*Official title: Feasibility and response of a novel training on dynamic balance and physical activity in adolscents with cerebral palsy*

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*Study design and participant recruitment*

Our study utilized a randomized controlled trial with parallel group allocation suitable for assessing feasibility in early-stage research. Recruitment involved advertisements placed on clinical trial websites, flyers posted in the around the University of Alabama at Brimingham (UAB) campus buildings, referrals from healthcare providers, and word-of-mouth recommendations. Interested individuals reached out to research staff via email or phone and were screened for eligibility through telephone interviews.

Inclusion criteria included: (1) adolescents aged 11-21 years, (2) confirmed diagnosis of spastic cerebral palsy (CP) or spina bifida (SB), (3) ability to walk independently (Gross Motor Function Classification System [GMFCS] level I–II), (4) capacity to understand and follow verbal instructions in English, and (5) willingness of participants and their parents to commit to the full duration of the study. Exclusion criteria were: (1) having undergone orthopedic surgery or botulinum toxin A injections in the lower limbs within the past 6 months, (2) participation in structured lower limb exercise training within the past 6 months, (3) plans to engage in structured exercise training outside the study, (4) presence of cardiac, pulmonary, visual, auditory, or other physical conditions that could hinder study participation, and (5) any additional medical conditions that could interfere with performance of independent physical activity.

As this study focused on feasibility rather than efficacy, no formal sample size calculation was performed. Our study was reviewed and approved by the University of Alabama at Birmingham Institutional Review Board ensuring compliance with ethical standards for research involving human participants.

*Exercise dose determination*

Two baseline sessions were performed for exercise dose determination which was customized for each type of exercise movement and each participant. Thus, we minimized the learning effect. At the 1st baseline, all participants were asked to perform 3 sets (30sX3) of each of the 5 exercises (Figure 1A) with the instruction: do as many as you can with the correct form in 30s. Before any exercise dose determination testing, a single tester demonstrated all the exercises to our participants. The tester showed both the correct and incorrect ways of doing the exercises. Then, all the participants tried the exercise movement 1-5 times to familiarize themselves. Rest periods of 30s and 90s were provided between each set and exercise-type, respectively. After the end of each set, we recorded the participant's rating of perceived exertion (RPE).

For the participants who successfully completed all sets of exercises, we recorded the repetitions/set for each exercise and used the lowest number as their starting dose for that specific exercise. At their 2nd baseline session, which was within 7 days of their 1st baseline visit, we asked them to perform the pre-determined exercise dose/exercise. A successful completion with the pre-determined exercise dose/exercise at the 2nd baseline visit confirmed their unique starting dose. In cases where the participant indicated that they could achieve higher repetition for 3 sets for any specific exercise, we performed another assessment to adjust the exercise dosage per the new number achieved.

For the participants who failed to complete any of the three sets for the full 30 secs at the 1st baseline, we recorded the maximum number of repetitions that were performed. Then, we reduced that number by 10% and tested the participant's performance again for the same exercise. These participants also performed the pre-determined exercise dose/exercise at their 2nd baseline visit for their unique exercise dose determination. Thus, we were able to determine customized dose for each participant per exercise.

*Exercise Intervention:*Three participants (1 CP and 2 SB) completed a 4-week intervention (2x/week) involving either HIT (n=1, SB) or FUNHIT (n=2, CP + SB). All the three participants performed the same exercises: split squats, chair squats, side steps, heel rises, and jumps (**Figure 1A**) for the same duration. Each participant's exercise dose and progression for each session followed a personalized order based on their baseline exercise dose per exercise. Each participant in the intervention groups (HIT or FUNHIT) was instructed to increase their repetitions for each exercise by two at the start of every week, beginning on day 1 week 1 of the intervention. A metronome was used to help them maintain a consistent pace. Participants were encouraged to do more repetitions in the last set of each exercise if they felt comfortable. The exercise was only increased for those participants who successfully complete the determined exercise volume for the specific week. On Day 2 of each week, the participants performed the same number of repetitions as of Day 1. Next, on Day 1 of the following week, the participants increased the repetitions by two (with respect to the previous week count) for each exercise and repeated the process until the end of the intervention period.

Notably, during the exercise dose determination sessions, we asked each participant to rate the 5 exercises based on their perceived difficulty. We used this information to design a personalized exercise sequence for each participant with the least difficult exercise as the starting exercise. Next, we arranged the remaining 4 exercises to alternate between higher and lower perceived difficulty levels to ensure that the 'difficult' and 'easy' exercise followed each other. This was mainly done to ensure that the participants could finish the full exercise session without undue fatigue interfering with their exercise performance. The description of each exercise is outlined in **Appendix 1**.

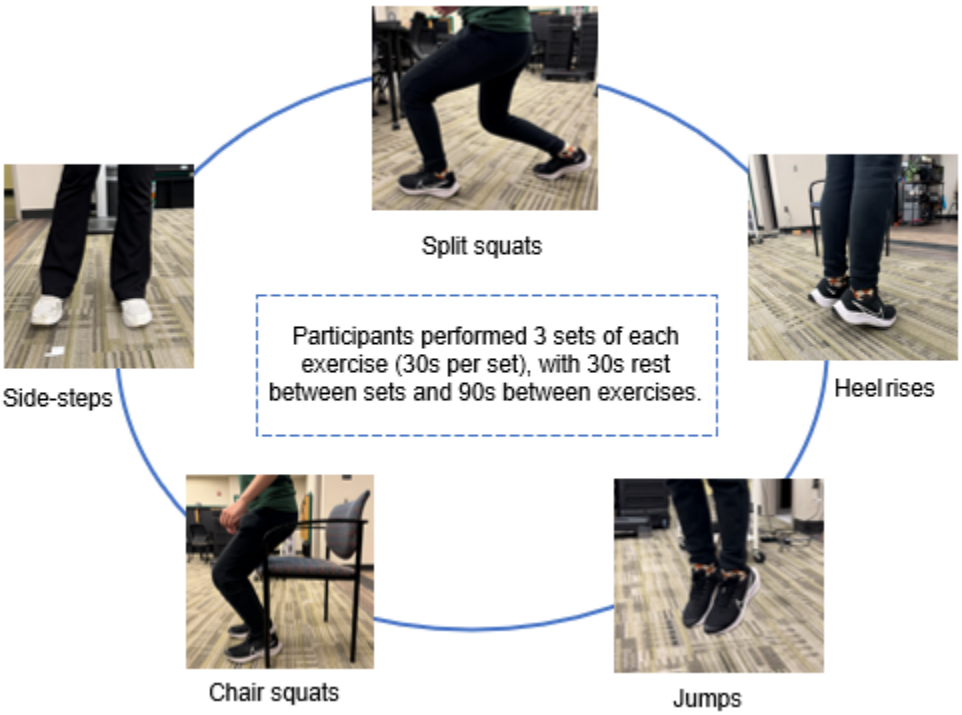



**Figure.** Representative images of the exercise movements that were performed by participants in our study. A detailed description of these exercises is provided in Appendix 1.

All the exercises were the same between the HIT and FUNHIT group; with the FUNHIT group performing these exercises while wearing weighted vests (Fun and Function, LLC; see **Figure 1B**). The FUNHIT participants started their 1st exercise session at 2.5% of their body weight and increased by 2.5% weekly, reaching 10% by the week 4. Each session lasted approximately 20 minutes. The control group (n=2, SB) continued to receive their usual care and participated only in pre- and post-intervention testing.



**Figure 1B.** Weighted vest used in FUNHIT intervention.

*Feasibility metrics*

Feasibility metrics are shown in **Table** as follows:

**Table:** Feasibility metrics and assessment approaches

| **Metric** | **Outcome** | **Assessment approach** | **Importance to future studies** |
|---|---|---|---|
| **Process metrics:** evaluate participant recruitment, retention, and adherence | 1. Recruitment, eligibility, and refusal rates<br>2. Retention rate<br>3. Adherence rate | 1. Number of people were screened and were eligible to participate in the study<br>2. Number of participants enrolled in the study<br>3. Number of participants declining to participate and reasons.<br>4. Percentage of participants who completed two pre-intervention assessments<br>5. Percentage of participants who completed the 4-week intervention.<br>6. Percentage of participants who completed the post-intervention assessment. | • To provide strategies for improving recruitment methods, anticipating recruitment rate, and understanding reasons for participant refusal<br>• To identify key areas for improving participant retention and adherence |
| **Resource metrics:** evaluate the time and money | 1. Time spent on recruitment, pre/post assessment, and intervention phases | 1. Time from first contact participant to enrollment (days)<br>2. Time to screen for eligibility (minutes) | • To identify time requirements for each step, highlighting any |

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|---|---|---|---|
| needed for the study | 2. Financial resources necessary to conduct the study | 3. Time spent on the pre-assessment phases<br>4. Time spent on the post-assessment phase<br>5. Time spent on the intervention phase<br>6. Total cost | issues or challenges<br>• To track time commitments and assess any necessary adjustments<br>• To evaluate the financial demands of the study and explore opportunities for cost reduction |
| **Management metrics:** evaluate data management and safety reporting procedure | 1. Time and completeness of data collection and entry | 1. Time for participants to complete FoF Questionnaire (minutes)<br>2. Time for participants to complete PA Questionnaire (minutes)<br>3. Personnel time to download and process Zeno walkway path data (hours) | • To emphasize timely completion of this study measures and approaches for ensuring data integrity. |
| **Scientific metrics:** evaluate safety, burden, and treatment effect | 1. Adverse events, serious adverse events, and clinical emergencies<br>2. Participants' ability to adhere to the prescribed intervention dosage and repetitions throughout the study<br>3. Intervention effects measured via:<br>• FSST<br>• TUG, TUG with a cup, TUG with counting<br>• LSUT at low and high level<br>• Zeno walkway<br>• FoF Questionnaire<br>• PA Questionnaire | 1. Number of adverse events, serious adverse events, and clinical emergencies<br>2. Assessment of participants' adherence to the prescribed intervention frequency, duration, and repetitions.<br>3. Intervention effects were assessed via effect size and changes in dynamic balance and muscle strength outcome variables | • To evaluate the safety and feasibility of the intervention and identify potential areas for modification<br>• To assess the acceptability of the intervention along with the compliance rate<br>• To gather preliminary data for power analysis and estimate the potential clinical significance of the intervention |
| *LSUT, Lateral Step Up Test; FoF, Fear of Falling; PA, Physical activity*<br>*FSST, Four square step test; TUG, Timed Up and Go* | | | |

*Assessments*

Following are the tests used in our study:

- The Four-Square Step Test (FSST) utilized four canes arranged in a cross on the floor, forming four squares, where participants were instructed to step forward, sideways, and backward in a specific sequence as quickly as

possible without touching the canes, with the time recorded in seconds using a stopwatch to assess dynamic balance and coordination.

- The Lateral Step-Up Test (LSUT) required participants to stand beside an adjustable step (height set at low level (~17 cm) and high level (~37 cm) and step laterally onto it with one leg, fully extending the knee, then return to the starting position, repeating this for 20 seconds, with the number of completed steps counted to measure lower limb strength.
- The Timed Up and Go Test (TUG) involved participants rising from a standard chair, walking 3 meters to a marked cone, turning 180 degrees, and returning to sit, with time recorded in seconds using a stopwatch to evaluate functional mobility.
- The TUG with counting backward required participants to count aloud by subtracting 3 from a random number between 20 - 80 while performing the standard TUG.
- The TUG with a full cup of water required participants to carry a full plastic cup of water (around 250 ml) while performing the standard TUG and not spilling the water.
- The Unrestrained Maximum Walking Speed Test employed a 6-meter-long pressure-sensitive mat (ProtoKinetics Zeno™ Walkway Gait Analysis System), where participants started two steps before and walked past the mat at their fastest safe speed, with the mat capturing spatiotemporal gait measures (such as speed (m/s), step length (cm), and cadence (steps/min)) to measure their functional mobility.
- The Restrained Maximum Walking Speed Test, on the same Zeno™ walkway system, required participants to start by standing on the mat and then walking at their fastest safe speed and stopping at a marked position on the mat near its endpoint.
- The PROMIS Physical Activity (PA) Questionnaire consists of 10 questions assessing the participant's physical activity over the past 7 days. Responses are scored on a scale from 1 to 5 (1 = no days, 2 = 1 day, 3 = 2–3 days, 4 = 4–5 days, 5 = 6–7 days), with higher total scores indicating greater levels of physical activity during the previous week.
- The Pediatric Fear-of-Falling (FoF) Questionnaire includes 34 questions evaluating the participant's fear of falling during various daily activities. Responses are rated on a scale from 0 to 2 (0 = never, 1 = sometimes, 2 = always) or marked as N/A (not applicable), with higher total scores indicating greater fear of falling.

All the tests were assessed by the same consistent tester.

As this study focused on feasibility rather than efficacy, no formal sample size calculation was performed. Our study was reviewed and approved by the University of Alabama at Birmingham Institutional Review Board ensuring compliance with ethical standards for research involving human participants.

**Statistical Analyses: Due to the pilot and feasibility design of our study, we report our results of feasibility and treatment response metrics as absolute numbers. Mean and SD (Standard deviation) are reported for exercise dosage determination and progression. Treatment**
responses for the pre-post changes are reported as percentages.