

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

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**To cite:** Haddon M, West L, Elliott C, *et al.* Kindy Moves: the feasibility of an intensive interdisciplinary programme on goal and motor outcomes for preschool-aged children with neurodisabilities requiring daily equipment and physical assistance. *BMJ Open* 2023;**13**:e068816. doi:10.1136/bmjopen-2022-068816

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-068816>).

Received 30 September 2022  
Accepted 25 April 2023



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## ABSTRACT

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

**Design** A single group feasibility study.

**Setting** An Australian paediatric community therapy provider.

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

**Intervention** A goal-directed programme of three 2-hour sessions per week for 4 weeks (24 hours total).

This consisted of treadmill and overground walking, communication practice, and upper limb tasks tailored by an interdisciplinary team.

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

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

## STRENGTHS AND LIMITATIONS OF THIS STUDY

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

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

**Trial registration number** ACTRN12619000064101.

## BACKGROUND

Clinical practice guidelines<sup>1 2</sup> and systematic reviews<sup>3 4</sup> 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.<sup>1–4</sup> 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.<sup>5</sup> Neurodisability has been described through consensus<sup>6</sup> as ‘a group of congenital or acquired long-term conditions that are attributed to impairment of the brain and/or neuromuscular system and create functional limitations. A specific diagnosis may not be identified. Conditions may vary over time, occur alone or in combination, and include a broad range of severity and complexity. The impact may include difficulties with movement, cognition, hearing and vision, communication, emotion, and behaviour.’ Examples of neurodisability include CP, spina bifida, KAT6A syndrome, acquired brain injury and Down’s syndrome.<sup>6</sup> CP is a neurodisability that is most commonly cited and studied due to its relatively higher prevalence.<sup>7</sup> 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.<sup>8</sup> CP is often associated with pain (3 in 4), intellectual disability (1 in 2), epilepsy (1 in 3), visual impairment (1 in 10) and hearing loss (1 in 25).<sup>9</sup> Most co-occurring impairments are more frequently present in children with greater motor impairment.<sup>9</sup> The five-level Gross Motor Function Classification System (GMFCS)<sup>10</sup> 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.<sup>11</sup> These children predominantly mobilise in their homes and the community using a wheelchair and/or walking device.<sup>10</sup> Although the GMFCS was developed specifically for children with CP, descriptors of functional mobility can apply to the broader neurodisability population.<sup>10</sup> 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.<sup>10</sup> 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.<sup>10</sup> 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.<sup>10,12</sup> This group of children have a greater reduction in physical activity and participation levels than their more mobile peers,<sup>13–16</sup> contributing to a greater risk of adverse long-term health outcomes.<sup>17</sup> There is a scarcity of exercise-based interventions in those with lower functional mobility<sup>18</sup> despite this being a highly ranked research priority.<sup>19</sup>

Early intervention is of paramount importance to optimise a time of peak neuroplasticity while establishing a foundation for a physically active future.<sup>2,3,20–22</sup> Early intervention also yields higher rates of economic return when compared with intervening later in childhood.<sup>23,24</sup> Children with CP classified within GMFCS III–V reach 90% of their gross motor function potential before the age of 5 years<sup>25</sup> and experience a functionally relevant decline

into adolescence.<sup>26</sup> This warrants early intervention to increase peak gross motor ability and provide opportunities early in life to participate and be physically active with peers.<sup>2,27</sup> Neurodisability predisposes vulnerabilities in school preparedness with the rapid introduction of new cognitive, gross motor, social and upper limb challenges in a foreign environment.<sup>28</sup> 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.<sup>28</sup> 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.<sup>1,29</sup>

Walking-related goals are common in children with neurodisability, with locomotor treadmill training (LTT) being increasingly used as a targeted approach to address these.<sup>30–32</sup> LTT involves a combination of partial body weight supported treadmill training with overground walking to allow for safe, intense and repetitious practice.<sup>33</sup> Treadmill and overground training increase walking speed and endurance, and likely improve gross motor function in children with CP.<sup>1,4</sup> Benefits extend into broader populations of preschool children with neuromotor delay who demonstrate accelerated motor development following treadmill interventions.<sup>34</sup> There is a substantial variation in dosages delivered for LTT, often ranging from 4 weeks<sup>27</sup> to 3 months,<sup>22</sup> with the optimal frequency and duration yet to be defined.<sup>34</sup> Although, intensive blocks and higher doses of therapy are recommended over lower doses and regular distributed therapy.<sup>1</sup> Intensive blocks are frequently described as involving at least three sessions per week for a period of time.<sup>35</sup> 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.<sup>36</sup> Consistent with this dosage, improvements in motor function have been shown following 18 hours of LTT over 6 weeks in children aged 5–12 years old with CP (GMFCS III–V),<sup>33</sup> and following 14 hours of treadmill training in preambulatory children aged 1–5 years old with neuromotor delay.<sup>34</sup> 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<sup>30,32,37</sup> and those under the age of 5 years.<sup>27,38</sup> 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.<sup>21,26</sup>

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

goal-directed outcomes for preschool-aged children with non-progressive neurodisabilities (GMFCS III–V or equivalent).<sup>1–4 34 39</sup> 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,<sup>4 40</sup> a group-based environment to encourage play while addressing socialisation goals is warranted. As such, this study aims to determine the feasibility<sup>41</sup> of LTT embedded within an interdisciplinary framework in preschool-aged children with non-progressive neurodisabilities requiring daily equipment and physical assistance (ie, GMFCS levels III–V or equivalent). The primary hypothesis was that this intervention would be feasible as measured by limited-efficacy testing, acceptability, demand, implementation and practicality.

## METHODS

### Design

This single group feasibility study aimed to determine the feasibility of the Kindy Moves intervention.<sup>42</sup> Children with non-progressive neurodisability aged 2–5 years were recruited. Participants undertook 4 weeks of intervention, completing a 2-hour session three times per week. Feasibility was assessed through limited-efficacy testing (testing the effect of an intervention in a limited way), acceptability (how the participants reacted to the intervention), demand (the demand of the intervention), implementation (how the intervention was implemented as proposed) and practicality (how the intervention was delivered with constrained resources, time or commitment).<sup>38</sup> Limited-efficacy testing was determined by comparing objective changes from baseline 2 weeks before the intervention (T1) to the week following intervention completion (T2) and at follow-up 4 weeks post-intervention (T3). The shorter 4-week follow-up period was chosen to limit the effect of maturation on results. Acceptability was measured according to attendance rates and adverse events. Demand was determined through the ease and extent of recruitment during a 2-year time frame. Implementation was assessed by comparing the delivered intervention to the planned protocol and practicality was determined by attendance rates and an intervention dosage evaluation. The research team met on completion of the study to discuss the results and establish what changes could be made to the methodology in a future definitive trial. The intervention was completed at The Healthy Strides Foundation, a not-for-profit community therapy provider in Western Australia that delivers

intensive intervention for children and adolescents with neurological conditions and injuries. An interdisciplinary team of physiotherapists, occupational therapists, allied health assistants and a speech pathologist delivered the intervention. An exploration of patient and caregiver perspectives, levels of enjoyment and engagement will be reported in a future qualitative paper. This study was reported according to the Consolidated Standard of Reporting Trials (CONSORT) 2010 statement: extension to randomised pilot and feasibility trials.<sup>43 44</sup>

### 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.<sup>6</sup> 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 (CFCFS)<sup>45</sup> and Manual Ability Classification System (MACS)<sup>46</sup> levels I–V (or equivalent). Lastly, children with all motor presentations such as increased tone, reduced tone and varying tone were included. Children were not included in the study if they had orthopaedic surgery within 6 months of the study, unstable hip subluxation, uncontrolled seizure disorder or engagement in LTT in the month prior to the study. A semistructured interview was used for caregivers to answer open-ended questions to state diagnoses, medical conditions and co-occurring impairments. The sample size was based on practical considerations for the 2-year period such as year-by-year funding parameters and resource availability (staffing, equipment, time and space). Participants were recruited through The Healthy Strides Foundation social media pages.

### Intervention

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



**Figure 1** Treadmill training.

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

consistently underpinned by evidence-based recommendations.<sup>1–4</sup> The intervention was tailored to account for individual co-occurring impairments of the participants where possible. For example, activities for children with visual impairment involved high-contrast images and supplementary auditory and tactile stimuli. A Template for Intervention Description and Replication document can be viewed in online supplemental material 2.

## Outcome measures

### Canadian Occupational Performance Measure

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

### Goal Attainment Scaling

The Goal Attainment Scaling (GAS)<sup>49</sup> 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).<sup>12</sup> The fPRC conceptualises a health condition and the interplay of various constructs based on the WHO's International Classification of Functioning, Disability and Health (ICF).<sup>50</sup> The GAS is valid and reliable,<sup>51</sup> and has detected change across a variety of paediatric populations.<sup>52</sup> The GAS produces a t-score for analysis, with a t-score of 50 or more indicating clinical meaningfulness.<sup>53</sup> 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<sup>54</sup> 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.<sup>55</sup> 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.<sup>56</sup> 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.<sup>27 32 57</sup> However, there is less evidence of reliability and validity for children within GMFCS levels IV–V (or equivalent).<sup>51</sup> Participants walked as fast as possible in a mobility device across a 10 m distance. Facilitation of one step was provided for children who did not initiate stepping after 30s.<sup>33</sup> If a child did not complete the 10m distance in 360s, this time was recorded as the maximal result.<sup>33</sup> The clinically meaningful change in 10MWT speed is 0.1 m/s.<sup>58</sup> The GMFM-66 and 10MWT were selected as activity-based outcome measures according to the ICF because of the activity-focused nature of the intervention. These outcome measures also demonstrated meaningful improvements in a similar study protocol for children aged 5–12years with CP (GMFCS III–V),<sup>33</sup> warranting investigation in a younger age group.

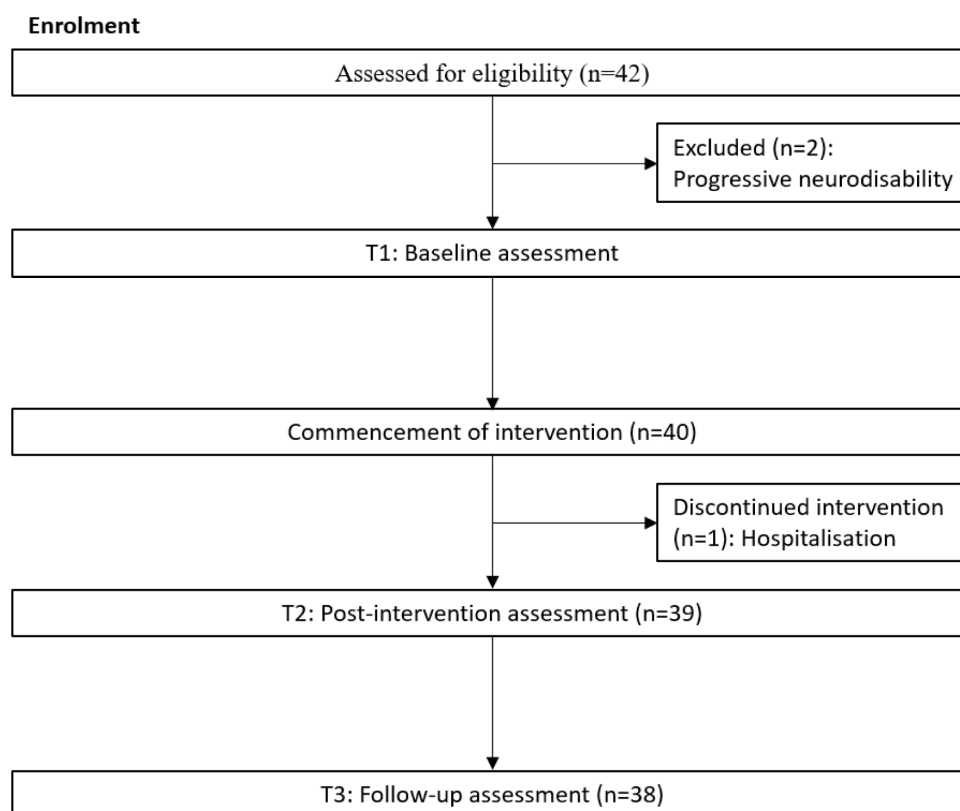
### Statistical analysis

Intention-to-treat analysis was applied. Data were presented as means and SD for continuous data, or medians and IQRs when the data were skewed and required transformation. Linear mixed models were used to compare within-group differences for all outcomes except the 10MWT where quantile regression was used due to the skewed distribution. Mean or median differences were produced along with their corresponding 95% CIs. The Smithers-Sheedy *et al*'s<sup>8</sup> 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<sup>47</sup> were used to categorise GAS across relevant domains including activity capacity, activity performance, participation (attendance), participation (involvement) and self-regulation. Descriptors of the COPM domains and subdomains were also used to categorise these goals.<sup>47 59</sup>

### RESULTS

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



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

**Table 1** Characteristics of participants

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

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

for play) and self-care: functional mobility (table 1). Most GAS were categorised as activity-based (93.3%).

### Feasibility

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

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

## DISCUSSION

### Feasibility

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

**Table 2** Outcome measure changes across all time points

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

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

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

### Goal outcomes

Improvements in goal attainment following Kindy Moves add to the growing literature in young children with neurodisabilities. Several interventions have shown results consistent with this study in improving goal attainment in children with neurodisabilities.<sup>60–63</sup> Two of these studies investigated goal-directed therapy in children with CP who were 4–5 years and classified across most GMFCS levels.<sup>60 62</sup> 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.<sup>60 62</sup> 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.<sup>63–65</sup> Although, research in this area often includes school-aged children<sup>63 64 66</sup> or infants,<sup>65</sup> with trials involving children aged 2–5 years being less frequently completed.<sup>67</sup> Data exploring the retention of outcomes in a period after

programme completion are important in establishing the extent of real-life skill application. Goal performance and satisfaction remained high 4 weeks after this intervention, suggesting that participants maintained their level of goal-related function without additional intensive therapy input. Further research into retained outcomes with longer-term follow-up may help to establish the required frequency of intensive therapy programmes throughout a child's lifespan.

With nearly all GAS in this study being activity-based and many participants functioning within levels IV–V (or equivalent) according to GMFCS (n=24), MACS (n=33) and CFCS (n=35), it is clear that families set skill acquisition goals irrespective of gross motor, upper limb or communication ability. Parents report that exercise interventions for non-ambulant children with CP are a high priority.<sup>19</sup> This is consistent with the literature shift in developing approaches beyond the level of body functions and structures for these children.<sup>4</sup> 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.<sup>68</sup> 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.<sup>9</sup> A relatively high proportion of the children in this study had visual and hearing impairment, or epilepsy, suggesting that these comorbidities do



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

Over one-third of GAS were related to activity performance according to the fPRC; this domain refers to the skills that a child uses in their everyday settings, reflecting the real-life application of skills learnt.<sup>12</sup> 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.<sup>12</sup> One possible explanation of this is that at the early stage of these children's development before school and involvement in other life situations, caregivers may have a larger focus on what skills their child needs to learn before considering the context of using those learnt skills. The use of a clinical space for the intervention rather than a school environment may have also meant that the application of skills in real-life settings was less apparent. However, categorised COPM goals covered the breadth of areas required for school preparedness,<sup>28</sup> with a relatively even distribution across functional mobility, socialisation, and school and/or play goals. Improvements in COPM goals across this range of areas highlight the effective use of an interdisciplinary team in streamlining service provision for an intensive therapy programme. This also shows the potential efficacy of an interdisciplinary team following clinical practice guidelines to facilitate goal-directed outcomes for preschool-aged children with wide-ranging comorbidities and functional ability levels. Future research may involve part, or all of the intervention being delivered in the school or home environment

to facilitate context-focused practice.<sup>1 2</sup> 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.<sup>12</sup> This is to be expected of an activity-based intervention with the aim of improving functional capacity.<sup>4</sup> 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.<sup>69</sup> Assessment tools such as the Child Engagement in Daily Life<sup>70</sup> or the Young Children's Participation and Environment Measure<sup>71</sup> can be used to evaluate these participation interventions. Participation-focused interventions have emerged in recent years and initial results show great promise.<sup>63 72</sup>

### 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<sup>73-75</sup> and younger<sup>27 38 76</sup> children with neurodisabilities. For CP populations, there is a strong evidence supporting locomotor training for walking speed, and promising literature for gross motor function.<sup>1 4</sup> Although, there is limited evidence for these effects in children with other neurodisabilities.<sup>34</sup> Among the available literature, children requiring equipment and assistance throughout their day are highly underrepresented. One of the few studies that did include these children with greater mobility requirements showed similar changes to Kindy Moves in four children with CP aged 1.7–2.3 years who completed 40–50 hours of therapy over 4 months.<sup>77</sup> Despite being a promising pilot study,<sup>77</sup> it is probable that natural maturation affected the results in the 4-month intervention, particularly at an age of rapid motor development. To account for this in Kindy Moves, a shorter intervention timeframe and only a 4-week follow-up period were selected. Although longer follow-up periods beyond 3 months provide vital information into retained clinical outcomes, we aimed to limit the extent of maturation as a confounding factor in interpreting the results of this feasibility study. In addition, the GMFMER was implemented to evaluate change in the context of this maturation.<sup>56</sup> Children with neurodisabilities receive regular therapy under the Australian funding model, meaning that a shorter follow-up duration also limited the impact of such external factors on results. At postintervention assessment, 76.5% of participants improved their gross motor function more than what was expected due to natural maturation as estimated by reference curves.<sup>56</sup> 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.<sup>78 79</sup> 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 360s. This was particularly evident in children functioning within GMFCS levels IV–V (or equivalent). The 6min Walk Test may be an appropriate alternative for this population to reduce the ceiling effect and record distance rather than time.<sup>51</sup> Although community ambulation may not be an achievable goal for all participants in Kindy Moves, newly learnt walking skills act as a means of daily exercise and an opportunity to reduce sedentary behaviour in line with the 24-hour activity guidelines for children with CP.<sup>80 81</sup> Improvements in walking speed postintervention may suggest that the participants have a greater ability to exercise during their day by walking with a mobility device. The possible implications of intensive activity-based programmes for sedentary populations are diverse and yet to be fully understood. Expanding beyond goals and motor capacity, benefits may relate to chronic disease,<sup>80</sup> bone mineral density,<sup>81 82</sup> sleep,<sup>80 81</sup> contractures<sup>2 4 81</sup> and hip displacement.<sup>2 81</sup> Parents of children with CP (GMFCS III–V) have reported similar desired health outcomes beyond motor function from a locomotor training intervention,<sup>83</sup> further warranting activity-based interventions irrespective of motor ability. Important research in this field of health and well-being is much needed with the hopes of positively impacting quality of life, hospitalisations and mortality.

The dosage required to achieve goals and improve motor function for children with neurodisabilities varies in the literature. Although greater consensus has been reached for upper limb goal attainment and function in children with CP,<sup>36</sup> a large variety in treatment dosages remains. Some locomotor training interventions have shown meaningful improvements in as little as three 1-hour sessions per week for 4 weeks (12 hours total),<sup>27</sup> whereas others have explored up to 3 months of 1 hour sessions four times per week (48 hours total).<sup>22</sup> 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.<sup>64</sup> A similar protocol of HABIT-ILE in children with unilateral CP aged 1–4 years resulted in goal and gross motor improvements after 50 hours of therapy over 2 weeks.<sup>67</sup> The outcomes of Kindy Moves highlight improvements in goals and motor function after 24 hours of therapy across 4 weeks. With many interventions showing clinically meaningful improvements at starkly different dosages, the question arises as to the minimum input required for a favourable and economical outcome. The lives of children with disabilities should

not centre around therapy, and the importance of family, fun, friends, rest and leisure cannot be forgotten when considering dosing intervention. The burden of travel, cost and time associated with therapy on families must also be considered. As such, the shortest possible time required to achieve desired outcomes needs to be determined.<sup>36</sup> The commitment involved in the Kindy Moves intervention appeared to be practical for participants, with high attendance rates. The intervention dosage is also reasonably low compared with other intensive interventions reported in the literature while achieving meaningful outcomes. With the knowledge that intensive block practice is recommended over regular distributed therapy,<sup>1</sup> 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.<sup>84</sup> This is particularly pertinent for children who have genetic or metabolic presentations with individually distinct traits. Such designs may assist in guiding intervention dosage for future populations to achieve desired outcomes in a family-centred and economical manner.

### Limitations

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

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

### Implications for future research

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

### CONCLUSION

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

highlights preliminary evidence for improving goal-driven outcomes and motor capacity in this population, warranting a well-powered randomised controlled trial to establish its efficacy.

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**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.

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

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

**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** Consent obtained from parent(s)/guardian(s)

**Ethics approval** This study involves human participants and 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. Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available on reasonable request. Data can be made available for research purposes on request.

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