Neurol* 2017;59:625–33.

66 Palisano RJ, Rosenbaum P, Bartlett D, *et al*. Content validity of the expanded and revised gross motor function classification system. *Dev Med Child Neurol* 2008;50:744–50.

67 Eliasson A-C, Krumlinde-Sundholm L, Rösblad B, *et al*. The manual ability classification system (MACS) for children with cerebral palsy: scale development and evidence of validity and reliability. *Dev Med Child Neurol* 2006;48:549–54.

68 Hidecker MJC, Cunningham BJ, Thomas-Stonell N, *et al*. Validity of the communication function classification system for use with preschool children with communication disorders. *Dev Med Child Neurol* 2017;59:526–30.

69 Graham HK, Harvey A, Rodda J, *et al*. The functional mobility scale (FMS). *J Pediatr Orthop* 2004;24:514–20.

70 Livingstone R, Paleg G. Measuring outcomes for children with cerebral palsy who use gait trainers. *Technology* 2016;4:1–19.
71 Cusick A, McIntyre S, Novak I, *et al*. A comparison of goal attainment scaling and the Canadian occupational performance measure for paediatric rehabilitation research. *Pediatr Rehabil* 2006;9:149–57.
72 Novak I, Cusick A, Lannin N. Occupational therapy home programs for cerebral palsy: double-blind, randomized, controlled trial. *Pediatrics* 2009;124:e606–14.
73 Meyer-Heim A, Borggraefe I, Ammann-Reiffer C, *et al*. Feasibility of robotic-assisted locomotor training in children with central gait impairment. *Dev Med Child Neurol* 2007;49:900–6.
74 Mattern-Baxter K. Effects of partial body weight supported treadmill training on children with cerebral palsy. *Pediatr Phys Ther* 2009;21:12–22.
75 Romeo DM, Bruni O, Brogna C, *et al*. Application of the sleep disturbance scale for children (SDSC) in preschool age. *Eur J Paediatr Neurol* 2013;17:374–82.
76 Russell DJ, Avery LM, Rosenbaum PL, *et al*. Improved scaling of the gross motor function measure for children with cerebral palsy: evidence of reliability and validity. *Phys Ther* 2000;80:873–85.
77 Wang H-Y, Yang YH. Evaluating the responsiveness of 2 versions of the gross motor function measure for children with cerebral palsy. *Arch Phys Med Rehabil* 2006;87:51–6.
78 Ko J. Sensitivity to functional improvements of GMFM-88, GMFM-66, and PEDI mobility scores in young children with cerebral palsy. *Percept Mot Skills* 2014;119:305–19.
79 Behrman AL, Harkema SJ. Spinal Cord Injury Special Series Locomotor Training After Human Spinal Cord Injury : A Series of Case Studies. *Physical Therapy* 2000;80:688–700.
80 Imms C, Granlund M, Wilson PH, *et al*. Participation, both a means and an end: a conceptual analysis of processes and outcomes in childhood disability. *Dev Med Child Neurol* 2017;59:16–25.
81 Guba EG. Criteria for assessing the trustworthiness of naturalistic inquiries. *Educ Comm Technol J* 1981;29:75–91.
82 Smith B, McGannon KR. Developing rigor in qualitative research: problems and opportunities within sport and exercise psychology. *Int Rev Sport Exerc Psychol* 2018;11:101–21.
83 Portney LG, Watkins MP. *Foundations of clinical research: applications to practice*. 3rd edn. New Jersey: Person Prentice Hall, 2009.
84 Barwick M. Building scientist capacity in knowledge translation: development of the knowledge translation planning template. *Technol Innov Manage Rev* 2016;6:9–15.

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.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3-4
	2b	Specific objectives or research questions for pilot trial	4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	5
	4c	How participants were identified and consented	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	4-6
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	4
Sample size	7a	Rationale for numbers in the pilot trial	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	4-6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	6
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4, 6
	14b	Why the pilot trial ended or was stopped	4, 5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6-7
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	7-8
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	7-8
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	6-8
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	6
	19a	If relevant, other important unintended consequences	6
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	11-12
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	10-14
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	10-13
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	8-12
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	2
Protocol	24	Where the pilot trial protocol can be accessed, if available	14, 17
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	12
	26	Ethical approval or approval by research review committee, confirmed with reference number	4

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of study as randomised pilot or feasibility trial	p1 line 1
Authors *	Contact details for the corresponding author	P1 line 14-18
Trial design	Description of pilot trial design (eg, parallel, cluster)	5
Methods		
Participants	Eligibility criteria for participants and the settings where the pilot trial was conducted	6-11
Interventions	Interventions intended for each group	12-14
Objective	Specific objectives of the pilot trial	2-4
Outcome	Prespecified assessment or measurement to address the pilot trial objectives**	15-19
Randomization	How participants were allocated to interventions	N/A
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	N/A
Results		
Numbers randomized	Number of participants screened and randomised to each group for the pilot trial objectives**	7
Recruitment	Trial status†	
Numbers analysed	Number of participants analysed in each group for the pilot objectives**	7
Outcome	Results for the pilot objectives, including any expressions of uncertainty**	20-25
Harms	Important adverse events or side effects	25
Conclusions	General interpretation of the results of pilot trial and their implications for the future definitive trial	26-28
Trial registration	Registration number for pilot trial and name of trial register	29
Funding	Source of funding for pilot trial	P12 line 42

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

**this item is specific to conference abstracts*

***Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those that are a priori agreed as the most important to the decision to proceed with the future definitive RCT.*

†For conference abstracts.

BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-068816.R3
Article Type:	Original research
Date Submitted by the Author:	25-Apr-2023
Complete List of Authors:	Haddon, Matthew; The Healthy Strides Foundation, West, Loren; The Healthy Strides Foundation Elliott, Catherine; Curtin University, School of Allied Health; Telethon Kids Institute Walmsley, Corrin; The Healthy Strides Foundation Valentine, Jane; Perth Children's Hospital, Paediatric Rehabilitation; Telethon Kids Institute Bear, Natasha; Child and Adolescent Health Service Healthy Strides Research Advisory Council, .; The Healthy Strides Foundation Pool, Dayna; Curtin University, School of Occupational Therapy Social Work and Speech Pathology; The Healthy Strides Foundation,
Primary Subject Heading:	Paediatrics
Secondary Subject Heading:	Rehabilitation medicine, Sports and exercise medicine, Evidence based practice
Keywords:	Developmental neurology & neurodisability < PAEDIATRICS, Neurological injury < NEUROLOGY, Clinical trials < THERAPEUTICS

SCHOLARONE™ Manuscripts

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

Authors: Haddon M[1], West L[1], Elliott C PhD[2&3], Walmsley CP PhD[1], Valentine J FRACP PhD[3&4], Bear N[5], Healthy Strides Research Advisory Council[1], Pool D PhD[1&2]

1. The Healthy Strides Foundation, Perth, Western Australia, 6101
2. School of Allied Health, Curtin University, Perth, Western Australia, 6027
3. Telethon Kids Institute, Perth, Western Australia, Western Australia, 6009
4. Perth Children's Hospital, Child and Adolescent Health Service, Perth, Western Australia, 6009
5. Child and Adolescent Health Service, Perth, Western Australia, 6009

Corresponding author details:
Mr Matthew Haddon – matthew.haddon@health.wa.gov.au
Contact number – +8 0404315015
ORCID ID – 0000-0003-2795-902X
Postal address – Suite 23/954 Albany Hwy, East Victoria Park WA 6101.

Word length for main text excluding reference, abstract and tables: 6132
Word length for abstract: 300
Number of references: 84
Number of tables: 2
Number of figures: 2

Abstract
Objectives: To determine the feasibility of an intensive interdisciplinary program 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 to 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 six months, unstable hip subluxation, uncontrolled seizure disorder, or treadmill training in the past month.
Intervention: A goal-directed program of three two-hour sessions per week for four 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 pre-intervention (T1) to post-intervention (T2) and four-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 (MD 27.7, 95% CI 25.8-29.5) as well as COPM performance (MD 3.2, 95% CI 2.8-3.6) and satisfaction (MD 3.3, 95% CI 2.8-3.8). The GMFM-66 (MD 2.3, 95% CI 1.0-3.5) and 10MWT (median difference -2.3, 95% CI -28.8-0.0) 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 program is feasible in improving goal and motor outcomes for preschool children with neurodisabilities (GMFCS III-V). A randomised controlled trial is warranted to establish efficacy.
Trial registration: Australian New Zealand Clinical Trials Registry (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 program 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 program makes it difficult to differentiate the effects of individual elements of the program.
- 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 syndrome.[6] Cerebral palsy 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] Cerebral palsy 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 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 to 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] Locomotor treadmill training 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 four weeks[27] to three 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 six weeks in 5 to 12 year old children with CP (GMFCS III-V),[33] and following 14 hours of treadmill training in 1 to 5 year old pre-ambulatory children 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 program 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 (i.e. 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 to 5 years were recruited. Participants undertook four weeks of intervention, completing a two-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 two weeks before the intervention (T1) to the week following intervention completion (T2) and at follow-up four weeks post-intervention (T3). The shorter four-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 two-year timeframe. 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 upon 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 CONSORT 2010 statement: extension to randomised pilot and feasibility trials.[43, 44] Approval for this study was obtained by the Human Research Ethics Committee of Curtin University (Approval number: HRE2019-0073) and written informed consent was received by the participants' primary caregivers.

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 six months of the study, unstable hip subluxation, uncontrolled seizure disorder, or engagement in LTT in the month prior to the study. A semi-structured 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 two-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 (Supplementary Material 1).[42] Kindy Moves is an intensive program 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 two-hour sessions per week for four weeks (24 hours of therapy). Locomotor treadmill training was a large focus of the program, 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 practiced 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 two-hour intervention was separated into 30 minutes of floor time as a group to practice gross motor, socialisation and play skills through games, songs, and book reading. This was followed by one hour of LTT, separated into 30 minutes of partial body weight supported treadmill training (Figure 1) and 30 minutes of overground walking in a mobility device which was designed based upon 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 minutes 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 the supplementary materials (Supplementary Material 2).

Figure 1. Treadmill Training.

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 two 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 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 World Health Organization'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-metre distance. Facilitation of one step was provided for children who did not initiate stepping after 30 seconds.[33] If a child did not complete the 10-metre distance in 360 seconds, this time was recorded as the maximal result.[33] The clinically meaningful change in 10MWT speed is 0.1m/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 5 to 12 year old children 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 standard deviations for continuous data, or medians and interquartile ranges 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% confidence intervals (CI). The Smithers-Sheedy et al[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 sub-domains 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. Upon review of their pre-intervention 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 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%).

Figure 2. 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-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)

Abbreviations: GMFCS, Gross Motor Function Classification System[10]; MACS, Manual Ability Classification System[46]; CFCS, Communication Function Classification System[45]; COPM, Canadian Occupational Performance Measure[47]; GAS, Goal Attainment Scaling.[49]

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 two-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 eight hours. All outcomes measured were assessed as per the study protocol, however, 18 participants could not complete the 10MWT within the designated 360 seconds 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 post-intervention 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 post-intervention 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.

Table 2. Outcome Measure Changes Across All Time Points.

Outcome	Assessment Time Point			Outcome Measure Changes		
	Mean (SD)			Mean Difference (95% CI)		
	T1	T2	T3	T2 vs T1	T3 vs T1	T3 vs T2
GAS t-score	20.2	47.9	51.1	27.7	30.9	3.3

	(1.4) n=39	(5.5) n=39	(7.0) n=38	(25.8 to 29.5)	(29.1 to 32.8)	(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 (secs)	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)

Abbreviations: T1, Baseline; T2, Post-Intervention; T3, Follow-up; GAS, Goal Attainment Scaling[49]; COPM, Canadian Occupational Performance Measure[47]; GMFM-66, 66-item Gross Motor Function Measure[54]; 10MWT, 10-Metre Walk Test.[57]

DISCUSSION

Feasibility

This study aimed to determine if implementing Kindy Moves, a four-week intensive LTT program 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, GMFM-66, and 10MWT. These improvements were largely maintained four weeks after program 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 program in 2 to 5 year old children 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 to 5 years old 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 to 5 years being less frequently completed.[67] Data exploring the retention of outcomes in a period after program completion is important in establishing the extent of real-life skill application. Goal performance and satisfaction remained high four 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 programs 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 post-intervention (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 co-morbidities while bringing to light assessment considerations that may reduce the burden of time on families.

Over a 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 learned.[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 learned 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 program. 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 co-morbidities 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 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 to 2.3 years who completed 40 to 50 hours of therapy over four months.[77] Despite being a promising pilot study,[77] it is probable that natural maturation affected the results in the four-month intervention, particularly at an age of rapid motor development. To account for this in Kindy Moves, a shorter intervention timeframe and only a four-week follow-up period were selected. Although longer follow-up periods beyond three 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. Additionally, 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 post-intervention 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 seconds. This was particularly evident in children functioning within GMFCS levels IV-V (or equivalent). The 6-Minute 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 learned 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 post-intervention 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 programs 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 wellbeing 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 four weeks (12 hours total),[27] whereas others have explored up to three 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 to 4 years resulted in goal and gross motor improvements after 50 hours of therapy over two weeks.[67] The outcomes of Kindy Moves highlight improvements in goals and motor function after 24 hours of therapy across four 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 to 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. Firstly, 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 program 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. Additionally, 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. Firstly, 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 post-intervention 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 program satisfaction and acceptability. To reduce the possibility of a ceiling effect, the 6-Minute 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 semi-structured 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 co-morbidities 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 program 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 program 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.

Acknowledgements: The authors acknowledge the Healthy Strides Research Advisory Council for consulting and providing guidance on the development of the intervention.

Collaborators: The Healthy Strides Research Advisory Council comprises of the Healthy Strides clinical team: Dr Dayna Pool, Loren West, Dr Corrin Walmsley, Georgia Hoffman, Marissa Smith, Eddie Pool, Meagan Smith, Georgina Jones, Matthew Haddon, Jordan Dinh and Bridget Chapman. Research Advisors: Dr Ashleigh Thornton, Dr Sue McCabe, and Dr Claire Willis. Consumer Advisors: Ben O'Rourke, Noraishah Naim.

Author Contributions: 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 co-developed 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 conceptualised, planned, developed, and wrote the study protocol.

Funding Statement: This work has been supported by the Telethon7 Trust 2019 and 2020. Award/Grant number is not applicable.

Competing Interests Statements: None declared.

Patient Consent: Consent was provided for the inclusion of Figure 1 in the paper through the BMJ Patient Consent Form.

Data Sharing: Data can be made available for research purposes upon request.

Reporting Checklist Flow Diagram: The CONSORT 2010 statement: extension to randomised pilot and feasibility studies.[40]

Ethics Approval: Approval for this study was obtained by the Human Research Ethics Committee of Curtin University (Approval number: HRE2019-0073) and written informed consent was received by the participants' primary caregivers.

REFERENCES

1. Jackman M, Sakzewski L, Morgan C, et al. Interventions to improve physical function for children and young people with cerebral palsy: International clinical practice guideline. *Dev Med Child Neurol*2021; 64(5):536-549. doi:10.1111/dmcn.15055.
2. Morgan C, Fetters L, Adde L, et al. Early intervention for children aged 0 to 2 years with or at high risk of cerebral palsy: International clinical practice guideline based on systematic reviews. *JAMA Pediatr*2021; 175(8):846-858. doi:10.1001/jamapediatrics.2021.0878.
3. Damiano DL, Longo E. Early intervention evidence for infants with or at risk for cerebral palsy: An overview of systematic reviews. *Dev Med Child Neurol*2021; 63(7):771-784. doi:10.1111/dmcn.14855.
4. Novak I, Morgan C, Fahey M, et al. State of the evidence traffic lights 2019: Systematic review of interventions for preventing and treating children with cerebral palsy. *Curr Neurol Neurosci Rep*2020; 20(2):3. doi:10.1007/s11910-020-1022-z.
5. Novak I, Honan I. Effectiveness of paediatric occupational therapy for children with disabilities: A systematic review. *Aust Occup Ther J*2019; 66(3):258-273. doi:10.1111/1440-1630.12573.
6. Morris C, Janssens A, Tomlinson R, Williams J, Logan S. Towards a definition of neurodisability: A delphi survey. *Dev Med Child Neurol*2013; 55(12):1103-1108. doi:10.1111/dmcn.12218.
7. Cans C. Surveillance of cerebral palsy in Europe: A collaboration of cerebral palsy surveys and registers. *Dev Med Child Neurol*2000; 42(12):816-824. doi:10.1017/s0012162200001511.
8. Smithers-Sheedy H, Badawi N, Blair E, et al. What constitutes cerebral palsy in the twenty-first century? *Dev Med Child Neurol*2014; 56(4):323-328. doi:10.1111/dmcn.12262.
9. Novak I, Hines M, Goldsmith S, Barclay R. Clinical prognostic messages from a systematic review on cerebral palsy. *Pediatrics*2012; 130(5):e1285-1312. doi:10.1542/peds.2012-0924.
10. Palisano R, Rosenbaum P, Walter S, et al. Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Dev Med Child Neurol*1997; 39(4):214-223. doi:10.1111/j.1469-8749.1997.tb07414.x.
11. Australian Cerebral Palsy Register Group. Australia and the Australian cerebral palsy register for the birth cohort 1993 to 2006. *Dev Med Child Neurol*2016; 58 Suppl 2:3-4. doi:10.1111/dmcn.13002.
12. Imms C, Granlund M, Wilson PH, et al. Participation, both a means and an end: A conceptual analysis of processes and outcomes in childhood disability. *Dev Med Child Neurol*2017; 59(1):16-25. doi:10.1111/dmcn.13237.
13. Aviram R, Harries N, Shkedy Rabani A, et al. Comparison of habitual physical activity and sedentary behavior in adolescents and young adults with and without cerebral palsy. *Pediatr Exerc Sci*2019; 31(1):60-66. doi:10.1123/pes.2017-0285.
14. Fauconnier J, Dickinson HO, Beckung E, et al. Participation in life situations of 8-12 year old children with cerebral palsy: Cross sectional European study. *BMJ*2009; 338:b1458. doi:10.1136/bmj.b1458.

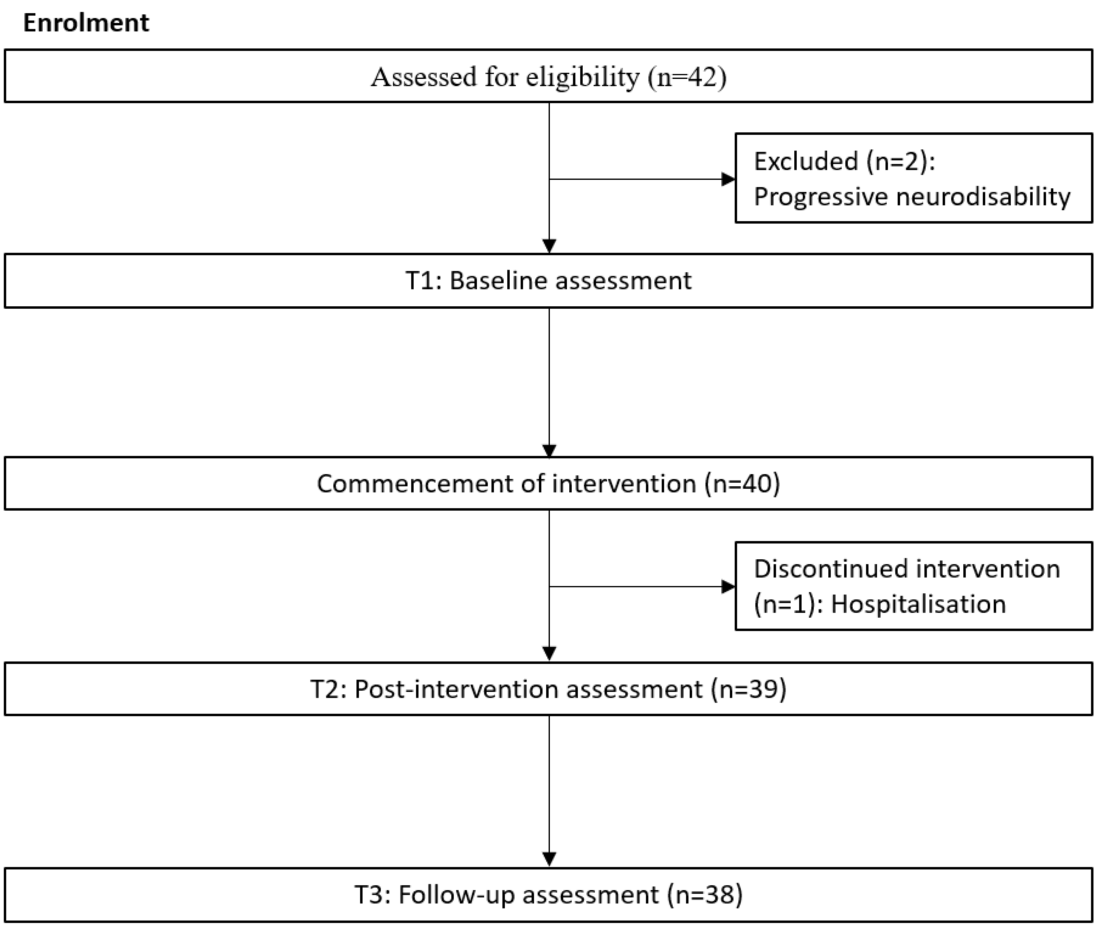
15. Imms C. Children with cerebral palsy participate: A review of the literature. *Disabil Rehabil*2008; 30(24):1867-1884. doi:10.1080/09638280701673542.
16. Shkedy Rabani A, Harries N, Namoora I, et al. Duration and patterns of habitual physical activity in adolescents and young adults with cerebral palsy. *Dev Med Child Neurol*2014; 56(7):673-680. doi:10.1111/dmcn.12394.
17. Peterson MD, Gordon PM, Hurvitz EA. Chronic disease risk among adults with cerebral palsy: The role of premature sarcopoenia, obesity and sedentary behaviour. *Obes Rev*2013; 14(2):171-182. doi:10.1111/j.1467-789X.2012.01052.x.
18. Ryan JM, Cassidy EE, Noorduyn SG, O'Connell NE. Exercise interventions for cerebral palsy. *Cochrane Database Syst Rev*2017; 6:CD011660. doi:10.1002/14651858.CD011660.pub2.
19. Gross PH, Bailes AF, Horn SD, et al. Setting a patient-centered research agenda for cerebral palsy: A participatory action research initiative. *Dev Med Child Neurol*2018; 60(12):1278-1284. doi:10.1111/dmcn.13984.
20. Byrne R, Noritz G, Maitre NL, NCH Early Developmental Group. Implementation of early diagnosis and intervention guidelines for cerebral palsy in a high-risk infant follow-up clinic. *Pediatr Neurol*2017; 76:66-71. doi:10.1016/j.pediatrneurol.2017.08.002.
21. Johnston MV, Ishida A, Ishida WN, et al. Plasticity and injury in the developing brain. *Brain Dev*2009; 31(1):1-10. doi:10.1016/j.braindev.2008.03.014.
22. Yang JF, Livingstone D, Brunton K, et al. Training to enhance walking in children with cerebral palsy: Are we missing the window of opportunity? *Semin Pediatr Neurol*2013; 20(2):106-115. doi:10.1016/j.spen.2013.06.011.
23. Daelmans B, Darmstadt GL, Lombardi J, et al. Early childhood development: The foundation of sustainable development. *Lancet*2017; 389(10064):9-11. doi:10.1016/S0140-6736(16)31659-2.
24. Richter LM, Daelmans B, Lombardi J, et al. Investing in the foundation of sustainable development: Pathways to scale up for early childhood development. *Lancet*2017; 389(10064):103-118. doi:10.1016/S0140-6736(16)31698-1.
25. Rosenbaum PL, Walter SD, Hanna SE, et al. Prognosis for gross motor function in cerebral palsy: Creation of motor development curves. *JAMA*2002; 288(11):1357-1363. doi:10.1001/jama.288.11.1357.
26. Hanna SE, Bartlett DJ, Rivard LM, Russell DJ. Reference curves for the gross motor function measure: Percentiles for clinical description and tracking over time among children with cerebral palsy. *Phys Ther*2008; 88(5):596-607. doi:10.2522/ptj.20070314.
27. Mattern-Baxter K, Bellamy S, Mansoor JK. Effects of intensive locomotor treadmill training on young children with cerebral palsy. *Pediatr Phys Ther*2009; 21(4):308-318. doi:10.1097/PEP.0b013e3181bf53d9.
28. Gehrmann FE, Coleman A, Weir KA, Ware RS, Boyd RN. School readiness of children with cerebral palsy. *Dev Med Child Neurol*2014; 56(8):786-793. doi:10.1111/dmcn.12377.
29. Choi BC, Pak AW. Multidisciplinarity, interdisciplinarity and transdisciplinarity in health research, services, education and policy: 1. Definitions, objectives, and evidence of effectiveness. *Clin Invest Med*2006; 29(6):351-364. Available from: https://www.ncbi.nlm.nih.gov/pubmed/17330451.
30. Dodd KJ, Foley S. Partial body-weight-supported treadmill training can improve walking in children with cerebral palsy: A clinical controlled trial. *Dev Med Child Neurol*2007; 49(2):101-105. doi:10.1111/j.1469-8749.2007.00101.x.
31. Mattern-Baxter K. Locomotor treadmill training for children with cerebral palsy. *Orthop Nurs*2010; 29(3):169-173; quiz 174-165. doi:10.1097/NOR.0b013e3181db5441.
32. Willoughby KL, Dodd KJ, Shields N. A systematic review of the effectiveness of treadmill training for children with cerebral palsy. *Disabil Rehabil*2009; 31(24):1971-1979. doi:10.3109/09638280902874204.
33. Pool D, Valentine J, Taylor NF, Bear N, Elliott C. Locomotor and robotic assistive gait training for children with cerebral palsy. *Dev Med Child Neurol*2021; 63(3):328-335. doi:10.1111/dmcn.14746.
34. Valentin-Gudiol M, Mattern-Baxter K, Girabent-Farres M, et al. Treadmill interventions in children under six years of age at risk of neuromotor delay. *Cochrane Database Syst Rev*2017; 7:CD009242. doi:10.1002/14651858.CD009242.pub3.

35. Tinderholt Myrhaug H, Ostensjo S, Larun L, Odgaard-Jensen J, Jahnsen R. Intensive training of motor function and functional skills among young children with cerebral palsy: A systematic review and meta-analysis. *BMC Pediatr*2014; 14:292. doi:10.1186/s12887-014-0292-5.
36. Jackman M, Lannin N, Galea C, et al. What is the threshold dose of upper limb training for children with cerebral palsy to improve function? A systematic review. *Aust Occup Ther J*2020; 67(3):269-280. doi:10.1111/1440-1630.12666.
37. Bryant E, Pountney T, Williams H, Edelman N. Can a six-week exercise intervention improve gross motor function for non-ambulant children with cerebral palsy? A pilot randomized controlled trial. *Clin Rehabil*2013; 27(2):150-159. doi:10.1177/0269215512453061.
38. Mattern-Baxter K, McNeil S, Mansoor JK. Effects of home-based locomotor treadmill training on gross motor function in young children with cerebral palsy: A quasi-randomized controlled trial. *Arch Phys Med Rehabil*2013; 94(11):2061-2067. doi:10.1016/j.apmr.2013.05.012.
39. Mattern-Baxter K. Analysis of a group-based treadmill program for children with neuromotor delay who are pre-ambulatory. *Phys Occup Ther Pediatr*2021; 41(3):271-283. doi:10.1080/01942638.2020.1834055.
40. Kleim JA, Jones TA. Principles of experience-dependent neural plasticity: Implications for rehabilitation after brain damage. *J Speech Lang Hear Res*2008; 51(1):S225-239. doi:10.1044/1092-4388(2008/018).
41. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med*2009; 36(5):452-457. doi:10.1016/j.amepre.2009.02.002.
42. Pool D, Elliott C, Healthy Strides Research Advisory Council. 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. *BMJ Open*2021; 11(8):e046831. doi:10.1136/bmjopen-2020-046831.
43. Eldridge SM, Chan CL, Campbell MJ, et al. Consort 2010 statement: Extension to randomised pilot and feasibility trials. *BMJ*2016; 355:i5239. doi:10.1136/bmj.i5239.
44. Lancaster GA, Thabane L. Guidelines for reporting non-randomised pilot and feasibility studies. *Pilot Feasibility Stud*2019; 5:114. doi:10.1186/s40814-019-0499-1.
45. Hidecker MJ, Cunningham BJ, Thomas-Stonell N, Oddson B, Rosenbaum P. Validity of the communication function classification system for use with preschool children with communication disorders. *Dev Med Child Neurol*2017; 59(5):526-530. doi:10.1111/dmcn.13373.
46. Eliasson AC, Krumlinde-Sundholm L, Rosblad B, et al. The manual ability classification system (MACS) for children with cerebral palsy: Scale development and evidence of validity and reliability. *Dev Med Child Neurol*2006; 48(7):549-554. doi:10.1017/S0012162206001162.
47. Law M, Baptiste S, McColl M, et al. The canadian occupational performance measure: An outcome measure for occupational therapy. *Can J Occup Ther*1990; 57(2):82-87. doi:10.1177/000841749005700207.
48. Cusick A, Lannin NA, Lowe K. Adapting the canadian occupational performance measure for use in a paediatric clinical trial. *Disabil Rehabil*2007; 29(10):761-766. doi:10.1080/09638280600929201.
49. Kiresuk TJ, Sherman RE. Goal attainment scaling: A general method for evaluating comprehensive community mental health programs. *Community Ment Health J*1968; 4(6):443-453. doi:10.1007/BF01530764.
50. World Health Organization. International classification of functioning, disability and health: ICF. Geneva, Switzerland; 2001. p.
51. Livingstone R, Paleg G. Measuring outcomes for children with cerebral palsy who use gait trainers. *Technologies*2016; 4:1-19. doi:10.3390/technologies4030022.
52. Cusick A, McIntyre S, Novak I, Lannin N, Lowe K. A comparison of goal attainment scaling and the canadian occupational performance measure for paediatric rehabilitation research. *Pediatr Rehabil*2006; 9(2):149-157. doi:10.1080/13638490500235581.
53. Harpster K, Sheehan A, Foster EA, et al. The methodological application of goal attainment scaling in pediatric rehabilitation research: A systematic review. *Disabil Rehabil*2019; 41(24):2855-2864. doi:10.1080/09638288.2018.1474952.
54. Russell DJ, Avery LM, Rosenbaum PL, et al. Improved scaling of the gross motor function measure for children with cerebral palsy: Evidence of reliability and validity. *Phys Ther*2000; 80(9):873-885. Available from: https://www.ncbi.nlm.nih.gov/pubmed/10960935.

55. Ko J. Sensitivity to functional improvements of GMFM-88, GMFM-66, and PEDI mobility scores in young children with cerebral palsy. *Percept Mot Skills*2014; 119(1):305-319. doi:10.2466/03.25.PMS.119c14z1.
56. Marois P, Marois M, Pouliot-Laforte A, et al. Gross motor function measure evolution ratio: Use as a control for natural progression in cerebral palsy. *Arch Phys Med Rehabil*2016; 97(5):807-814 e802. doi:10.1016/j.apmr.2015.07.024.
57. Graser JV, Letsch C, van Hedel HJA. Reliability of timed walking tests and temporo-spatial gait parameters in youths with neurological gait disorders. *BMC Neurol*2016; 16:15. doi:10.1186/s12883-016-0538-y.
58. Oeffinger D, Bagley A, Rogers S, et al. Outcome tools used for ambulatory children with cerebral palsy: Responsiveness and minimum clinically important differences. *Dev Med Child Neurol*2008; 50(12):918-925. doi:10.1111/j.1469-8749.2008.03150.x.
59. Ostensjo S, Oien I, Fallang B. Goal-oriented rehabilitation of preschoolers with cerebral palsy--a multi-case study of combined use of the canadian occupational performance measure (COPM) and the goal attainment scaling (GAS). *Dev Neurorehabil*2008; 11(4):252-259. doi:10.1080/17518420802525500.
60. Lowing K, Bexelius A, Brogren Carlberg E. Activity focused and goal directed therapy for children with cerebral palsy--do goals make a difference? *Disabil Rehabil*2009; 31(22):1808-1816. doi:10.1080/09638280902822278.
61. Lowing K, Thews K, Haglund-Akerlind Y, Gutierrez-Farewik EM. Effects of botulinum toxin-a and goal-directed physiotherapy in children with cerebral palsy GMFCS levels I & II. *Phys Occup Ther Pediatr*2017; 37(3):268-282. doi:10.3109/01942638.2016.1150384.
62. Sorsdahl AB, Moe-Nilssen R, Kaale HK, Rieber J, Strand LI. Change in basic motor abilities, quality of movement and everyday activities following intensive, goal-directed, activity-focused physiotherapy in a group setting for children with cerebral palsy. *BMC Pediatr*2010; 10:26. doi:10.1186/1471-2431-10-26.
63. Willis C, Nyquist A, Jahnsen R, Elliott C, Ullenhag A. Enabling physical activity participation for children and youth with disabilities following a goal-directed, family-centred intervention. *Res Dev Disabil*2018; 77:30-39. doi:10.1016/j.ridd.2018.03.010.
64. Bleyenheuft Y, Ebner-Karestinos D, Surana B, et al. Intensive upper- and lower-extremity training for children with bilateral cerebral palsy: A quasi-randomized trial. *Dev Med Child Neurol*2017; 59(6):625-633. doi:10.1111/dmcn.13379.
65. Morgan C, Novak I, Dale RC, Guzzetta A, Badawi N. Single blind randomised controlled trial of GAME (goals - activity - motor enrichment) in infants at high risk of cerebral palsy. *Res Dev Disabil*2016; 55:256-267. doi:10.1016/j.ridd.2016.04.005.
66. Armstrong EL, Boyd RN, Horan SA, et al. Functional electrical stimulation cycling, goal-directed training, and adapted cycling for children with cerebral palsy: A randomized controlled trial. *Dev Med Child Neurol*2020; 62(12):1406-1413. doi:10.1111/dmcn.14648.
67. Araneda R, Klocker A, Ebner-Karestinos D, et al. Feasibility and effectiveness of HABIT-ILE in children aged 1 to 4 years with cerebral palsy: A pilot study. *Ann Phys Rehabil Med*2021; 64(3):101381. doi:10.1016/j.rehab.2020.03.006.
68. Novak I, Smithers-Sheedy H, Morgan C. Predicting equipment needs of children with cerebral palsy using the gross motor function classification system: A cross-sectional study. *Disabil Rehabil Assist Technol*2012; 7(1):30-36. doi:10.3109/17483107.2011.556210.
69. Shields N, Synnot A. Perceived barriers and facilitators to participation in physical activity for children with disability: A qualitative study. *BMC Pediatr*2016; 16:9. doi:10.1186/s12887-016-0544-7.
70. Chiarello LA, Palisano RJ, McCoy SW, et al. Child engagement in daily life: A measure of participation for young children with cerebral palsy. *Disabil Rehabil*2014; 36(21):1804-1816. doi:10.3109/09638288.2014.882417.
71. Khetani MA. Validation of environmental content in the young children's participation and environment measure. *Arch Phys Med Rehabil*2015; 96(2):317-322. doi:10.1016/j.apmr.2014.11.016.
72. Reedman SE, Boyd RN, Trost SG, Elliott C, Sakzewski L. Efficacy of participation-focused therapy on performance of physical activity participation goals and habitual physical activity in

children with cerebral palsy: A randomized controlled trial. *Arch Phys Med Rehabil*2019; 100(4):676-686. doi:10.1016/j.apmr.2018.11.012.
73. Chrysagis N, Skordilis EK, Stavrou N, Grammatopoulou E, Koutsouki D. The effect of treadmill training on gross motor function and walking speed in ambulatory adolescents with cerebral palsy: A randomized controlled trial. *Am J Phys Med Rehabil*2012; 91(9):747-760. doi:10.1097/PHM.0b013e3182643eba.
74. Schindl MR, Forstner C, Kern H, Hesse S. Treadmill training with partial body weight support in nonambulatory patients with cerebral palsy. *Arch Phys Med Rehabil*2000; 81(3):301-306. doi:10.1016/s0003-9993(00)90075-3.
75. Swe NN, Sendhilnnathan S, van Den Berg M, Barr C. Over ground walking and body weight supported walking improve mobility equally in cerebral palsy: A randomised controlled trial. *Clin Rehabil*2015; 29(11):1108-1116. doi:10.1177/0269215514566249.
76. Cherng RJ, Liu CF, Lau TW, Hong RB. Effect of treadmill training with body weight support on gait and gross motor function in children with spastic cerebral palsy. *Am J Phys Med Rehabil*2007; 86(7):548-555. doi:10.1097/PHM.0b013e31806dc302.
77. Richards C, Malouin F, Dumas F, et al. Early and intensive treadmill locomotor training for young children with cerebral palsy: A feasibility study. *Pediatr Phys Ther*1997; 9(4):158-165.
78. MacCarthy M, Heyn P, Tagawa A, Carollo J. Walking speed and patient-reported outcomes in young adults with cerebral palsy. *Dev Med Child Neurol*2022; doi:10.1111/dmcn.15225.
79. Pirpiris M, Gates PE, McCarthy JJ, et al. Function and well-being in ambulatory children with cerebral palsy. *J Pediatr Orthop*2006; 26(1):119-124. doi:10.1097/01.bpo.0000191553.26574.27.
80. Verschuren O, Hulst RY, Voorman J, et al. 24-hour activity for children with cerebral palsy: A clinical practice guide. *Dev Med Child Neurol*2021; 63(1):54-59. doi:10.1111/dmcn.14654.
81. McLean LJ, Paleg GS, Livingstone RW. Supported-standing interventions for children and young adults with non-ambulant cerebral palsy: A scoping review. *Dev Med Child Neurol*2022; doi:10.1111/dmcn.15435.
82. Gannotti ME, Liquori BM, Thorpe DE, Fuchs RK. Designing exercise to improve bone health among individuals with cerebral palsy. *Pediatr Phys Ther*2021; 33(1):50-56. doi:10.1097/PEP.0000000000000765.
83. Pool D, Elliott C, Willis C, Thornton A. The experience of locomotor training from the perspectives of therapists and parents of children with cerebral palsy. *Frontiers in Rehabilitation Sciences*2021; 2. doi:10.3389/fresc.2021.740426.
84. Romeiser-Logan L, Slaughter R, Hickman R. Single-subject research designs in pediatric rehabilitation: A valuable step towards knowledge translation. *Dev Med Child Neurol*2017; 59(6):574-580. doi:10.1111/dmcn.13405.

Supplementary Materials: The Kindy Moves protocol paper,[42] Template for Intervention Description and Replication.


Enrolment
Assessed for eligibility (n=42)
Excluded (n=2):
Progressive neurodisability
T1: Baseline assessment
Commencement of intervention (n=40)
Discontinued intervention
(n=1): Hospitalisation
T2: Post-intervention assessment (n=39)
T3: Follow-up assessment (n=38)

Open access

Protocol

BMJ Open

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

Dayna Pool ,[1,2] Catherine Elliott,[1,3] Healthy Strides Research Advisory Council

To cite: Pool D, Elliott C, Healthy Strides Research Advisory Council. 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. *BMJ Open* 2021;**11**:e046831. doi:10.1136/bmjopen-2020-046831

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-046831).

Received 10 November 2020
Accepted 03 August 2021

For numbered affiliations see end of article.

Correspondence to
Dr Dayna Pool;
Dayna.Pool@curtin.edu.au

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

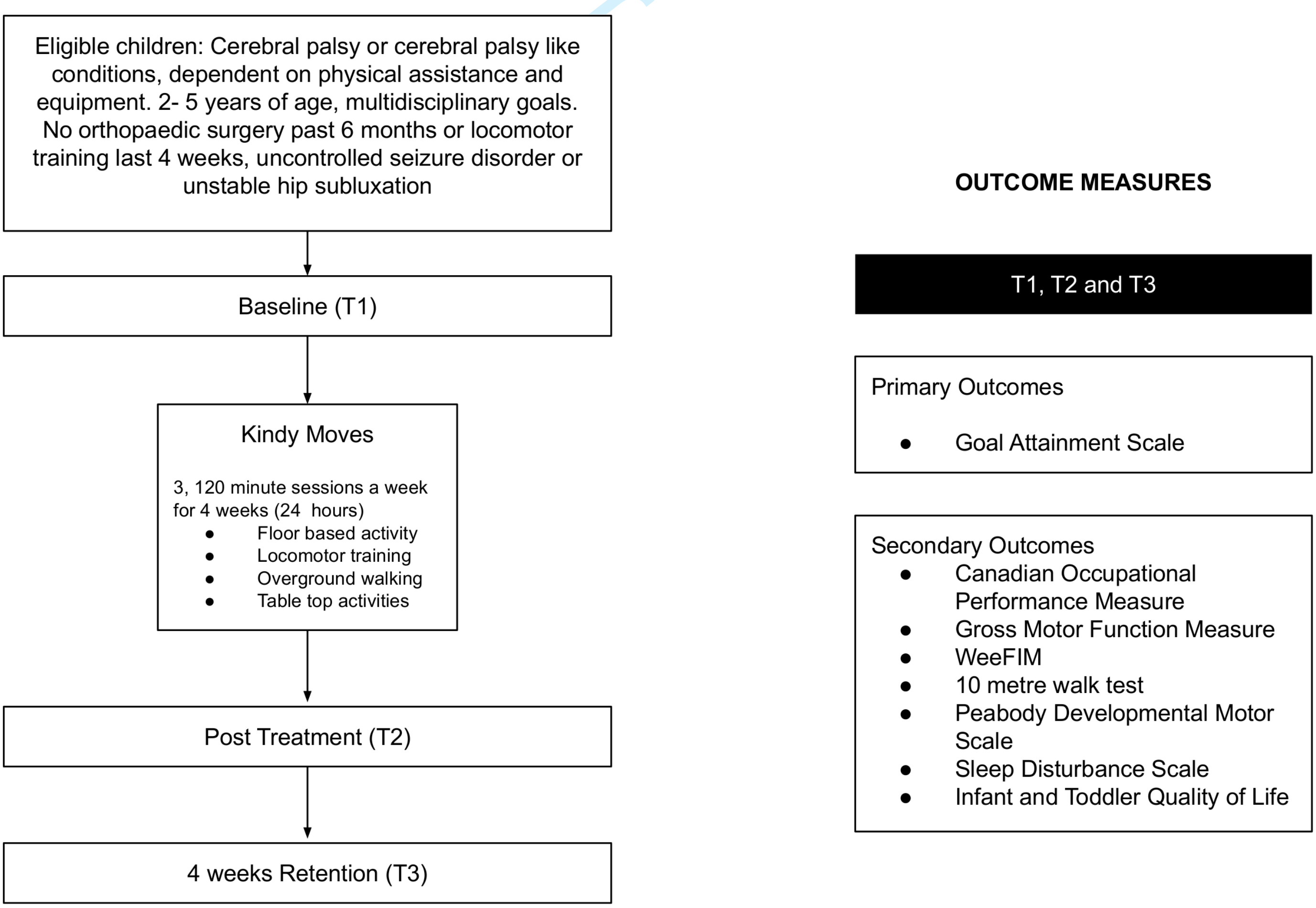


Figure 1 Study design and outcome measures. WeeFIM, Functional Independence Measure.

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.

Author affiliations
[1]School of Allied Health, Curtin University, Perth, Western Australia, Australia
[2]The Healthy Strides Foundation, Perth, Western Australia, Australia
[3]Telethon Institute for Child Health Research, Nedlands, Western Australia, Australia

Twitter Dayna Pool @daynapool

Acknowledgements The authors acknowledge the Healthy Strides Research Advisory Council for consulting and providing guidance on the development of the intervention.

Collaborators The Healthy Strides Research Advisory Council comprises of the Healthy Strides clinical team: Loren West, Corrin Walmsley, Georgia Hoffman, Marissa Smith, Eddie Pool, Meagan Smith, Georgina Jones, Matthew Haddon, Jordan Dinh and Bridget Chapman. Research Advisors: Dr Ashleigh Thornton, Dr Sue McCabe and Dr Claire Willis. Consumer Advisors: Ben O'Rourke, Noraishah Naim, Alishum Osman Ali.

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.

Funding This research was supported by the Telethon7 Trust 2019 and 2020.

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.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD
Dayna Pool http://orcid.org/0000-0001-8313-5661

REFERENCES

1 Human Early Learning Partnership & Commission on Social Determinants of Health. *Early child development : a powerful equalizer: final report for the World Health Organization's Commission on the Social Determinants of Health. / Prepared by Arjumand Siddiqi, Lori G. Irwin, Dr. Clyde Hertzman*. Vancouver: Human Early Learning Partnership, 2007.
2 Heckman JJ, Masterov DV. The productivity argument for investing in young children. *Rev Agri Econom* 2007;29:446–93.
3 Nores M, Barnett WS. Benefits of early childhood interventions across the world: (under) investing in the very young. *Econ Educ Rev* 2010;29:271–82.
4 Richter LM, Daelmans B, Lombardi J, *et al*. Investing in the foundation of sustainable development: pathways to scale up for early childhood development. *Lancet* 2017;389:103–18.
5 Goldfeld S, O'Connor E, O'Connor M, *et al*. The role of preschool in promoting children's healthy development: Evidence from an Australian population cohort. *Early Child Res Q* 2016;35:40–8.
6 Roberts G, Lim J, Doyle LW, *et al*. High rates of school readiness difficulties at 5 years of age in very preterm infants compared with term controls. *J Dev Behav Pediatr* 2011;32:117–24.
7 Gehrmann FE, Coleman A, Weir KA, *et al*. School readiness of children with cerebral palsy. *Dev Med Child Neurol* 2014;56:786–93.
8 Cairney J, Hay JA, Faught BE, *et al*. Developmental coordination disorder, generalized self-efficacy toward physical activity, and participation in organized and free play activities. *J Pediatr* 2005;147:515–20.
9 Van Hus JW, Potharst ES, Jeukens-Visser M, *et al*. Motor impairment in very preterm-born children: links with other developmental deficits at 5 years of age. *Dev Med Child Neurol* 2014;56:587–94.
10 Report of the Australian cerebral palsy register, birth years 1993-2009, 2016.
11 Palisano R, Rosenbaum P, Walter S, *et al*. Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Dev Med Child Neurol* 1997;39:214–23.
12 Palisano RJ, Hanna SE, Rosenbaum PL, *et al*. Validation of a model of gross motor function for children with cerebral palsy. *Phys Ther* 2000;80:974–85.
13 World Health Organization. Neurological disorders: public health challenges, 2006. Available: https://www.who.int/mental_health/neurology/neurological_disorders_report_web.pdf [Accessed 9 Nov 2020].
14 Smithers-Sheedy H, Badawi N, Blair E, *et al*. What constitutes cerebral palsy in the twenty-first century? *Dev Med Child Neurol* 2014;56:323–8.
15 Novak I, Honan I. Effectiveness of paediatric occupational therapy for children with disabilities: a systematic review. *Aust Occup Ther J* 2019;66:258–73.
16 Ostensjø S, Carlberg EB, Vøllestad NK. Everyday functioning in young children with cerebral palsy: functional skills, caregiver

assistance, and modifications of the environment. *Dev Med Child Neurol* 2003;45:603–12.
17 Cope S, Mohn-Johnsen S. The effects of dosage time and frequency on motor outcomes in children with cerebral palsy: a systematic review. *Dev Neurorehabil* 2017;20:376–87.
18 Bleyenheuft Y, Gordon AM. Hand-arm bimanual intensive therapy including lower extremities (HABIT-ILE) for children with cerebral palsy. *Phys Occup Ther Pediatr* 2014;34:390–403.
19 Størvold GV, Jahnsen RB, Evensen KAI, *et al*. Factors associated with enhanced gross motor progress in children with cerebral palsy: a register-based study. *Phys Occup Ther Pediatr* 2018;38:548–61.
20 Jackman M, Lannin N, Galea C, *et al*. What is the threshold dose of upper limb training for children with cerebral palsy to improve function? A systematic review. *Aust Occup Ther J* 2020;67:269–80.
21 Pool D, Valentine J, Taylor NF, *et al*. Locomotor and robotic assistive gait training for children with cerebral palsy. *Dev Med Child Neurol* 2021;63:328–35.
22 Geijen M, Ketelaar M, Sakzewski L, *et al*. Defining functional therapy in research involving children with cerebral palsy: a systematic review. *Phys Occup Ther Pediatr* 2020;40:231–46.
23 Novak I, Morgan C, Fahey M, *et al*. State of the evidence traffic lights 2019: systematic review of interventions for preventing and treating children with cerebral palsy. *Curr Neurol Neurosci Rep* 2020;20:3.
24 Jeglinsky I, Salminen A-L, Carlberg EB, *et al*. Rehabilitation planning for children and adolescents with cerebral palsy. *J Pediatr Rehabil Med* 2012;5:203–15.
25 Choi BCK, Pak AWP. Multidisciplinarity, interdisciplinarity and transdisciplinarity in health research, services, education and policy: 1. definitions, objectives, and evidence of effectiveness. *Clin Invest Med* 2006;29:351–64.
26 Soper AK, Cross A, Rosenbaum P, *et al*. Knowledge translation strategies to support service providers' implementation of the "F-words in Childhood Disability". *Disabil Rehabil* 2020;45:1–7.
27 Jan MMS. Cerebral palsy: comprehensive review and update. *Ann Saudi Med* 2006;26:123–32.
28 Trabacca A, Russo L, Losito L, *et al*. The ICF-CY perspective on the neurorehabilitation of cerebral palsy: a single case study. *J Child Neurol* 2012;27:183–90.
29 Glader L, Plews-Ogan J, Agrawal R. Children with medical complexity: creating a framework for care based on the International classification of functioning, disability and health. *Dev Med Child Neurol* 2016;58:1116–23.
30 Morgan C, Novak I, Dale RC, *et al*. Single blind randomised controlled trial of GAME (Goals - Activity - Motor Enrichment) in infants at high risk of cerebral palsy. *Res Dev Disabil* 2016;55:256–67.
31 Danger S, Landreth G. Child-centered group play therapy with children with speech difficulties. *Int J Play Ther* 2005;14:81–102.
32 Astramovich RL, Lyons C, Hamilton NJ. Play therapy for children with intellectual disabilities. *J Child Adolesc Couns* 2015;1:27–36.
33 Fauconnier J, Dickinson HO, Beckung E, *et al*. Participation in life situations of 8-12 year old children with cerebral palsy: cross sectional European study. *BMJ* 2009;338:b1458.
34 Michelsen SI, Flachs EM, Uldall P, *et al*. Frequency of participation of 8-12-year-old children with cerebral palsy: a multi-centre cross-sectional European study. *Eur J Paediatr Neurol* 2009;13:165–77.
35 Imms C. Children with cerebral palsy participate: a review of the literature. *Disabil Rehabil* 2008;30:1867–84.
36 Bleyenheuft Y, Arnould C, Brandao MB, *et al*. Hand and arm bimanual intensive therapy including lower extremity (HABIT-ILE) in children with unilateral spastic cerebral palsy: a randomized trial. *Neurorehabil Neural Repair* 2015;29:645–57.
37 Mutlu A, Krosschell K, Spira DG. Treadmill training with partial body-weight support in children with cerebral palsy: a systematic review. *Dev Med Child Neurol* 2009;51:268–75.
38 Peterson MD, Gordon PM, Hurvitz EA. Chronic disease risk among adults with cerebral palsy: the role of premature sarcopoenia, obesity and sedentary behaviour. *Obes Rev* 2013;14:171–82.
39 Willoughby KL, Dodd KJ, Shields N. A systematic review of the effectiveness of treadmill training for children with cerebral palsy. *Disabil Rehabil* 2009;31:1971–9.
40 Anderson DI, Campos JJ, Witherington DC, *et al*. The role of locomotion in psychological development. *Front Psychol* 2013;4:440.
41 Huang H-H, Chen C-L. The use of modified ride-on cars to maximize mobility and improve socialization-a group design. *Res Dev Disabil* 2017;61:172–80.
42 Ryan JM, Cassidy EE, Noorduyn SG, *et al*. Exercise interventions for cerebral palsy. *Cochrane Database Syst Rev* 2017;2017.
43 Fonzo M, Sirico F, Corrado B. Evidence-Based physical therapy for individuals with Rett syndrome: a systematic review. *Brain Sci* 2020;10:410.
44 Wheeler AC, Sacco P, Cabo R. Unmet clinical needs and burden in Angelman syndrome: a review of the literature. *Orphanet J Rare Dis* 2017;12:164.
45 Willoughby KL, Dodd KJ, Shields N, *et al*. Efficacy of partial body weight-supported treadmill training compared with overground walking practice for children with cerebral palsy: a randomized controlled trial. *Arch Phys Med Rehabil* 2010;91:333–9.
46 Dodd KJ, Foley S. Partial body-weight-supported treadmill training can improve walking in children with cerebral palsy: a clinical controlled trial. *Dev Med Child Neurol* 2007;49:101–5.
47 Day JA, Fox EJ, Lowe J, *et al*. Locomotor training with partial body weight support on a treadmill in a nonambulatory child with spastic tetraplegic cerebral palsy: a case report. *Pediatr Phys Ther* 2004;16:106–13.
48 Schindl MR, Forstner C, Kern H, *et al*. Treadmill training with partial body weight support in nonambulatory patients with cerebral palsy. *Arch Phys Med Rehabil* 2000;81:301–6.
49 Verschuren O, Helders PJM, Mattern-Baxter K. Effects of intensive locomotor treadmill training on young children with cerebral palsy. *Pediatr Phys Ther* 2009;21:319–19.
50 Valentín-Gudiol M, Mattern-Baxter K, Girabent-Farrés M, *et al*. Treadmill interventions in children under six years of age at risk of neuromotor delay. *Cochrane Database Syst Rev* 2017;7:Cd009242.
51 Ginsburg KR, American Academy of Pediatrics Committee on Communications, American Academy of Pediatrics Committee on Psychosocial Aspects of Child and Family Health. The importance of play in promoting healthy child development and maintaining strong parent-child bonds. *Pediatrics* 2007;119:182–91.
52 Novak I, McIntyre S, Morgan C, *et al*. A systematic review of interventions for children with cerebral palsy: state of the evidence. *Dev Med Child Neurol* 2013;55:885–910.
53 Patel DR. Therapeutic interventions in cerebral palsy. *Indian J Pediatr* 2005;72:979–83.
54 Mickan SM. Evaluating the effectiveness of health care teams. *Aust Health Rev* 2005;29:211–7.
55 Damiano DL, DeJong SL. A systematic review of the effectiveness of treadmill training and body weight support in pediatric rehabilitation. *J Neurol Phys Ther* 2009;33:27–44.
56 Bowen DJ, Kreuter M, Spring B, *et al*. How we design feasibility studies. *Am J Prev Med* 2009;36:452–7.
57 Rosenbaum P, Gorter JW. The 'F-words' in childhood disability: I swear this is how we should think! *Child Care Health Dev* 2012;38:457–63.
58 Turner-Stokes L. Goal attainment scaling (GAS) in rehabilitation: a practical guide. *Clin Rehabil* 2009;23:362–70.
59 Carswell A, McColl MA, Baptiste S, *et al*. The Canadian occupational performance measure: a research and clinical literature review. *Can J Occup Ther* 2004;71:210–22.
60 Booth ATC, Buizer AI, Meyns P, *et al*. The efficacy of functional gait training in children and young adults with cerebral palsy: a systematic review and meta-analysis. *Dev Med Child Neurol* 2018;60:866–83.
61 Ottenbacher KJ, Msall ME, Lyon N, *et al*. The WeeFIM instrument: its utility in detecting change in children with developmental disabilities. *Arch Phys Med Rehabil* 2000;81:1317–26.
62 Wang H-H, Liao H-F, Hsieh C-L. Reliability, sensitivity to change, and responsiveness of the peabody developmental motor scales-second edition for children with cerebral palsy. *Phys Ther* 2006;86:1351–9.
63 Romeo DM, Brogna C, Musto E, *et al*. Sleep disturbances in preschool age children with cerebral palsy: a questionnaire study. *Sleep Med* 2014;15:1089–93.
64 Spuijbroek AT, Oostenbrink R, Landgraf JM, *et al*. Health-related quality of life in preschool children in five health conditions. *Qual Life Res* 2011;20:779–86.
65 Bleyenheuft Y, Ebner-Karestinos D, Surana B, *et al*. Intensive upper- and lower-extremity training for children with bilateral cerebral palsy: a quasi-randomized trial. *Dev Med Child Neurol* 2017;59:625–33.
66 Palisano RJ, Rosenbaum P, Bartlett D, *et al*. Content validity of the expanded and revised gross motor function classification system. *Dev Med Child Neurol* 2008;50:744–50.
67 Eliasson A-C, Krumlinde-Sundholm L, Rösblad B, *et al*. The manual ability classification system (MACS) for children with cerebral palsy: scale development and evidence of validity and reliability. *Dev Med Child Neurol* 2006;48:549–54.
68 Hidecker MJC, Cunningham BJ, Thomas-Stonell N, *et al*. Validity of the communication function classification system for use with preschool children with communication disorders. *Dev Med Child Neurol* 2017;59:526–30.
69 Graham HK, Harvey A, Rodda J, *et al*. The functional mobility scale (FMS). *J Pediatr Orthop* 2004;24:514–20.

70 Livingstone R, Paleg G. Measuring outcomes for children with cerebral palsy who use gait trainers. *Technology* 2016;4:1–19.
71 Cusick A, McIntyre S, Novak I, *et al*. A comparison of goal attainment scaling and the Canadian occupational performance measure for paediatric rehabilitation research. *Pediatr Rehabil* 2006;9:149–57.
72 Novak I, Cusick A, Lannin N. Occupational therapy home programs for cerebral palsy: double-blind, randomized, controlled trial. *Pediatrics* 2009;124:e606–14.
73 Meyer-Heim A, Borggraefe I, Ammann-Reiffer C, *et al*. Feasibility of robotic-assisted locomotor training in children with central gait impairment. *Dev Med Child Neurol* 2007;49:900–6.
74 Mattern-Baxter K. Effects of partial body weight supported treadmill training on children with cerebral palsy. *Pediatr Phys Ther* 2009;21:12–22.
75 Romeo DM, Bruni O, Brogna C, *et al*. Application of the sleep disturbance scale for children (SDSC) in preschool age. *Eur J Paediatr Neurol* 2013;17:374–82.
76 Russell DJ, Avery LM, Rosenbaum PL, *et al*. Improved scaling of the gross motor function measure for children with cerebral palsy: evidence of reliability and validity. *Phys Ther* 2000;80:873–85.
77 Wang H-Y, Yang YH. Evaluating the responsiveness of 2 versions of the gross motor function measure for children with cerebral palsy. *Arch Phys Med Rehabil* 2006;87:51–6.
78 Ko J. Sensitivity to functional improvements of GMFM-88, GMFM-66, and PEDI mobility scores in young children with cerebral palsy. *Percept Mot Skills* 2014;119:305–19.
79 Behrman AL, Harkema SJ. Spinal Cord Injury Special Series Locomotor Training After Human Spinal Cord Injury : A Series of Case Studies. *Physical Therapy* 2000;80:688–700.
80 Imms C, Granlund M, Wilson PH, *et al*. Participation, both a means and an end: a conceptual analysis of processes and outcomes in childhood disability. *Dev Med Child Neurol* 2017;59:16–25.
81 Guba EG. Criteria for assessing the trustworthiness of naturalistic inquiries. *Educ Comm Technol J* 1981;29:75–91.
82 Smith B, McGannon KR. Developing rigor in qualitative research: problems and opportunities within sport and exercise psychology. *Int Rev Sport Exerc Psychol* 2018;11:101–21.
83 Portney LG, Watkins MP. *Foundations of clinical research: applications to practice*. 3rd edn. New Jersey: Person Prentice Hall, 2009.
84 Barwick M. Building scientist capacity in knowledge translation: development of the knowledge translation planning template. *Technol Innov Manage Rev* 2016;6:9–15.

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.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3-4
	2b	Specific objectives or research questions for pilot trial	4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	5
	4c	How participants were identified and consented	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	4-6
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	4
Sample size	7a	Rationale for numbers in the pilot trial	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	4-6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	6
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4, 6
	14b	Why the pilot trial ended or was stopped	4, 5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6-7
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	7-8
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	7-8
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	6-8
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	6
	19a	If relevant, other important unintended consequences	6
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	11-12
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	10-14
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	10-13
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	8-12
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	2
Protocol	24	Where the pilot trial protocol can be accessed, if available	14, 17
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	12
	26	Ethical approval or approval by research review committee, confirmed with reference number	4

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of study as randomised pilot or feasibility trial	p1 line 1
Authors *	Contact details for the corresponding author	P1 line 14-18
Trial design	Description of pilot trial design (eg, parallel, cluster)	5
Methods		
Participants	Eligibility criteria for participants and the settings where the pilot trial was conducted	6-11
Interventions	Interventions intended for each group	12-14
Objective	Specific objectives of the pilot trial	2-4
Outcome	Prespecified assessment or measurement to address the pilot trial objectives**	15-19
Randomization	How participants were allocated to interventions	N/A
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	N/A
Results		
Numbers randomized	Number of participants screened and randomised to each group for the pilot trial objectives**	7
Recruitment	Trial status†	
Numbers analysed	Number of participants analysed in each group for the pilot objectives**	7
Outcome	Results for the pilot objectives, including any expressions of uncertainty**	20-25
Harms	Important adverse events or side effects	25
Conclusions	General interpretation of the results of pilot trial and their implications for the future definitive trial	26-28
Trial registration	Registration number for pilot trial and name of trial register	29
Funding	Source of funding for pilot trial	P12 line 42

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

**this item is specific to conference abstracts*

***Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those that are a priori agreed as the most important to the decision to proceed with the future definitive RCT.*

†For conference abstracts.