Arm-based Sprint-Intensity Interval Training Movement-to-Music (arm-SIT-M2M) for Children With Cerebral Palsy: A Pilot Feasibility Randomized Controlled Trial

Study Protocol & Statistical Analysis Plan

NCT05619211

7 Nov 2025

Byron Lai, Assistant Professor, Principal Investigator

University of Alabama at Birmingham

Birmingham, AL 35294

PILOTING MOVEMENT-TO-MUSIC WITH ARM-BASED SPRINT-INTENSITY INTERVAL TRAINING AMONG CHILDREN WITH PHYSICAL DISABILITIES

Principal Investigator: Byron Lai, PhD

Sponsor: University of Alabama at Birmingham

National Clinical Trial (NCT) Identified Number: NCT05619211

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STATEMENT OF COMPLIANCE

The trial was conducted in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and applicable United States (US) Code of Federal Regulations (CFR). The Principal Investigator was assure that no deviation from, or changes to, the protocol was take place without prior documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial subjects. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all subject materials was submitted to the local Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any subject was enrolled. Any amendment to the protocol was require review and approval by the IRB before the changes were implemented to the study. All changes to the consent form was IRB approved; a determination was made regarding whether a new consent needs to be obtained from subjects who provided consent, using a previously approved consent form.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Arm-based Sprint-Intensity Interval Training Movement-to-Music (arm-SIT-M2M) for Children With Cerebral Palsy: A Pilot Feasibility Randomized Controlled Trial
Study Description:	This Phase I pilot randomized controlled trial tested the short-term effects of a 12-week home-based arm sprint-intensity interval training Movement-to-Music (arm-SIT-M2M) program among children with cerebral palsy. Parent–child dyads were randomized to either an immediate start intervention group or a 12-week waitlist control. Laboratory assessments were completed at baseline (week 0) and post-intervention or post-wait period (week 13), with exercise delivered at home under synchronous telehealth supervision.
Objectives:	*Aim 1: To examine the effects of arm-SIT-M2M on cardiorespiratory fitness compared with waitlist control.* *Aim 2: To explore effects of arm-SIT-M2M on indicators of cardiometabolic health.* *Aim 3: To evaluate feasibility, including adherence, enjoyment, recruitment, retention, and adverse events.*
Endpoints:	Primary endpoint: Peak oxygen consumption (pVO_2) measured during graded arm-ergometer exercise testing. Secondary endpoints: Blood pressure; body composition from dual-energy X-ray absorptiometry (DEXA); dried blood spot biomarkers including high-sensitivity C-reactive protein, hemoglobin A1c, fasting insulin, triglycerides, and total/LDL/HDL cholesterol.

	Feasibility endpoints: Exercise adherence (YouTube analytics), physical activity enjoyment (PACES), technology issues, recruitment and attrition rates, and adverse events.
Study Population:	Fifty children with cerebral palsy (ages 6–17 years; Gross Motor Function Classification System levels I–III; physically inactive) and one caregiver per child.
Phase:	Phase I (pilot feasibility).
Description of Study Intervention:	Participants in the immediate start group completed seated, arm-based sprint-intensity interval training synchronized to themed music videos three times per week for 12 weeks. Sessions were supervised in real time via a telehealth platform with chest-strap heart-rate monitoring and rating of perceived exertion–guided progression using resistance bands. Caregivers attended all sessions to support safety. Waitlist control participants maintained habitual activity for 12 weeks and then received the same intervention.
Study Duration:	The overall study spanned enrollment through completion of all post-intervention assessments, with each dyad completing baseline and week-13 laboratory visits.
Subject Duration:	Approximately 13 weeks per participant, from baseline assessment to post-intervention or post-waitlist evaluation.

1.2 SCHEDULE OF ACTIVITIES (SOA)

Participants completed screening and baseline laboratory assessments at Week 0, including informed consent/assent, eligibility screening, demographics, questionnaires, blood pressure, DEXA, dried blood spot biomarkers, and graded arm-ergometer testing for peak oxygen consumption. Caregivers received CPR/AED and equipment training at baseline.

During Weeks 1–12, participants randomized to the immediate start group completed supervised arm-based sprint-intensity interval training Movement-to-Music sessions three times per week via telehealth, with real-time heart rate monitoring and caregiver support. The waitlist control group maintained habitual activity during this period. Feasibility outcomes and adverse events were monitored continuously.

At Week 13, all participants completed post-intervention or post-wait laboratory assessments identical to baseline, including questionnaires, blood pressure, DEXA, dried blood spot biomarkers, and graded exercise testing. Study equipment was returned at this visit.

2 INTRODUCTION

2.1 STUDY RATIONALE

There are few evidence-based exercise options that children with cerebral palsy can utilize to improve their cardiorespiratory fitness and manage their cardiometabolic health.

2.2 BACKGROUND

Children with cerebral palsy (CwCP) have limited accessible exercise options that empower them to independently maintain their cardiorespiratory fitness, and this places them at high risk for mortality and numerous cardiometabolic complications across the lifespan. We developed an evidence-informed Movement-to-Music (M2M) program to improve cardiorespiratory fitness for children with mobility disabilities. The program includes 4 innovative components: 1) prerecorded videos with M2M exercises that are based on child-appropriate themes (e.g., superheroes, sports, pop music etc.); 2) replicable cloud-based tele-monitoring procedures; 3) behavioral tele-physical education supervision during exercise; and 4) sprint-intensity interval training (SIT) adapted for varying arm abilities. We aim to first pilot the health benefits and safety of the program among a cohort of children with CP, which inform the design of a scale-up trial that will include a broader group of children with mobility disabilities.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

- Chest pain or discomfort
- Heart palpitations
- Rapid or irregular heartbeats
- Unexplained wheezing
- Shortness of breath
- Fainting or near fainting
- Lightheadedness or dizziness
- Cardiac arrest for those who are severely deconditioned or are medically compromised

2.3.2 KNOWN POTENTIAL BENEFITS

Participation in regular exercise may have potential benefits towards health, but the benefits are not guaranteed. The study findings will help us understand the potential benefits of a telehealth arm-based Movement-to-Music program. The study findings will be used to inform a larger study that aims to improve cardiorespiratory fitness and cardiometabolic health among children with cerebral palsy.

3 STUDY DESIGN

3.1 OVERALL DESIGN

This Completed Phase I pilot randomized controlled trial evaluates the safety, feasibility, and preliminary efficacy of a 12-week home-based arm sprint-intensity interval training Movement-to-Music (SIT-M2M) program among children with cerebral palsy (ages 6–17, GMFCS I–III). Participants were randomized 1:1 to immediate intervention or waitlist control. Primary outcome was peak oxygen consumption (pVO2). Secondary outcomes included cardiometabolic indicators (DXA body composition, dried blood spot biomarkers, and blood pressure). Feasibility metrics included adherence, enjoyment, recruitment, and adverse events.

3.2 END OF STUDY DEFINITION

Immediate start participants completed the study in 12 weeks. Waitlist control participants completed the study in 24 weeks.

4 STUDY POPULATION

4.1 INCLUSION CRITERIA

Eligible child participants will (Inclusion Criteria):
-have a medical diagnosis of cerebral palsy, as determined by ICD-10 codes
-aged 6-17 years old
-a Gross Motor Function Classification System Level I-III (as determined via participant screening, explained in the protocol section below)
-medical clearance to participate in high-intensity exercise from a physician (using the attached medical screening form and explained in the intervention safety,
monitoring, and response plan)
-access to a Wi-Fi Internet connection in the home via mobile phone or tablet computer
-a caregiver who will support and monitor the participant's safety during the intervention and manage the child's exercise schedule.

Eligible caregivers will include parents or legal guardians of the child, who can commit sufficient time to support the child in their roles for the study and communicate
in English. Caregivers who have complete blindness or deafness will be excluded from participation.

4.2 EXCLUSION CRITERIA

Exclusion Criteria:
-physically active (defined as >150 minutes per week of self-reported moderate-to-vigorous intensity exercise in a typical week)
-cannot use their arms for exercise
-a Gross Motor Function Classification Level of IV-V

-complete blindness or deafness;
-contraindications to exercise testing according to American College of Sports Medicine (ACSM) guidelines (Liguori and American College of Sports Medicine, 2020):
recent significant change in the resting electrocardiogram suggesting significant ischemia;
recent myocardial infarction (within 2 days) or other acute cardiac event
unstable angina; uncontrolled cardiac dysrhythmias causing symptoms or hemodynamic compromise; symptomatic severe aortic stenosis; uncontrolled symptomatic
heart failure; acute pulmonary embolus or pulmonary infarction; acute myocarditis or pericarditis; suspected or known dissecting aneurysm; acute systematic
infection accompanied by fever, body aches, or swollen lymph glands; low bone-mineral density of the spine (a z-score of </= to -3, indicative of high risk for fracture
that could occur from torsion of spine, determined at baseline data collection via the DXA scan).
Liguori G, American College of Sports Medicine. ACSM's guidelines for exercise testing and prescription. Lippincott Williams & Wilkins; 2020 Dec 3.
-pregnant (due to radiation from a Dual Energy X-ray Absorptiometry [DEXA] scan)
-uses a pacemaker (a pacemaker will compromise the readings of the heart rate monitor used in this study)
-has not been seen by a physician within the last year
-uses a g-tube

4.3 SCREEN FAILURES

Participants could have been withdrawn by the study team after enrollment, should a criteria not be noticed during screening. However, this did not occur.

4.4 STRATEGIES FOR RECRUITMENT AND RETENTION

Recruitment occurred through clinics through the Division of Pediatric Rehabilitation Medicine at the University of Alabama at Birmingham and Children's of Alabama.

5 STUDY INTERVENTION

5.1 STUDY INTERVENTION(S) ADMINISTRATION

5.1.1 STUDY INTERVENTION DESCRIPTION

The exercises were guided by videos that included 5 themes: 3 related to superheroes, pop music, or football. Each theme included 3 sequential videos that coincided with the rest periods (1 video for wk 1; 1 video for wks 2–4; and 1 video for wks 5–12), totaling 15 videos. CwCP were able to choose to exercise with any themed video that corresponded to their exercise week. Videos included music related to the video themes. Music tempo and volume coincided with sprint and recovery periods. During each session, participants watched the video on their computer and followed along with the exercises, while the coach supervised them through a web camera. Sprint training incorporated repetitive arm movements related to video themes (e.g., Spiderman videos included web shooting; football included arm running/passing). Videos

included CP-specific adaptations to enhance engagement, including verbal cues, visualized movement adaptations for hemiparesis, slow and repetitive instructions, positive reinforcement, a judgment-free atmosphere, and imagery. Videos were archived within a private YouTube playlist unique to each participant. This allowed watched video minutes to be objectively recorded by YouTube cloud-based analytics linked to each participant's email address. WC participants were asked to maintain their habitual activity behavior for 12 weeks and then received the same program as those who did not wait before starting the program. All participants were asked to maintain their habitual diet and eating patterns for the 12-week period (immediate 12-week intervention or 12-week wait period). All sessions were supervised and monitored in real time via a custom-designed TeleRehab web platform.

5.1.2 DOSING AND ADMINISTRATION

The telecoach supported participants in maintaining maximal effort intensity by monitoring RPE and providing motivational support. Motivational strategies included positive verbal encouragement to bolster exercise confidence (i.e., self-efficacy) and performing the exercises with the participant to enhance learning through observation (i.e., vicarious learning). These strategies were informed by Social Cognitive Theory. To monitor exercise intensity, the telecoach asked participants how hard they were working after every change in song (~5 minutes) throughout the session. If participants reported <18 RPE, coaches/caregivers provided positive verbal encouragement to enhance motivation. Post-session, participants reported an overall RPE for the entire bout to determine the need to progress the exercise through the addition of resistance bands. Since caregiver knowledge and attitude are determinants of participation, caregivers were asked to help manage the child's exercise schedule.

5.2 MEASURES TO MINIMIZE BIAS: RANDOMIZATION

The randomization order was created by the project statistician and only the project coordinator had access to the order. The outcome assessor was blinded to randomization.

5.3 STUDY INTERVENTION COMPLIANCE

Compliance was measured by the percentage of sessions attended divided by those prescribed. Fidelity to the exercise intensity was maintained through telecoach encouragement during the intervention sessions.

5.4 CONCOMITANT THERAPY

Participants were asked to maintain their habitual daily activities, but were not explicitly instructed to refrain from participating in new treatments or therapies.

6 STUDY INTERVENTION DISCONTINUATION AND SUBJECT DISCONTINUATION/WITHDRAWAL

6.1 DISCONTINUATION OF STUDY INTERVENTION

Participants could withdraw or refrain from participating in an exercise session. Participants were allowed to schedule make-up sessions for missed sessions.

6.2 SUBJECT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Subjects were free to withdraw from participation in the study at any time upon request.
An investigator could discontinue or withdraw a subject from the study for the following reasons:

- Significant study intervention non-compliance
- If any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurred such that continued participation in the study would not be in the best interest of the subject

6.3 LOST TO FOLLOW-UP

- Before a participant was deemed lost to follow-up, the investigator or designee had to make strong effort to regain contact with the subject (where possible, 3 telephone calls or emails).
- If the participant was still unreachable, he or she was considered to have withdrawn from the study with a primary reason of lost to follow-up.

7 STUDY ASSESSMENTS AND PROCEDURES

7.1 STUDY ASSESSMENTS

Assessments were conducted at baseline and post-intervention (12 weeks), with select measures collected continuously throughout the intervention period. During each exercise session, heart rate was monitored in real time using a Bluetooth chest-worn heart rate monitor integrated with the TeleRehab platform. Session intensity was assessed using ratings of perceived exertion (RPE), collected approximately every 5 minutes (following each song change) and again at the end of each session to capture overall effort. These data informed individualized progression of exercise intensity, including the addition of resistance bands when indicated.

Intervention adherence was objectively tracked via cloud-based video analytics, which recorded minutes of exercise video viewing for each participant through individualized private playlists. Telecoaches also documented session attendance, technical issues, and participant engagement.

Participant safety and tolerance were monitored continuously through live videoconferencing, heart rate surveillance, and verbal check-ins. Caregivers assisted with scheduling and facilitating participation, and habitual diet and physical activity behaviors were maintained throughout the intervention or waitlist period.

7.2 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

7.2.1 DEFINITION OF ADVERSE EVENTS (AE)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

7.2.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An adverse event (AE) was considered “serious” if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

- Death
- A life-threatening adverse event (of note, the term “life-threatening” refers to an event in which the subject was at risk of death at the time of the event, rather than to an event which hypothetically might have caused death if it were more severe)
- inpatient hospitalization or prolongation of existing hospitalization
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- or a congenital anomaly/birth defect.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events included allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

7.2.3 CLASSIFICATION OF AN ADVERSE EVENT

7.2.3.1 SEVERITY OF EVENT

For adverse events (AEs), the following guidelines was used to describe severity:

- **Mild** – Events require minimal or no treatment and do not interfere with the subject’s daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- Severe – Events interrupt a subject’s usual daily activity and may require systemic drug therapy or other treatment. Severe events were usually potentially life-threatening or incapacitating. Of note, the term “severe” does not necessarily equate to “serious.”

7.2.3.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) must have their relationship to study intervention assessed by the clinician who examines and evaluates the subject based on temporal relationship and his/her clinical judgment. The degree of certainty about causality was graded using the categories below. In a clinical trial, the study product must always be suspect.

- Related – The AE was known to occurred with the study intervention, there was a reasonable possibility that the study intervention caused the AE, or there was a temporal relationship between the study intervention and event. Reasonable possibility means that there was evidence to suggest a causal relationship between the study intervention and the AE.
- Not Related – There was not a reasonable possibility that the administration of the study intervention caused the event, there was no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

7.2.3.3 EXPECTEDNESS

The Principal Investigator was responsible for determining whether an adverse event (AE) was expected or unexpected. An AE was considered unexpected if the nature, severity, or frequency of the event was not consistent with the risk information previously described for the study intervention.

7.2.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study subject presenting for medical care, or upon review by a study monitor.

All AEs including local and systemic reactions not meeting the criteria for SAEs was captured on the appropriate case report form. Information to be collected included event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs was followed to adequate resolution.

Any medical condition that was present at the time that the subject was screened was considered as baseline and not reported as an AE. However, if the study subject's condition deteriorates at any time during the study, it was recorded as an AE.

Changes in the severity of an AE was documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

7.2.5 ADVERSE AND SERIOUS ADVERSE EVENT REPORTING

All serious adverse events must be reported to the IRB and NIH according to regulatory requirements. The Principal Investigator immediately reported any serious adverse event, whether or not considered study intervention related.

7.3 UNANTICIPATED PROBLEMS

7.3.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

The Office for Human Research Protections considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that were described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research ("possibly related" means there was a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

7.3.2 UNANTICIPATED PROBLEM REPORTING

The investigator reported unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report included the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or were proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs was reported using the following timeline:

- UPs that were serious adverse events (SAEs) was reported to the IRB within 10 working days of the investigator becoming aware of the event.
- Any other UP was reported to the IRB within 10 working days of the investigator becoming aware of the problem.

8 STATISTICAL CONSIDERATIONS

8.1 STATISTICAL HYPOTHESES

Primary Hypothesis

Children with cerebral palsy randomized to the immediate telehealth sprint interval training Movement-to-Music (SIT-M2M) group demonstrated significantly greater improvements in cardiorespiratory fitness (VO_2peak) from baseline to 12 weeks compared with the waitlist control group.

Secondary Hypotheses

Compared with waitlist controls, participants in the SIT-M2M group demonstrated greater improvements in cardiometabolic risk indicators (e.g., resting heart rate, body composition, and blood pressure) and higher exercise adherence and engagement across the intervention period.

8.2 SAMPLE SIZE DETERMINATION

A target sample size of 50 participants permits at least 20 in each of the two study groups at 12-week follow-up after allowing for up to 20% dropout (in each arm). Power calculations were performed using nQuery, v. 8.7, for Aims 1 and 2, and SAS, v. 9.4, for Aim 3. For Aims 1 and 2, we will compare our baseline measurements with those obtained at 6 weeks and 12 weeks. We obtained estimates of the standard deviation (SD) for peak oxygen consumption (pVO2) of 7.11 ml/kg/min (1), percent body fat (% BF) of 8.5% (2), total cholesterol (TC) of 27.3 mg/dL (3), systolic blood pressure (SBP) of 14.0 mmHg (3), and diastolic blood pressure (DBP) of 11.7

mmHg (3). With these assumptions and those of a two-sided two-group t-test, an alpha of 0.05, and 20 participants per group, we will have at least 80% power to detect between-group differences of at least 6.47 ml/kg/min in pVO2, 7.7% BF, 24.9 mg/dL in TC, 12.8 mmHg in SBP, and 10.7 mmHg in DBP as being statistically significant (at any time point); with the previous assumptions and those of a two-sided paired t-test, an alpha of 0.05, and 20 participants, we will have at least 80% power to detect within-group changes of at least 4.70 ml/kg/min in pVO2, 5.6% BF, 18.1 mg/dL in TC, 9.3 mmHg in SBP, and 7.8 mmHg in DBP as being statistically significant (between any two time points). These estimates are conservative since we will be performing our statistical analyses using statistical methods that are more sophisticated than those that are mentioned here. For Aim 3, our pilot data indicate that adherence to the intervention will be 75%. For an adherence rate of 75%, and assuming 40 participants in total, with 20 per study arm, complete the study, the corresponding exact binomial 95% confidence intervals are (0.588, 0.873) and (0.509, 0.913).

8.3 STATISTICAL ANALYSES

8.3.1 GENERAL APPROACH

For **all aims**, data analyses will follow intent-to-treat principles. Descriptive statistics will be obtained for study variables. The normality of data distribution of the continuous outcomes will first be confirmed using graphical techniques and tests of normality; continuous outcomes that deviate greatly from a normal distribution will adjusted (e.g., transformed) so that the data distribution approximates a normal distribution. All statistical tests will be two-sided. Differences will be considered significant at $p<0.05$. Statistical analysis will be performed using SAS software (version 9.4). Missing data that are not rectified through ongoing review of source documents may be managed with multiple imputation, and the influence of the missing data will be assessed with sensitivity analyses. For **Aims 1 and 2**, our primary method of analysis will be general linear mixed models techniques, such as mixed models repeated measures analyses, as there will be two study groups (SIT-M2M and WC) and three time points (baseline, 6 weeks, and 12 weeks). An appropriate structure for the covariance matrix (e.g., unstructured) will be selected for these models using the final data. Post hoc analyses will be performed using the Tukey-Kramer multiple comparisons test. These models will allow us to assess the between-group effect, the within-group effect, and the group by time interaction. Covariates to be included in some models include age, sex, and GMFCS level. Analysis of categorical variables between groups will be performed using the chi-square test (or Fisher's exact test if needed). Pairwise correlations between study parameters will be assessed using Pearson (or Spearman, if needed) correlation analysis. For **Aim 3**, we will calculate adherence rates, adverse events rates, and other rates of interest, and corresponding exact binomial 95% confidence intervals. These rates will be calculated overall and stratified by study group. Exploratory comparisons of rates between groups will be performed using the chi-square test (or Fisher's exact test if needed).

1. Balemans AC, Van Wely L, De Heer SJ, Van den Brink J, De Koning JJ, Becher JG, et al. Maximal aerobic and anaerobic exercise responses in children with cerebral palsy. Med Sci Sports Exerc. 2013;45(3):561-8.
2. Finbråten AK, Martins C, Andersen GL, Skranes J, Brannsether B, Júlíusson PB, et al. Assessment of body composition in children with cerebral palsy: a cross-sectional study in N orway. Dev Med Child Neurol. 2015;57(9):858-64.

3. Barja S, Le Roy C, Sepúlveda C, Guzmán ML, Olivarez M, Figueroa MJ. Obesity and cardio-metabolic risk factors among children and adolescents with cerebral palsy. Nutrición hospitalaria. 2020;37(4):685-91.

8.3.2 ANALYSIS OF THE PRIMARY EFFICACY ENDPOINT(S)

Post-intervention at week 12.

8.3.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

N/A

8.3.4 SAFETY ANALYSES

Safety was monitored throughout the 12-week period and was evaluated by the data safety monitoring board.

8.3.5 BASELINE DESCRIPTIVE STATISTICS

Comparisons of rates between groups will be performed using the chi-square test (or Fisher's exact test if needed).

9 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

9.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

9.1.1 INFORMED CONSENT PROCESS

Digital consent was allowed for the first year of the study and was obtained through a secure-online database (RedCap). In-person written consent was obtained for most participants and required signature of two copies, one for the participant to keep and one for the research team.

9.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO SUBJECTS

Consent forms describing in detail the study intervention, study procedures, and risks were given to the subject and written documentation of informed consent was required prior to conducting study screening procedures. Assent forms were provided for children under the age of 13 years.

9.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Written informed consent was obtained from each caregiver (parent or legal guardian), and written assent was obtained from each child participant prior to completion of any study-specific procedures. The informed consent and assent process was conducted by trained research staff during the baseline laboratory visit.

Caregivers and children were provided with IRB-approved consent and assent documents describing the study purpose, procedures, potential risks and benefits, alternatives to participation, confidentiality protections, and the voluntary nature of participation. Research staff reviewed all documents with participants in language appropriate to their level of understanding and answered all questions prior to enrollment.

Participants were informed that participation was voluntary and that they could withdraw from the study at any time without penalty or loss of benefits. Caregivers were given adequate time to review the consent materials and were encouraged to discuss participation with family members before signing. Copies of signed consent and assent forms were provided to families for their records.

Documentation of informed consent and assent was maintained in study records in accordance with Institutional Review Board requirements. No study procedures were initiated prior to completion of the consent and assent process.

9.1.2 STUDY DISCONTINUATION AND CLOSURE

This study could have been temporarily suspended or prematurely terminated if there was sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, was provided by the suspending or terminating party to regulatory authorities. If the study was prematurely terminated or suspended, the Principal Investigator (PI) would promptly inform study subjects and the Institutional Review Board (IRB) and provide the reason(s) for the termination or suspension.

Circumstances that may warrant termination or suspension include, but were not limited to:

- Determination of unexpected, significant, or unacceptable risk to subjects
- Insufficient compliance to protocol requirements
- Determination that the primary endpoint has been met
- Determination of futility

9.1.3 CONFIDENTIALITY AND PRIVACY

Subject confidentiality and privacy was strictly held in trust by the participating investigators and their staff. Therefore, the study protocol, documentation, data, and all other information generated was held in strict confidence. No information concerning the study or the data was released to any unauthorized third party without prior written approval of the Principal Investigator.

All research activities was conducted in as private a setting as possible.

Representatives of the Institutional Review Board (IRB) may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the subjects in this study.

The study subject’s contact information was securely stored at each clinical site for internal use during the study. At the end of the study, all records must continue to be kept in a secure location for as long a period as dictated by the reviewing IRB and/or Institutional policies.

9.1.4 QUALITY ASSURANCE AND QUALITY CONTROL

The research team held monthly meetings for intervention fidelity checks.

9.1.5 DATA HANDLING AND RECORD KEEPING

All data analyses were conducted by the project statistician. Data were double checked by study staff for accuracy.

9.1.5.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection was the responsibility of the clinical trial staff at the site under the supervision of the Principal Investigator. The Principal Investigator was responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

9.1.5.2 STUDY RECORDS RETENTION

Study documents should be retained for a minimum of 3 years after the completion of the study. These documents should be retained for a longer period, however, if required by local regulations.

9.1.6 PROTOCOL DEVIATIONS

A protocol deviation was any noncompliance with the clinical trial protocol requirements. The noncompliance may be either on the part of the subject, the investigator, or the study site staff. As a result of deviations, corrective actions were to be developed by the site and implemented promptly.

These practices were consistent with ICH GCP:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It was the responsibility of the Principal Investigator to use continuous vigilance to identify and report deviations within 10 working days of identification of the protocol deviation. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. The Principal Investigator was responsible for knowing and adhering to the reviewing IRB requirements.

9.1.7 CONFLICT OF INTEREST POLICY

Any actual or perceived conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial was disclosed.

9.2 ABBREVIATIONS

AE	Adverse Event
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DHHS	Department of Health and Human Services
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
LSMEANS	Least-squares Means
NCT	National Clinical Trial
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOA	Schedule of Activities
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

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