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A protocol to evaluate the effect of Modified Scooter Board Therapy on Trunk Control and Hip muscles Activation in children with Cerebral Palsy ☆,☆☆

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MSBT on Trunk & Hip Muscles

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ABSTRACT

Cerebral palsy (CP) is a condition caused due to damage to a developing brain, leading to various motor, sensory and cognitive impairments. Being one of the leading cause of developmental disability among children worldwide, CP warrants a rehabilitation technique which is feasible and engaging for the child, cost effective for the family and based neurophysiological principles. Among the various impairments, the children with CP exhibit difficulty in sitting and ambulation due to abnormal tone and poor control in the muscles around the hip joint and the trunk. The previous literature supports the prone positioning and its effect in improving the girdle and trunk control, however there is lack in the studies which evaluate the type of interventions which consider the child and parent participation in intervention being delivered. Thus, the current double blinded randomized control trial aims to evaluate the effect of exercises done using Modified scooter board device in addition to conventional therapy in improving the hip muscle activation and trunk control in children with CP.

- A study evaluating the effectiveness of a novel scooter board device in children with CP.
- An intervention which is simple, self-engaging and cost effective to prevent most secondary complications seen in children with CP.
- An intervention which is aimed at reducing the hardship experienced by parents of children with CP towards improving their functional outcome.

Specifications table

Subject area:	Neuroscience
More specific subject area:	Cerebral palsy

(*continued on next page*)

☆ **Related research article:** none
☆☆ **For a published article:** none

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Name of your method	MSBT on Trunk & Hip Muscles
Name of your protocol:	*A protocol to evaluate the effect of Modified Scooter Board Therapy on Trunk Control and Hip muscles Activation in children with Cerebral Palsy*
Reagents/tools:	*Not applicable*
Experimental design:	*Randomized Controlled Trial*
Trial registration:	*CTRI/2023/07/055707; Clinical Trial Registry of India*
Ethics:	*The study will be conducted conforming to the declaration of Helsinki, has obtained the approval from the Institutional Ethics committee of Kasturba Medical College, Mangalore. The written informed consent obtained from the parent of the child and assent form if the child is below 8 years.*
Value of the Protocol:	*Describe the importance of the protocol in up to 3 bullet points.* • Evaluates a novel therapeutic approach and exercise protocol • Evaluate the effectiveness of the new device intended to alter the preactivated state of the muscle in children with cerebral palsy • Evaluates the usability of the low-cost therapeutic device by the children with cerebral palsy

Background

In children with CP, the altered brain function lead to altered muscle activity that is manifested as spasticity, reduced isometric force production, abnormal timing and reduced amplitude of muscle recruitment which in turn leads to reduced elasticity and reduced ability to stretch to full range, causing altered muscle growth and contracture [1]. Due to this, the normal interactions between the neuro-muscular system for the antigravity postural control become inadequate to facilitate the development of 'Trunk control' [2]. The trunk control means stabilization and deliberate controlled motions of the trunk to be working as the initial frame of reference to allow the child to move the head and extremities selectively for the needs of specific functional positions [3].

According to Curtis JD et al., the threshold for trunk control marks the changes between the various GMFM dimensions, and an improvement in trunk control is key to differentiating one GMFCS level from the next [4]. Thus, strengthening the trunk control segmentally by exercising or bracing the part of the trunk where control is lacking may result in clinically substantial enhancements in mobility and gross motor function [4].

Among the morphological changes, the resting length of the sarcomere (a functional unit of muscle) increases in spastic muscles that contribute to reduced force production by the muscles in children with CP, clinically manifested as weakness of muscles around the joints i.e. hip, knee, ankle etc. [5,6]. Moreover, the spasticity affects the adductors and flexors muscles of the hip, thus affecting the activation of hip abductors and extensors. This results in the atypical and unbalanced application of stress on the femoral head and acetabulum, leading to increased anteversion of femur and reduction in anterolateral growth of acetabulum, thereby ending with subluxation or dislocation of the hip [5,7].

The duration a child spends in the prone position influences motor development [8]. Studies show a strong link between prone positioning and early gross motor milestones like rolling, crawling, sitting (supported and unsupported), and early ambulation in typically developing children. Evaluation tools such as the Alberta Infant Motor Scale (AIMS), Infant Neurological International Battery (INFANIB), and Gross Motor Function Measure (GMFM) include prone positioning as a key item, highlighting its importance in motor development [9–13].

Recent studies explored the impact of trunk control exercises on hand function, improved sitting balance through virtual reality training, and enhanced postural control via modified Pilates in children with CP. However, these studies focused on ambulatory children (GMFCS level I–III), limited to one CP subtype, and used cognitively and physically demanding technology-based therapies. Additionally, they overlooked therapeutic exercises targeting both trunk and lower limb muscles (e.g., hip muscles), which could enhance functional outcomes in children with CP [14–16].

Based on the International Classification of Functioning, Disability and Health (ICF) framework for managing children with CP, the interventions should be focused on treating disabilities and improving a child's activities and participation. In addition, an intervention framework involving function, family, fitness, fun, friends and future would also be more beneficial [17]. Thus, there is a need to integrate therapy with fun-filled physical activity and design an innovative and integrative therapy for children with CP and identify if the intensity of exercises prescribed to children with CP has an impact on its effectiveness [18].

Description of protocol

Study design: Randomized controlled trial
Study setting: Neurosensory Developmental Unit, Kasturba Medical College, Mangalore
Study population: Children diagnosed with Spastic CP
Study Period: August 2023 – August 2027
Inclusion criteria:

- Children of either gender are diagnosed with CP by paediatrician or neurologist.
- Children in the age range of three to twelve years, who have no complete active control while sitting
- Children with GMFCS levels V, IV, III
- Children able to follow simple verbal commands.

- Children with variable degrees of spasticity of Upper limb and lower limb muscles measured graded using the Modified Ashworth scale (MAS) below grade 4 [19].

Exclusion criteria:

- Children with the acute form of musculoskeletal injury that may hinder participation in the exercise regime.
- Children on medications to modulate their tone, i.e. oral antispastic medication and intramuscular injections.
- Children with fixed skeletal deformity or contractures of the upper extremity (e.g. Elbow joint contracture), and lower extremities (e.g. Hip Dislocation, either unilateral or bilateral hip) and spine (e.g. structural scoliosis, kyphosis).
- Children with CP having associated genetic pathologies.
- Children with hearing or visual impairment.

Sampling Method: Non-probability sampling

Randomization: The participants will be allocated to either the treatment or control group using stratified randomization. The children will be divided into three strata based on GMFCS levels. The allocation ratio for the randomization sequence will be 1:1, and it will be generated through the utilization of www.sealedenvelope.com. The random block sizes of 2, 4, and 6 will be employed, and the process will be carried out by an independent individual. The concealment of the allocation sequence from the researcher will be achieved through the utilization of sequentially numbered, opaque, and stapled envelopes [20].

Sample size: The total sample size of 80 was calculated based on the following pilot study conducted of total 8 samples and using the following equation

$$n = \frac{2\left[Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right]^2 \sigma^2}{d^2}$$

n = Total sample size

$Z_{(1-\alpha/2)} = 1.96$ is standard normal value at 5 % level of significance

$Z_{(1-\beta)} = 0.84$ is standard normal values at 80 % power

$\sigma = \frac{(\sigma\ 1 + \sigma\ 2)}{2}$; a pooled standard deviation (σ, 0.0024) obtained from the pilot sample data of resting amplitude of adductor muscle of experimental (σ_1, 0.00245) and control (σ_2, 0.00238) group.

$d = (\bar{x}_1 - \bar{x}_2)$; Clinically significant difference obtained from the Mean difference of experiment $(\bar{x}_1, 0.003)$ and the control $(\bar{x}_2, 0.0046)$.

The total sample obtained was $n = 72$, with the consideration of 10 % attrition the final sample size obtained was 80 (40 in each group).

Materials:

- Bench with straps.
- Square-shaped foam.
- Video recording camera (Sony alpha® Digital Single Lens Translucent 24 MP camera using 25–50 mm lens) with Benro® adjustable tripod
- A disinfectant spirit along with Cotton swabs
- Surface Electromyography sensors and wireless Bluetooth receiver (Biometrics DataLITE wireless surface EMG sensors and DG2 wireless dongle)

Outcome measures:

Primary outcome:

- Amplitude *of Motor Unit Potential (MUP) at rest and during voluntary contraction measured using Surface electromyography*:
  The electromyography will be done using the Data LITE wireless sensors system, By Biometrics. Ltd. The Data LITE wireless EMG sensors (LE230 wireless EMG), the bandwidth of 20–480 Hz by 1000 gain amplifier, will be used to acquire muscle signals. The parents will briefly be explained about the surface EMG and what it measures, and what is expected from the child during the assessment. The data recording will be done in a quiet and non-distracting environment. The child will be positioned supine, prone, side-lying or sitting based on the muscles being analysed, ensuring comfort. The area of electrode placement will be exposed, and skin will be prepared by cleaning the area with alcohol dipped cotton swab. Wireless EMG sensor LE230 will be placed on the skin based on SENIAM guidelines (Table 1) [26] using two-sided medical adhesive stickers. The Motor Unit Potential (MUP) will be obtained from trunk flexors and extensors, Iliopsoas, Gluteus maximus, Gluteus Medius and Adductors. Following this, the active signals are monitored, calibrated and verified by observing appropriate baseline signals and increased signal amplitude during voluntary movement.
  Data acquisition and analysis:
  The MUP signal will be captured by a DG2 wireless Bluetooth dongle and interfaced with Biometrics DataLOG/DataLITE PC software version 10.13. The signal amplitude will be set at 0–10 mV, and a Low-frequency filter (High pass) and high-frequency filter (Low pass) will be set at 10 Hz to 500 Hz, with a frequency sampling rate (sampling frequency) of 5 kHz. The MUP will be rectified and smoothed using a 50 ms Root Mean Square (RMS) moving window to obtain the absolute value of the MUP signal.

Table 1
Description of surface EMG electrode placement.

Muscle	Electrode placement	Testing position	Testing movement
Trunk flexor	a. A two-finger width lateral from the umbilicus, aligned vertically	Sitting	Maintain the seated position and raise the arm
Trunk Extensor (Lumbar)	a. Two finger width laterally from the spine of L1, vertically oriented b. Aligned with a line from the caudal tip posterior superior iliac spine (PSIS) to the interspace between L1 and L2 interspace at the level of the L5 spinous process (i.e. about 2 - 3 cm from the midline)	Sitting	
Gluteus Maximus	a. Placed at 50 % on the line between the sacral vertebrae and the greater trochanter, aligned with a line joining PSIS and posterior thigh	Prone	Lifting the leg against the gravity
Gluteus Medius	a. Placed at 50 % on the line from the iliac crest to the trochanter.	At rest in supine and Side-lying	Lifting the leg upward
Adductor mass of the hip	a. Placed at upper one-third of the medial side of the thigh and just below the inguinal area, oriented vertically	At rest in supine	Move the lower extremity medial
Flexor mass of the hip	a. Placed directly medial to the Anterior Superior Iliac Spine (ASIS), oriented with a line joining the ASIS and Greater trochanter of the femur.	Supine	Lift the leg away from the mat

ASIS, Anterior Superior Iliac Spine; PSIS, Posterior superior iliac spine.

The analysis of MUP will be made under the following conditions (a) Amplitude of MUP at rest, (b) Amplitude of MUP following the test, (c) Difference in the Maximum amplitude of the MUP between agonist and antagonist (d) MUP firing frequency between agonist and antagonist and (e) Muscle co-activation index

- Trunk *control in sitting using Segmental assessment of trunk control (SATCo):*
  The Segmental Assessment of Trunk Control provides systematic methods of assessing discrete levels of trunk control in children with motor disabilities. The test will be carried out according to the standard guidelines [24].
- Change *in gross motor function using Gross Motor Functional Measure (GMFM 66):*
  The Gross Motor Function Measurement is a reliable and valid tool for the assessment of gross motor function in children with CP. It consists of 88 items, and these items are organized into five dimensions as lying and rolling (A), sitting (B), crawling and kneeling (C), standing (D), and walking, running, and jumping (E). Items are scored on a four-point ordinal scale by observation of a child's performance on each item (0 = does not initiate, 1 = initiates <10 % of activity, 2 = partially completes 10–100 % of activity, 3 = completes activity). Scores of each dimension are expressed as a percentage of the maximum score for that dimension; finally, the total score of the GMFM-66 is obtained by GMAE 2 software [25].

Secondary outcome:

- Physiological range of motion of Hip joint, i.e. Flexion, extension, abduction using Baseline® Digital Goniometer (Table 3).

Data collection:

The study protocol will be submitted to the scientific review committee and ethics committee, Kasturba Medical College, Mangalore, Manipal Academy of Higher Education, for approval. The study will be registered under the Clinical Trail Registry of India (CTRI). Upon approval, children visiting the Neurosensory developmental unit, KMC Bejai referred by a paediatrician/neurologist, will be approached. The study procedure will be explained to the parents, and from those agreeing to participate, a written informed consent (assent form if the child is below eight years) will be obtained. Thereafter, demographic details will be collected, and children will be screened based on the proposed inclusion and exclusion criteria. The child will be allocated to a treatment or control group using stratified randomization using a random sequence generated (ex. MSBT, Conventional, Conventional, MSBT). Following this, the children who are allocated to the treatment group will receive Modified Scooter Board (MSB) intervention in addition to the conventional exercises (Table 2). The children in the control group will receive only conventional therapy (Table 2). The total treatment duration will be eight weeks. The child will be treated at the Neurosensory developmental unit, KMC Bejai, for three days/week by the investigator, and the remaining four days of therapy in a week will be practiced at home. The MSBT will be a fun/playful intervention and will be practiced for a duration of 4 h/day. Every parent will be given a diary to record the day and duration for which therapy is practiced and will be asked to record the treatment using a mobile camera; and the same will be verified during the follow-ups to ensure compliance. The interventions are reported based on TIDieR guideline (Table 2) [21].

Measurements:

Each included child will be assessed by an independent tester for primary and secondary outcome measures at baseline, i.e. prior to inclusion in the intervention; second measurements will be taken at the end of 8 weeks, and final measurements will be taken after 4 months. The measurement will be done by the independent tester, in the order, SATCo, EMG analysis of Gluteus Medius, Gluteus maximus, Iliopsoas, adductor brevis and longus and Trunk flexor and extensor (Table 1), then Gross motor function measure (GMFM) and the passive range of motion using a digital goniometer for hip flexion, extension, abduction will be recorded (Table 3). The measurements will be recorded and archived for every individual sample for analysis (Fig. 1).

Table 2
Description of intervention Modified scooter board therapy and Conventional exercise program.

Intervention	Position of child	Exercise	Parameters	Precaution & Termination
Modified scooter board therapy	Prone on MSB a. Line joining ASIS placed at an anterior end of MSB. b. Bilateral lower extremities will be secured in abduction using removable Velcro® straps.	*Static*: Child will maintain the prone position on the MSB, will be done for 1–2 weeks until child master's the static position. *Dynamic*: Child will be allowed to propel the forward on the scooter board using their upper extremities.	The total duration of the therapy will be 8 weeks and further will be followed for a period of 16 weeks unsupervised. *Frequency*: Daily for 8 weeks daily supervised by therapist & parent – 3 days at NSDU OPD, remaining days practiced at own residence. *Duration*: Minimum 4 h/day; at NSDU OPD visit 90 min at OPD and rest of the hour will be completed at own residence. *Intensity*: Progression from static to dynamic module which is Initiated with slow and progressed to self-paced propulsion by the child. Further progression is done by a. Placing the child more anterior with most of the pelvis is unsupported by the MSB. b. Addition of weights on the upper extremities.	a. Duration of MSBT followed with adequate rest at every 10 m of propulsion. b. Progression from module I to Module II will be based on adequate maintenance of elbow extension in static. c. Pause the therapy if any complaints of undue fatigue by the child. d. Pause the therapy if the child is unwell and resumes when the child can perform the exercises.
Conventional exercise	The child will be placed in a prone, supine or sitting position according to the type of exercise performed. The exercises will be initiated on the floor and progressed on the therapeutic ball.	Conventional exercises are based on the principles of Bobath and NDT, which are widely practiced therapy regimens. The exercises are divided into muscle range of motion, joint mobility and muscle strength for trunk and lower extremity.	The total duration of the therapy will be 8 weeks and further will be followed for a period of 16 weeks unsupervised. *Frequency*: During the period of 8 weeks, a child will receive daily conventional exercises. Three days a week as outpatient and remaining days will be practiced at own residence. *Duration*: A duration of 4 hour/day the exercises will be practiced. During outpatient days the 90 min of therapy will be done at NSDU OPD, and the rest of the hour will be completed at own residence. During non-outpatient days it will be rendered at own residence by the parents. *Intensity*: The intensity is made of the total duration of the exercises received by the child, i.e. 4 h/day for 8 weeks. The exercises are performed under three categories, i.e. muscle range of motion, joint mobility and muscle strength. The progression will be based on the improvement in the range of joints and muscle, improvement in the muscle activity demonstrated by change in the posture and sitting control and improved range of hip abduction.	

MSB, Modified Scooter Board; NSDU OPD, Neurosensory Development Unit Outpatient department; NDT, Neurodevelopmental Therapy.

Table 3
Description of the passive range of motion assessments.

Joint movement	Position	Fulcrum	Stable arm	Movable arm	Description
Hip Flexion	Supine	Greater Trochanter	Parallel to the long axis of the vertebral column	Parallel to the long axis of the femur	Move the Thigh toward the abdomen with the contralateral leg stabilized in extension
Hip Extension	Prone	Greater Trochanter	Parallel to the long axis of the vertebral column	Parallel to the long axis of the femur	The thigh is moved away from the stabilizing surface
Hip Abduction	Supine	Anterior Superior Iliac Spine	Anterior Superior Iliac Spine	Parallel to the long axis of the femur	The Contralateral leg will be stabilized in neutral hip range of movement

Data analysis:

The data will be coded and entered the JAMOVI version 2.3.21 [22], and descriptive statistics will be used to express the qualitative data as percentages. Data will be tested for normality using the Shapiro-Wilk test. The quantitative data will be expressed as mean and standard deviation. The independent and paired sample *t*-test will be used to compare group means with the significance level set at $p < 0.05$. Analysis of Variance (ANOVA) will be used to test the differences among the groups at three different intervals. Based on the rate of attrition, intention to treat analysis will be applied.

Protocol validation

A pilot trial was conducted to evaluate the feasibility and applicability of Modified Scooter Board Therapy (MSBT) as an adjunct to conventional therapy in children with cerebral palsy (CP) classified at Gross Motor Function Measure (GMFM) levels III, IV, and V. The

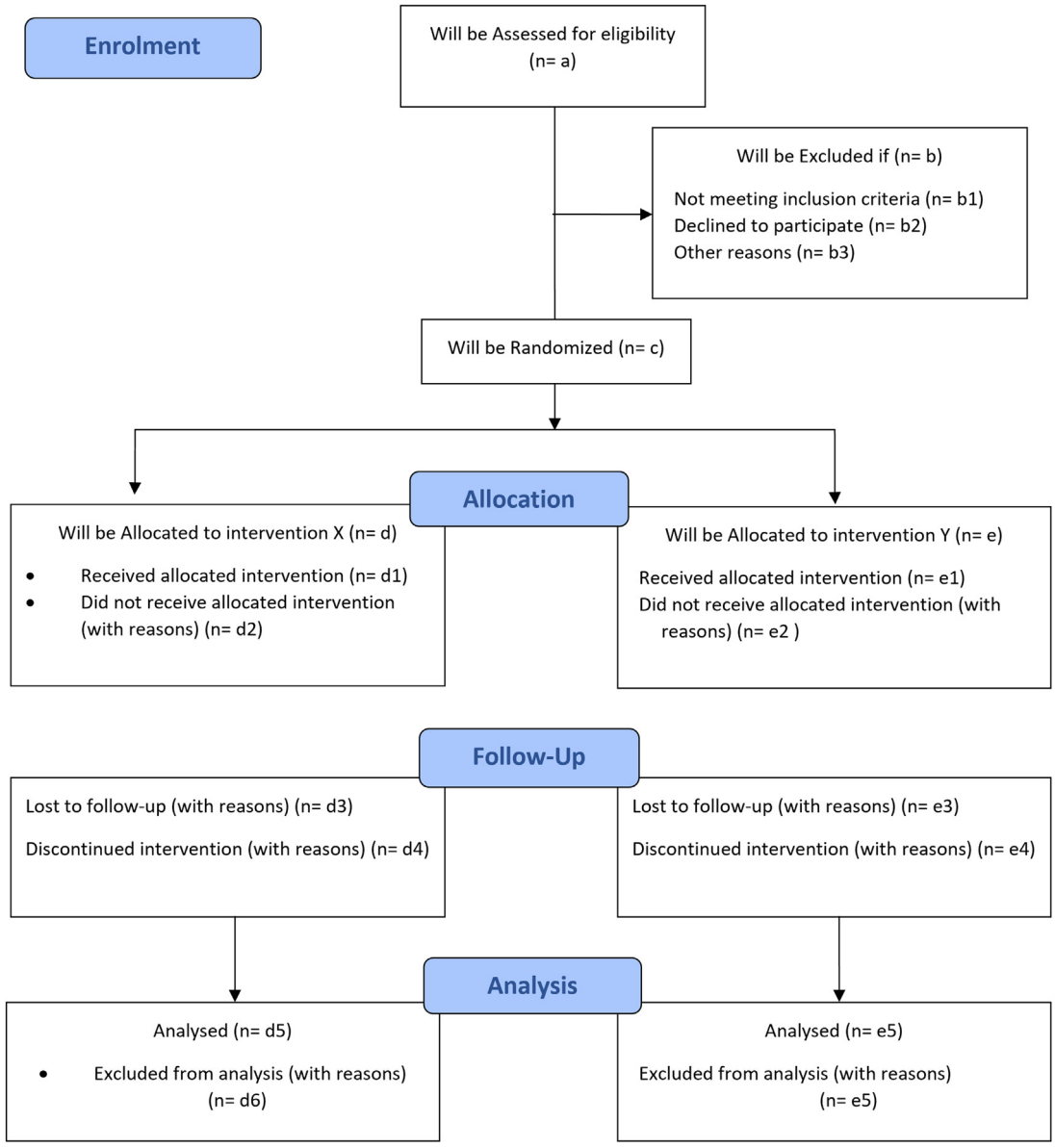

Fig. 1. Consort flow diagram.

findings indicated a mild to moderate effect of the MSBT program in combination with conventional therapy in reducing hypertonicity of the muscles surrounding the hip joint. The study included a sample of eight children with CP who exhibited significant limitations in sitting control and mobility in lower functional positions. Although the differences in motor unit potentials (MUP) between the MSBT and conventional therapy groups did not reach statistical significance, the mean difference values were notable in key muscle groups, including the hip adductors, hip abductors, trunk flexors, and, to a lesser extent, trunk extensors. The observed differences in MUP may reflect reduced hypertonicity in these muscle groups, potentially attributable to enhanced agonist-antagonist co-contraction following MSBT. This mechanism could exert an inhibitory effect on overactive muscles while promoting more effective muscle contraction. Additionally, non-neural factors may have contributed to these effects, particularly the reduction in viscous damping and elastic stiffness of the muscles, which are influenced by the positioning patterns utilized in the MSBT program [23].

The MSBT intervention was delivered over an 8-week period, consisting of three outpatient sessions per week, with home-based practice on the remaining days. Parents reported that the intervention protocol was easy to follow, and children were comfortable performing exercises on the modified scooter board. Parents found the therapy straightforward to administer, as it involved children propelling themselves forward using their arms while keeping their lower extremities within functional hip joint ranges. The parents' primary role was to provide motivation and guidance. However, as the therapy was practiced at home three times per week, some parents reported difficulty accurately tracking and maintaining the recommended practice duration of four hours per day. Despite this, the MSBT protocol was deemed feasible, and no modifications to the therapy regimen were required.

Limitations

Despite careful consideration of potential limitations during study design, we acknowledge that adherence to home-based therapy modules for children with cerebral palsy may be suboptimal. Additionally, maintaining follow-up beyond 24 weeks could pose significant challenges. Regarding the assessment of muscle activity using surface electromyography (sEMG), we anticipate that the assessment duration may need to be extended to accommodate the child's understanding of the assessor's instructions. Furthermore, evaluating multiple muscles may require prolonged cooperation, which could be difficult for some children.

Credit author statement

Shreekanth D. Karnad: Conceptualization, Data curation, Methodology, Formal analysis, Investigation, Visualization, Writing - original draft, Writing - review & editing. **Amitesh Narayan:** Conceptualization, Methodology, Validation, Supervision, Project administartion,Writing - review & editing. **Nutan Kamath:** Methodology, Validation, Supervision, Project administartion, Writing - review & editing. **Bhamini K. Rao:** Methodology, Validation, Supervision, Writing - review & editing. **Monika Sharma:** Methodology, Validation, Supervision. **Vijaya Kumar K:** Validation, Supervision.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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