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Complete List of Authors:	Santamaria, Victor; New York Medical College, Physical Therapy Department Ai, Xupeng; Columbia University, Mechanical Engineering Chin, Karen; Columbia University; Burke Neurological Institute Dutkowsky, Joseph; Columbia University, Orthopaedic Surgery Gordon, Andrew; Columbia University, Biobehavioral Sciences Department Agrawal, Sunil; Columbia University, Mechanical Engineering
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Study protocol for a randomized controlled trial to determine the efficacy of an intensive seated postural intervention delivered with robotic and rigid trunk support systems.

Victor Santamaria[1], Xupeng Ai[2], Karen Chin[3], Joseph P. Dutkowsky[4], Andrew M. Gordon[3], Sunil K. Agrawal[2,5].

Affiliations

[1] Physical Therapy Department, New York Medical College, NY, USA
[2] Mechanical Engineering Department, Columbia University, NY, USA
[3] Biobehavioral Sciences Department, Teachers College, NY, USA
[4] Orthopaedic Surgery Department, Columbia University, NY, USA
[5] Rehabilitation and Regenerative Medicine Department, Columbia University, NY, USA

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Address correspondence to:
Victor Santamaria, PT, MSc, PhD, PCS.
Department of Physical Therapy
New York Medical College, School of Health Sciences and Practice
Valhalla, NY, USA
vsantama@nymc.edu

ABSTRACT

Introduction: Children with cerebral palsy (CP) classified as Gross Motor Function Classification System (GMFCS) levels III-IV demonstrate impaired sitting and reaching control abilities that hamper their overall functional performance. Yet, efficacious interventions for improving sitting-related activities are scarce for these children. We recently designed a motor learning-based intervention delivered with the robotic Trunk-Support-Trainer (TruST-intervention), in which we apply force field technology to individualize sitting balance support. We propose a randomized controlled trial to test the efficacy of the motor intervention delivered with robotic TruST or a static trunk support system.

Methods and analysis: We will recruit 82 participants with CP, GMFCS III-IV, and aged 6-17yrs. Concealed allocation to either TruST- or static trunk-support intervention will be ensured by enrolling participants with opaque sealed envelopes prepared by someone unrelated to our study. We will apply an intention-to-treat protocol. Intervention schedules will be 2H/sessions, 3/week, over 4 weeks. Participants will start both interventions with pelvic strapping. In TruST-intervention, postural task-progression will be implemented by a progressive increase of the force field boundaries, and then by removing the pelvic straps. In static trunk support-intervention, we will progressively lower the trunk support and remove pelvic strapping. Outcomes will be assessed at baseline, midpoint of the motor training, 1week post-intervention, and 3month follow-up. Primary outcomes will include modified functional reach test, sitting workspace area, and Box & Block test. Secondary outcomes will include: Segmental Assessment of Trunk Control test, Seated Postural & Reaching Control test, Gross Motor Function Measure-Item Set, Canadian Occupational Performance Outcome, The Participation and Environment Measure and Youth, and postural and reaching kinematics.

Ethics and dissemination: Approval for this first study protocol version was granted by the Institutional Review Board at Columbia University (AAAS7804). This study has been funded by the National Institutes of Health (1R01HD101903-01) and is registered at clinicaltrials.gov (NCT04897347).

Strengths and limitations of this study

- This RCT investigates an understudied sub-population of participants with CP.
- This RCT design will elucidate the clinical value of postural task progression via robotics and rigid support systems.
- This RCT studies a novel seated motor intervention founded on current motor-related neuroplasticity evidence.
- Motor training and assessments are accessible for people with CP and cognitive limitations but may not benefit those with severe intellectual deficits.

INTRODUCTION

Cerebral palsy (CP) is the most common life-long childhood physical disability with 2.0-3.5 per 1000 births, and a lifetime cost per person of $921,000 in the US.[1,2] Approximately 29% of these children have moderate-to-severe bilateral CP (BCP)—Gross Motor Function Classification System (GMFCS) levels III-V.[3–5] Abnormal posture and motor deficits are some of the most disabling impairments.[3,5,6] Yet, efficacious therapies targeting sitting postural control that result in long-lasting functional benefits are scarce.[7] This is particularly problematic for children with BCP, GMFCS III-IV, who require sitting abilities for wheeled mobility, activities of daily living (ADLs), an active physical life, and community participation.[8–12] Sitting control deficits are commonly resolved by assistive systems and by modifying contextual factors (i.e., power wheelchairs, head and lateral trunk supports, seating adaptations, and personal assistance).[13,14] This assistive approach facilitates participation; however, these children may not be performing at their maximal independent motor potential. Thus, promoting postural and reaching abilities during independent sitting are essential to enhance the functional life of these children. Nonetheless, what is the best evidence-based therapeutic strategy to target seated functions in children with BCP?

Children with GMFCS III-IV show segmental trunk control deficits at middle or lower thorax, and reaching impairments—as determined by the Segmental Assessment of Trunk Control (SATCo) and Seated Postural & Reaching Control (SP&R-co) Tests.[15,16] Consequently, changing an external support from mid-ribs to pelvis significantly decreases sitting and reaching control.[17] This suggests the potential application of external support on specific trunk regions to deliver seated postural interventions.[18,19] A recent randomized controlled trial (RCT) in CP, GMFCS III-V, compared conventional therapy with a home-based activity training delivered with external support at the impaired trunk segment. The intervention resulted in significant short-term postural improvements (i.e., sway) but not in long-term motor benefits.[20] The absence of long-term effects may be because the intervention was not structured around motor learning and control principles; which are quintessential for inducing neural plasticity and lasting functional outcomes.[21–25]

In the present study, we have developed a robotic Trunk-Support-Trainer (TruST) to evaluate sitting balance and implement a motor learning-based postural intervention (TruST-intervention).[26,27] TruST is a motorized-cable driven belt that applies force field technology. A key factor is that the force field matches the participants' sitting stability region and supplements their motor efforts when their trunk is beyond such postural limits. Thus, force fields are tailored to the stability status of the participants as their postural control improves across intervention sessions (i.e., postural task-progression). Moreover, TruST displays real-time feedback about the trunk's location with respect to the stability boundaries, which allows the clinician to target postural strategies within, at, or beyond sitting control boundaries. Our current RCT investigates the efficacy of TruST-intervention compared to the same motor intervention implemented with a static trunk support system in children with BCP, GMFCS III-IV.

AIMS AND HYPOTHESES

Overall Aim

We will test whether a motor learning-and-control-based intervention can improve seated postural and reaching abilities in children with BCP, GMFCS III-IV. We expect improvements with TruST and the static trunk support system. However, we hypothesize superiority of TruST-intervention.

Primary Hypotheses

In the TruST-intervention group, we expect greater sitting workspace improvements, as measured by a customized postural-star sitting test (PSST) and the modified functional reach test (mFRT). Nonetheless, we expect improvements in upper extremity control in both groups, as determined by the Box and Block (B&B) test and video-coding analysis.

Secondary Hypothesis

We expect improvements in both intervention groups. However, we expect a greater improvement rate with TruST-intervention in segmental trunk control (SATCo), postural sitting and reaching control (Seated Postural & Reaching Control Test, SP&R-co), gross motor function (Gross Motor Function Measure-Item Set, GMFM-IS), child- and family-centered functional and participation outcomes (Canadian Occupational Performance Outcome, COPM, The Participation and Environment Measure and Youth, PEM-CY), as well as in postural and reaching kinematics.

METHODS

Study design

The study is an explanatory parallel RCT conducted at Columbia University (New York, US) in 82 children with BCP GMFCS III-IV, aged 6-17yrs. The study timeline is from February 2022 to December 2026. After baseline measurements, we will test potential improvements at mid-point of the intervention (6th session), 1week post-intervention, and 3mos follow-up. The Consolidated Standards of Reporting Trials (CONSORT) will be followed to design the trial, conduct experiments, and report the results.[28,29]

Recruitment

Participants will have a confirmed medical diagnosis of BCP. They will be recruited by advertising on our and other websites, social media platforms, clinicaltrials.gov (NCT04897347), and through NYC school districts. This study involves local centers and hospitals such as New York-Presbyterian: Columbia Irving Medical Center, Weill Cornell Medicine, and Weinberg Cerebral Palsy Center. Testing and training sessions will be adjusted to the family's schedule before starting the study. During initial pre-screening, a phone survey will be scheduled to interview families, caregivers, or legal guardians by KC or VS. We will obtain information beforehand on participants' eligibility criteria and discuss our study design, research goals, potential risks, and reciprocal commitment with

participants and families. We expect that our recruitment strategies will maximize retention and intervention benefits.

Inclusion and exclusion criteria are included in table 1.

Table 1. Inclusion & Exclusion Criteria

Inclusion Criteria
1. Age 6-17 years. 2. Diagnosis of BCP: diplegia, triplegia, or quadriplegia. 3. GMFCS levels III or IV. 4. Ability to sit 5s with manual support provided to any trunk region mid-ribs and pelvis (SATCo = 3-7). 5. Cognitive capacity to follow basic verbal instructions (e.g., "do not put your hands on your lap", “keep your hands up in the air”, or "follow and reach or touch the toy").
Exclusion Criteria
1. Absent head control (SATCo = 1). 2. Current medical illness unrelated to CP at the time of the study. 3. Severe dyskinesia that impedes the child to sit and/or when the child performs postural and/or reaching movements. 4. History of recurrent seizures (daily) or refractory epilepsy. 5. Severe structural deformities of the spine: scoliosis >40° and/or kyphosis >45°. 6. Orthopedic surgery of the spine, upper and/or lower extremities in the last 6 months prior to the start of the study. 7. Severe spasticity of biceps/triceps in both upper extremities that prevent reaching movements (Modified Ashworth Scale = 4). 8. Chemodenervation or neurolysis (e.g., botulinum toxin or phenol/ethyl alcohol injections) in upper or lower extremity muscles in the previous 3 months or are planned during the length of the study. 9. Other major surgeries in the previous 6 months (only if medically contraindicated).

Randomization and Participant Allocation

A researcher oblivious to our study will create computer-generated lists of random numbers assigned to seven blocks with 10 participants and to one block with 12 participants (n = 82). To prevent selection bias, the allocation sequence will be concealed from the research team. After randomization to either TruST- or static trunk support-intervention group, an independent researcher will communicate to the research team the assigned group by opaque and sealed envelopes. Carbon paper inside the envelope will be used to transfer the information onto an allocation card that will be kept with the participant’s record. The envelopes will be opened after the enrolled participant is consented and completes the corresponding baseline assessments.

Blinding

All assessments will be videotaped and scored by clinical evaluators with expertise in CP. The evaluator will be blinded to group allocation and testing sessions. Blinding of families and children to the intervention will not be possible due to equipment characteristics—i.e., robotic-TruST versus static trunk support system.

Study Locations

The TruST-intervention will take place at the Robotics and Rehabilitation (ROAR) Laboratory; whereas, the static trunk support-intervention will be carried at the Center for Cerebral Palsy, Teachers College. Excluding clinical evaluations, the same research personnel will collect data and deliver the motor interventions in the assigned study locations at Columbia University.

Study Interventions

Participants will follow their regular therapeutic care during the study. The TruST- and static trunk support-interventions are detailed in table 2, following the Template for Intervention Description and Replication (TIDieR) Checklist.[30,31] The same motor learning and control principles, and activities will be applied to both interventions.[26]

Table 2. TiDiER checklist for comparison between TruST-intervention and static trunk support-interventions

Name	Trunk-Support-Trainer Intervention (Experimental)	Static Trunk Support-intervention (Control)
Why	Motor learning principles and motor-task progression implemented. Postural task-progression is objectively tailored to the child's sitting balance status and systematically progressed in each training session.	The therapeutic elements and intervention protocol are the same. However, the postural task-progression is implemented by lowering the static trunk support as the child improves in segmental trunk control stability across sessions.
What: Equipment	Toys, balloons, balls, cups, blocks, board games, buzzers, white board and colors. A bench with adjustable height and straps to support the pelvis is fixed to a mechanical lifter. The robotic TruST dynamically controls the trunk in sitting; and thus, the entire upper body moves within the pre-	Same equipment and bench. However, the bench is integrated with a rigid apparatus to adjust the level of support at the specific sub-region of the torso where the child loses sitting balance control. Thus, only the upper body region above the rigid support can freely move

	defined sitting stability boundaries.	during the motor intervention.
What: Procedures	Age-appropriate discrete, serial, and continuous motor tasks, including: reaching (pointing and grasping with whole hand and fingers), catching, throwing, punching, hitting (or tapping), and lifting. Motor activities will be practiced along 8 star-radiated directions that are approximately spaced 45° apart and have their center at the child's pelvis. Motor practice will be within and beyond reaching distance in each one of the 8 directions covering the full child's peripersonal space (360°). A total of 30-50 repetitions will be trained in a clockwise and counterclockwise fashion to train the more- and less-impaired upper limbs.	Same intervention structure and procedures.
Providers	Two researchers with clinical/kinesiology knowledge and a bioengineer will participate in each session. The assignment of the personnel providing the intervention will be counterbalanced.	Same providers and counterbalance design.
How	A one-on-one intervention delivery. Motor learning-based intervention that is task-oriented (predefined motor goal), age-appropriate (engaging practice), intensive mass practice (training > resting, high number of trials, and reduced performance	Same therapeutic program, clinical delivery, and motor learning and control principles will be applied. The motor tasks are equally practiced at two distances: "within maximum active reaching distance" and "beyond active reaching distance".

	time), sequential skill progression (part-task training), and motor randomization (variability during task practice). Motor control parameters modulated to challenge motor performance. TruST via visual feedback on a screen guides the clinician to train two distances: "within boundaries" (maximum active reaching distance) and "beyond boundaries" (beyond active reaching distance"). TruST-force fields assist the child in performing postural trunk movements.	The rigid trunk support system assists the postural trunk movements by statically holding the sub-region of the child's torso where the loss of sitting balance is found.
Where	Laboratory setting	Same setting
When and how much: **a) Intensity** **b) Frequency** **c) Session Time** **d) Overall Duration**	The training dosage and schedule will be 2hour-sessions, 3 X week, over 4 weeks, with an estimated overall duration of 24 hours of training.	Same intervention schedule and dosage.
Tailoring	Postural task-progression will be implemented via *assist-as-needed* force fields that are equivalent to 10% of the child's body weight. These force fields will be determined by the area and boundaries of stable sitting control measured by a customized postural star-sitting test (i.e., a trunk control-based kinematic measurement). Force fields are re-adjusted at the beginning of each training session to maintain the postural and motor challenge at a maximum level during the motor intervention.	The static support will be placed at the trunk region at which the child loses sitting balance, as determined by the SATCo. Postural task-progression will be implemented by lowering the rigid support, as the child acquires greater trunk control. The SATCo, starting at the most-impaired trunk segment, will be systematically used prior to starting the motor intervention to re-adjust the support system and ensure the maximum level of postural challenge during the intervention.

Modifications	Games and motor activities will be selected based on the child's preferences. Otherwise, no modifications are expected to occur.	Same method for the selection of games and motor activities.
How Well: **Planned** **a) Fidelity strategies** **b) Fidelity assessment**	Videos and logs to monitor: i) study attendance, ii) discomfort/pain (Wong-Baker FACES pain scale),[32] iii) perceived physical exertion (OMNI),[26] iv) motor control parameters used and modulated during training. Video-coding of training session recordings to determine effectiveness of training (i.e., performance of active movements without considering breaks, setup, transfers time between activities, toilet use), type of motor activity and practice time, and motor capacity (e.g., successful trials).	Same procedure to monitor study attendance, child's discomfort/pain, and motor learning/control modulation for ensuring intervention fidelity.
How Well: Actual	We will determine whether the study and intervention plans are achieved based on attendance to measure participation, data from the customized postural star-sitting test (i.e., increases in force fields boundaries will indicate improved sitting workspace area), and video-coding data to measure motor capacity improvements. The presence of unexpected accidents or therapeutic adverse effects together with the level of fatigue and discomfort or	Similarly, we will determine whether the study and intervention plans are achieved based on attendance to measure participation, data from the SATCo across sessions to determine enhanced trunk control, and video-coding data about the type of motor activity to study improved motor capacity. The presence of unexpected accidents or therapeutic adverse effects together with the level of fatigue and discomfort or pain will inform on

	pain will determine intervention safety and feasibility in a large scale of children with BCP.	intervention safety and feasibility in a large scale of children with BCP.

Common Intervention Procedures: TruST- & Static Trunk Support-Interventions

Dosage

The dosage for both interventions will be identical, 2H/session, 3x/week, over 4 weeks (12 training sessions in total). In our previous study,[26] we found the proposed intervention schedule and dosage to be effective in promoting short- and long-term improvements in seated postural and reaching abilities and gross motor functions.

Therapeutic Approach

In both intervention groups, all motor activities will be trained along 8 star-radiated directions spaced at 45° and with the center at the participant's pelvis. The goal of this postural intervention scheme is to cover the 360° peripersonal space around the participant in sitting while being trained at different reaching distances (Fig 1A).

Activities will be practiced under moderate-high intensity but never beyond extreme fatigue, as reported by the child or by the presence of clinical signs such as muscle trembling. Any potential pain or discomfort will be monitored with the Wong-Baker Faces pain scale during and after the intervention.[33]

Parameterization of the Motor Intervention

The motor intervention features have already been investigated in previous studies (Table 3).[26,34] A subset of modified motor parameters defined by Fleishman (1972) will be used to modulate postural and reaching control strategies during the motor intervention.[35] Motor learning-based interventions depend upon participants' own preference, motivation, and cognitive-motor abilities. Thus, these parameters will be adjusted across participants and intervention sessions.[21,23,36]

Table 3. Activities & Motor Learning and Control Parameters

Motor Activity	Descriptors
Hand Actions	Reaching, grasping, catching, throwing, drawing, punching, or coloring
Games	Connect Four®, Jenga®, white board and pens
Toys and Objects	Balloons, punching bag, balls, marbles, cars, bowling pins, strings, light- and sound-emitting buzzers, constructions blocks, small cups, and shape-like puzzles

Motor Learning Parameters	Descriptors
Task nature	Discrete: Task characterized by a defined start and end. Continuous: Motor task that stops arbitrarily. Serial: An orderly sequence of discrete tasks
Movement Repetitions	30-50 trials
Motor skill progression	50% success required to progress the complexity of the motor task: object features (size, shape, or weight) and task constraints (pointing versus grasping)
Motor practice	First practice without objects. Then, objects are incorporated. Whole-task training is emphasized. However, in case of learning deficits, a part-task training following a segmentation method is applied (i.e., splitting the motor activity into components so that the first component is trained first, and then this component is combined with the second, and set forth)
Sequence skill progression	Motor task variations are progressively trained in a sequence from less to more complex
Verbal feedback	In case of learning deficits of the task goal or how to perform it, verbal feedback is incorporated. Knowledge of results (action outcomes) is prioritized over knowledge of performance (movement-based information). A bandwidth mode with a 50% acceptable performance error will be delivered as terminal feedback after motor practice of a block of trials (e.g., in 10 trials, feedback delivered after a block of 5 unsuccessful trials).
Motor randomization	Motor variability (e.g., object location or moving versus stationary targets) and motor parameters (control strategies) are addressed during postural and reaching tasks performed beyond maximum reaching distance.
Motor Control Parameters	**Descriptors**
Control precision	Ability to perform rapid and precise movements to control devices, games, or toys.
Response orientation	Ability to move to specific direction/s.
Arm movement speed	Ability to perform rapid arm movements.
Rate control	Ability to time continuous anticipatory and compensatory movements in response to speed/directional changes.
Multilimb Coordination	Ability to move and coordinate upper extremities to achieve symmetrical/asymmetrical bilateral tasks.
Manual dexterity	Ability to perform skillful in-hand movements.

Finger dexterity	Ability to perform skillful finger movements with small objects such as coins.
Arm-hand steadiness	Ability to maintain steady hand-arm and/or postures during an interval of time.
Wrist, finger speed	Ability to perform rapid and repetitive wrist and finger movements.
Aiming and accuracy	Ability to move the hand or finger to static and/or moving targets of different dimensions; or throwing tasks that demand visual accuracy.
Reaction time	Ability to respond as quick as possible and with rapid movements to external visual/auditory cues.

Mode of Intervention Delivery and Setting

One-to-one interventions will be delivered in a lab setting by a physical or occupational therapist. All research personnel will be trained and supervised. A physical therapist and researcher (VS) will provide direct supervision every two intervention sessions. Also, a bioengineer (XA) will operate TruST while another researcher/clinician collects kinematic data or deliver the motor intervention.

Postural-Task Progression Procedures

TruST-Intervention: Postural Assistive-Force Fields

The TruST-belt will be placed on lower ribs ($T_{9\text{-}12}$) to provide *"assist-as-needed"* forces. The PSST will be used to match the assistive force-tunnel to the participant's sitting control boundaries and measure sitting workspace (cm^2).[26,37] This test is based on the Star Excursion Balance Test; in which the person displaces the foot along eight directions, following the shape of a star during one leg stance.[38] Similarly, the PSST is a game-oriented test in which the seated participant performs maximal trunk excursions. A large ball is presented nearby the participant's face to guide the 8 trunk movements that radiate in a star-like fashion. After each maximum trunk displacement, the participant needs to recover sitting posture without suing the hands for support.

During TruST-intervention, the assistive-force field intensity equals 10% of the child's body weight (Fig 1B). These forces assist sitting balance toward the pre-defined stability boundaries and not to the center of the star-shaped region. Moreover, assistive forces are only provided when the trunk is beyond the boundaries to supplement the participant's motor efforts. This configuration promotes continuous active sitting control without hand support to practice goal-oriented tasks. As the participant expands the sitting control boundaries across intervention sessions, the assistive-force fields are increased to the new sitting control boundaries (i.e., postural-task progression).

Another critical parameter to the achievement of independent sitting will be the removal of pelvic strapping (i.e., unsupported sitting). We will follow one of two criteria to remove the straps. The child shows a pre-training sitting workspace area above two standard

errors (SE) of the mean from the two, or more, previous pre-training sessions; or pelvic strapping is removed after the 6th session. Our previous study indicates that participants will likely acquire unsupported sitting (unstrapped) by the 6th intervention session.

Static Trunk Support-Intervention: Segment-by-Segment Approach

The static trunk support system (Figure 1C) design follows engineering principles, kinematic and electromyographic data in sitting and reaching control that apply to healthy adults, developing infants, and children with CP.[17,19,20,39–43] As determined by the SATCo, we will follow a top-down segment-by-segment approach to evaluate trunk control in sitting at the beginning of each intervention session. We will define the most-impaired trunk segment, place the support, and deliver the motor intervention. The constraint of caudal trunk segments to the one being trained might help to reduce the overload of sensorimotor information to process and to control the body dynamics during seated motor activities.[39,43]

For postural task-progression, when there is an improvement in the SATCo—i.e., improved sitting balance at a lower trunk segment—the support is lowered one level. The trunk support system will offer a firm support for a systematic, objective, and reliable SATCo evaluation across participants and sessions.

Discontinuation Criteria for Motor Interventions

We will discontinue TruST-intervention if pervasive postural control detriments are observed—calculated as a decrease in workspace area during 3 consecutive days and below 2SE of the averaged pre-intervention sessions before the detriment onset. Static trunk control-intervention will be discontinued if the SATCo score decreases 1 level, or more, for 3 consecutive days with respect to the previous pre-intervention sessions.

Motor-Task Progression Procedure

In TruST-intervention, we will follow the next sequential skill motor training:

1. *Within sitting boundaries (inactive TruST-force field):* The participant performs 30-50 simple reaches (i.e., pointing) with the less- and more-impaired upper extremities. The target is placed at maximum active reaching distance without eliciting additional trunk movements on the right and left sides of the body, following the 8 star-like directions—as we follow in the postural star-sitting test. If 60% of attempts are successful in a minimum of 5 out of the 8 directions (clockwise or counterclockwise), the participant progresses to stage 2.
2. *Beyond sitting control boundaries (active TruST-force field):* The target is placed beyond stability boundaries (~120% active reaching distance) along the 8 directions to elicit trunk movements. In this stage, the participant relies on assistive-force fields to complete the motor activity and return to sitting posture without using the hands to recover sitting stability. As in stage 1, the participant can progress to stage 3 when 60% of attempts are successful at least in 5 out of the 8 directions (clockwise or counterclockwise).

3. *Beyond sitting control boundaries under challenging motor conditions:* The training procedure is like stage 2. However, in stage 3, the clinician modulates specific motor control parameters (see table 3 above), adds practice variability—movement distance and directionality—and introduce diverse goal-oriented activities (i.e., contextual interference) to address maximum motor complexity.

In the static trunk support-group, we will follow the same sequential motor skill training. However, in stage 2 and 3, the participants will rely on a static trunk support to perform the postural and reaching activities without the additional use of the hands for support.

Adverse events and safety

As per our IRB-protocol, major risks or serious long-term harm are not expected. Thus, pre-established compensation has not been determined. Major falls from the bench will be prevented with a slacked harness—to avoid weight support during the intervention. Minor equipment- or intervention-related injuries that do not require medical attention are muscle fatigue, minor dermic abrasions, and localized erythema or petechiae under the belt or trunk support. If adverse events such as muscle or articular pain, excessive physical or cognitive fatigue, musculotendinous strains, or ligament sprains occur, these will be reported in our study protocols (see “Fidelity” section) and study IRB.

Fidelity

Supervisory team: researchers attributes, scientific documentation, and personnel training.

We will have a multisite Manual of Procedures (MOP) in place. The MOP will describe the study design, personnel roles, experimental procedures, interventions, data analyses, precautions and safety measures, and how to handle blinded and private data. It will register adverse events, and protocol or procedure modification logs.

All research personnel (including volunteers) in direct contact with participants will receive training in ethical, safety, experimental, and intervention protocols to achieve optimal ethical and professional attributes to carry the study. This training will include IRB-related coursework (e.g., “Good Clinical Practice”), basic first aid and CPR training, communication skills to interact with participants and families, information on RCT designs—ensuring internal and external validity of the study—and a two-hour in-person training seminar to learn on postural- and reaching-related deficits in CP, motor intervention design, and basic operations of TruST and static trunk support systems.

Data Monitoring during the Study

Attendance will be used to measure participation and monitor potential dropouts, including if the reason is internal or external to our study. Video footage of training sessions will be video-coded to determine training effectiveness (i.e., time-on-task), type and frequency of motor activities practiced, toys or objects used, and motor capacity (e.g., success to achieve the goal, time to achieve the task, and repetitions). An external

researcher with expertise in video-coding analyses, who is independent to our study team, will analyze masked video data with Datavyu software (https://datavyu.org/).

A data monitoring committee has not been established. In weekly meetings, we will monitor if all study protocols are implemented as planned. Aside from an external statistical analysis, interim statistical analyses will be carried to monitor the progression of the two study arms. If 50% of the projected sample size does not improve in either intervention, we will inform the funding agency and discontinue our RCT.

Participant's Data

Using the ICF framework, we will collect data within the body structure and function, activity, and participation domains.[14] Figure 2 depicts study outline and data collections.

Medical and Demographic Data

NIH questionnaires will be used to gather demographic data, sex, age, race, and ethnicity. This data will be used to ensure cultural diversity. Medical information such as CP diagnosis and subtype, brain injury, and other comorbidities will be obtained from medical records. We will record the current medical and therapeutic regimens of participants for further interpretation of our study outcomes. Any communication that involves personal or medical information will follow the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[44]

Screening and descriptive measures

GMFCS: The GMFCS comprises five levels of severity. It categorizes functional abilities such as sitting, walking, running or jumping while considering the need for assistive equipment (postural support, wheeled mobility, or walkers).[45]

Manual Ability Classification System (MACS): The MACS categorizes how children manipulate objects during ADL depending on their functional independence.[46]

Spasticity will be measured with the Modified Ashworth Scale (MAS): The MAS can be used to assess spasticity in CP. [47,48] It scores the increase in muscle resistance through passive limb movements. The score ranges from 0 (no increase in muscle tone) to 4 (limb rigid in flexion or extension). We will be cautious interpreting spasticity as MAS scores depend upon joint and muscle features, and examiners.[48]

Primary Outcomes

mFRT: The mFRT measures proactive postural control during maximum reaching distance. It is a valid and reliable tool in CP; and it discriminates GMFCS levels.[49,50] Test responsiveness is unknown in CP.

PSST: It will be performed before and after interventions to monitor sitting control progression in both TruST- and static trunk control-intervention groups. The investigators have several motivations that rationalize this customized measurement. It: 1) is age-appropriate, 2) is goal-oriented, 3) directly measures sitting based on trunk control improvements, 4) is responsive to capture sitting workspace area increases, and 5) offers data with a straightforward functional interpretation.

B&B: It examines manual dexterity. The child moves the maximum number of blocks (2.5cm^2), one at a time, between the compartments of a partitioned box in 60s.[51] B&B is sensitive to post-intervention changes with the more- and less-affected hand.[52,53] Arm displacement and grasping will be analyzed with Datavyu.[54] An instruction manual has been created to standardize video-coding procedures and define the reaching variables. Grasping will be defined from the moment the hand contacts the block to the time this is lifted from the surface. Arm displacement will be defined from end of grasping to block release. Reaching performance will be the summation of grasping and arm displacement. Two, or more, coders will be used to determine video-coding reliability.

Secondary Outcomes

GMFM-IS: The GMFM-IS determines the gross motor function of children with CP—A: lying and rolling, B: sitting, C: crawling, D: standing and E: walking, running & jumping. It is an abbreviated and validated version of the GMFM-66. It includes an algorithm with three critical items to decide which one of four item sets is most appropriate to assess motor function and obtain a GMFM-66 score.[55] GMFM has been shown to be valid, reliable, and responsive to change in CP. The minimum clinically important difference (MCID) is 0.8-1.6 for a medium effect size and 1.3-2.6 for a large effect size.[56]

COPM: The COPM will be used to investigate perceived parent- and child-based goals, and preferences that are specific to motor impediments in seated posture and reaching abilities that restrict participation.[57] COPM can detect clinical important differences across time and above the MCID of 2 points.[58,59]

PEM-CY: The PEM-CY is a valid and reliable tool to measure participation—home, school and community—including environmental factors.[60,61] PEM-CY can capture post-intervention changes in each of its dimensions in children with physical disabilities.[62]

SP&R-co test: The theoretical framework, reliability, internal consistency, and construct validity of the SP&R-co has been validated in CP. It targets children with moderate-to-severe CP within a play-oriented framework. Like the SATCo, the SP&R-co follows a segment-by-segment trunk approach to assess quantitatively sitting control across static, active, proactive (via bimanual and unimanual reaches), and reactive dimensions. Responsiveness has not been addressed, but the standard error measurements for each seated postural dimension of the SP&R-co test are available.[15]

Postural and reaching kinematics: We will follow the seated postural framework validated in the SP&R-co to capture motor improvements in the next tasks:

- ***Static Seated Task:*** Postural orientation and balance in sitting during 20s.
- ***Active Seated Task:*** Simultaneous control of the trunk and head rotations when the child visually follows an object 90° to the right and left (i.e., chin over shoulder).
- ***Proactive Seated Task:*** Seated anticipatory and compensatory postural control during direction-specific reaches performed straight, and 45° to the right and left.

SATCo: It is a valid and reliable test in CP. The evaluator offers support at various trunk segments (shoulders, axillae, inferior angle of scapulae, on lower ribs, below lower ribs, and pelvis) to measure trunk control across 3 dimensions: static (during 5s), proactive (visually following an object to the right and left), and reactive (postural responses to nudges). The score is from 1 (no head control) to 8 (full trunk control).[16] Test

responsiveness has not been established but studies show potential to identify trunk balance improvements in each of the tested trunk segments.[19,43]

Data Management and Data Collections

After subject's eligibility is confirmed, we will assign a code to each participant only accessed by the PIs (SKA and AMG), co-investigator (VS), and research coordinator (KC). All data collections will be digitized and saved in encrypted endpoint hard drives. Paper forms will be collected as safe copies in a private locked cabinet in the PI's office.

To keep young children informed and engaged during the study, each one will receive a personalized fun "Research Passport" that lists each study stage and explains the purpose of each visit. Upon completion of each procedure, the child will earn a stamp on each page. Additionally, we will offer families the possibility of receiving a brief clinical informative report with the functional status of the child after the study by VS—who is a board-certified pediatric and licensed physical therapist in NY.

We will divide our three main data collection events (baseline, 1-week post-training, and 3-mos follow-up) into two sub-sessions to reduce the burden and physical fatigue that the evaluations may cause (Fig 2). We will empower participants with the ability to stop any study session and request breaks verbally or with a laminated red stop sign.

Data Analysis

Sample size estimation

We used our previous study and literature to estimate sample and effect sizes.[17,26] *G-Power* (version 3.1.9.4., Dusseldorf University) and SPSS (version 25, IBM) were applied. Our primary outcome was upper body balance during seated reaching (Pilot average = 30˚ ± SD = 22˚, partial η^2 = 0.10, n = 11). With a mixed Analysis of Variance (ANOVA), we estimated 68 subjects to achieve a power = 0.8, considering a two-tailed α rate = 0.01. We will recruit an additional 20% of participants (a total of 82 participants) to account for potential groups heterogeneity and dropouts.

Statistical Procedures

An alpha rate = 0.01 will be used for statistical analyses. The effect of interventions on primary and secondary outcomes will be analyzed with a two-factor mixed ANOVA, including groups as a between-subjects factor (TruST- and static trunk support groups), and testing sessions as a repeated measures factor (baseline, mid-point training, 1week post-training, and 3mos follow-up). The group X testing session interaction will be used to test the hypothesis that TruST-intervention is superior to static trunk support-intervention. If the ANOVA model is significant, we will perform *post-hoc* comparisons with Holm-Bonferroni procedure to control familywise error.

Statistical Handling of Non-Normally Distributed and Missing Data

In the event that participants miss sessions for unpredicted reasons (e.g., illness) or drop the study, we will apply a Generalized Estimating Equations (GEE) as an alternative

statistical plan. In this way, we will account for missing data and follow an *intent-to-treat* principle. The GEE will analyze events-in-trials following a repeated-measures procedure with subjects as clusters, test session as the within-subject variable, and intervention groups as the between-subject variable. A linear model will be selected, and the covariance structure will be specified as correlation matrix based on the quasi-likelihood under independence criterion (QIC) goodness of fit coefficient.[63]

Ethics, Resource Sharing Plan, and Dissemination

The present RCT has been registered in clinicalgov.org (#NCT04897347). The study protocol, recruitment materials, and assent and consent forms have been approved by the Columbia University Institutional Review Board (IRB AAAS7804). Study information, assent, and informed consent forms will be signed by all participants and caregivers prior to requesting medical records and starting the study. Participants will be verbally reminded they can withdraw consent at any time without penalty. All de-identified data will be stored for 3 years after study completion in password protected computers. We will store de-identified data in an online HIPAA-compliant database (REDCap). The study protocols follow standardized procedures in RCT such as CONSORT and TIDieR to facilitate appropriate scientific, ethical, and safety assessments and to increase the likelihood of research success.[28,30,31]

We will make available the study data via the Data and Specimen Hub (DASH)—a data sharing platform of the Eunice Kennedy Shriver National Institute of Child Health and Development. Findings will be disseminated through peer-reviewed publication and national and international conferences. Participants and families will be informed on the study progress via newsletters and meetings.

Discussion

We are expanding on our previous feasibilty study in which we did not include a control group—the static trunk support-intervention of our current RCT.[26] We expect our motor learning-based postural intervention to induce postural and reaching improvements with TruST and the static trunk support system. Nonetheless, we expect that postural-task progression tailored to the participant's sitting balance boundaries via TruST-force fields will have a synergistic effect with the motor intervention and will lead to greater improvements. If our hypothesis is supported, a critical point will be knowledge translation of TruST-intervention. The team will study the potential conversion of TruST into a versatile, affordable, and accessible equipment for clinical settings. Moreover, we will investigate how to develop a user-friendly interface to operate TruST-system in clinical settings by non-specialized personnel. Regarding our intervention, we will also study whether a distributed motor practice, more similar to regular therapy schedules (30-60min versus 120min), would be equally effective. Finally, if participants acquire unsupported sitting, further studies will be necessary to objectively address how to modify the child's context (physical barriers) to transfer the functional gains to ADLs.

Public/patient involvement statement

There was not a patient or family advisory board included during the planning of the proposed RCT study.

Contributors: SKA and AMG are the principal investigators. VS is a co-investigator. SKA, AMG, and VS have designed the RCT and standardized study procedures and training personnel documentation. VS trains research personnel in the motor intervention. SKA, AMG, and VS supervises data collections. KC is the research coordinator. XA is the PhD candidate and bioengineer involved in data collections. SKA, AMG, VS, and XA will process, analyze, and interpret the data. SKA, AMG, VS, XA, and KC will collaborate in the final scientific write-up of the research work.

Funding: This work is supported by the National Institutes of Health (1R01HD101903-01). NIH grants the funds and will annually review research progress. NIH will make our research work publicly available.

Competing interests: None declared.

Patient and public involvement: Participants and families participate in the study and offer valuable insights about it. However, they are not directly involved in the conducting, reporting, or dissemination plans of this research.

Patient consent for publication: Not required.

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Figure Captions

Figure 1

Fig 1. Figure A depicts the star-shaped scheme applied during the motor intervention with TruST and rigid trunk support systems. The postural star-sitting test follows the same scheme to compute sitting workspace area (cm^2). Figure B shows a model of TruST with a child. The main components are numbered: motors (1), pulleys and cable tension sensors (2), cables (3), mechanical lifting platform (4), bench with pelvic strapping (5), and ball used during the postural star-sitting test (6). The arrow depicts the active trunk excursion. Figure C depicts the static trunk support system and the main components: principal rigid column (1), U-shaped trunk support that slides along the vertical column (2), trunk support adjustments in the frontal and sagittal planes (3), base of the frame with wheels that can be locked (4). Note that the frontal belt and bench are not shown in this model.

Figure 2

Fig 2. Diagram depicting the timeline data collections and type of data gathered during the study.

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Figure 1

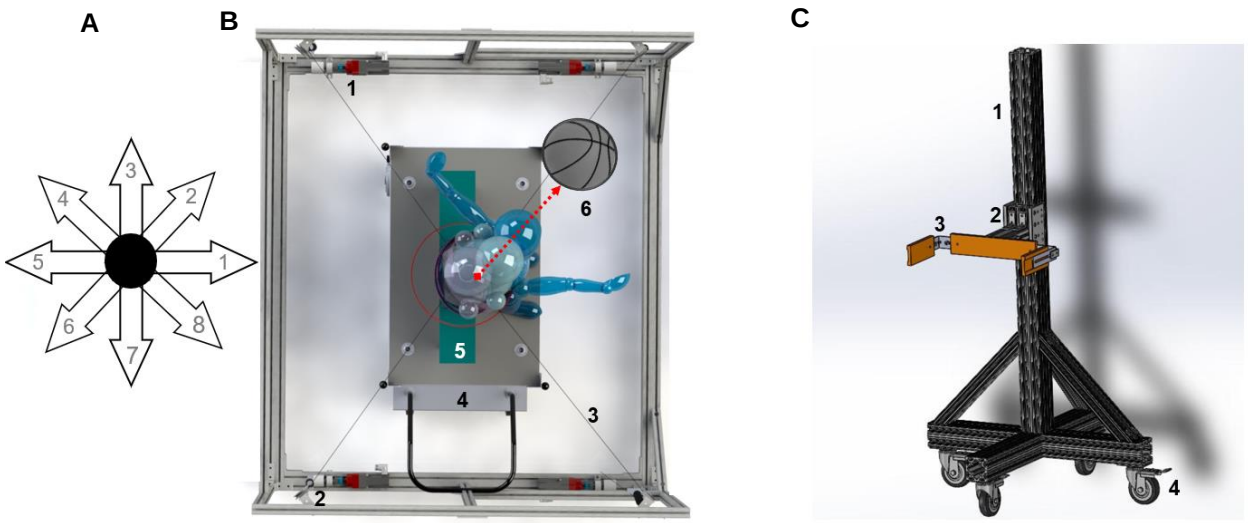
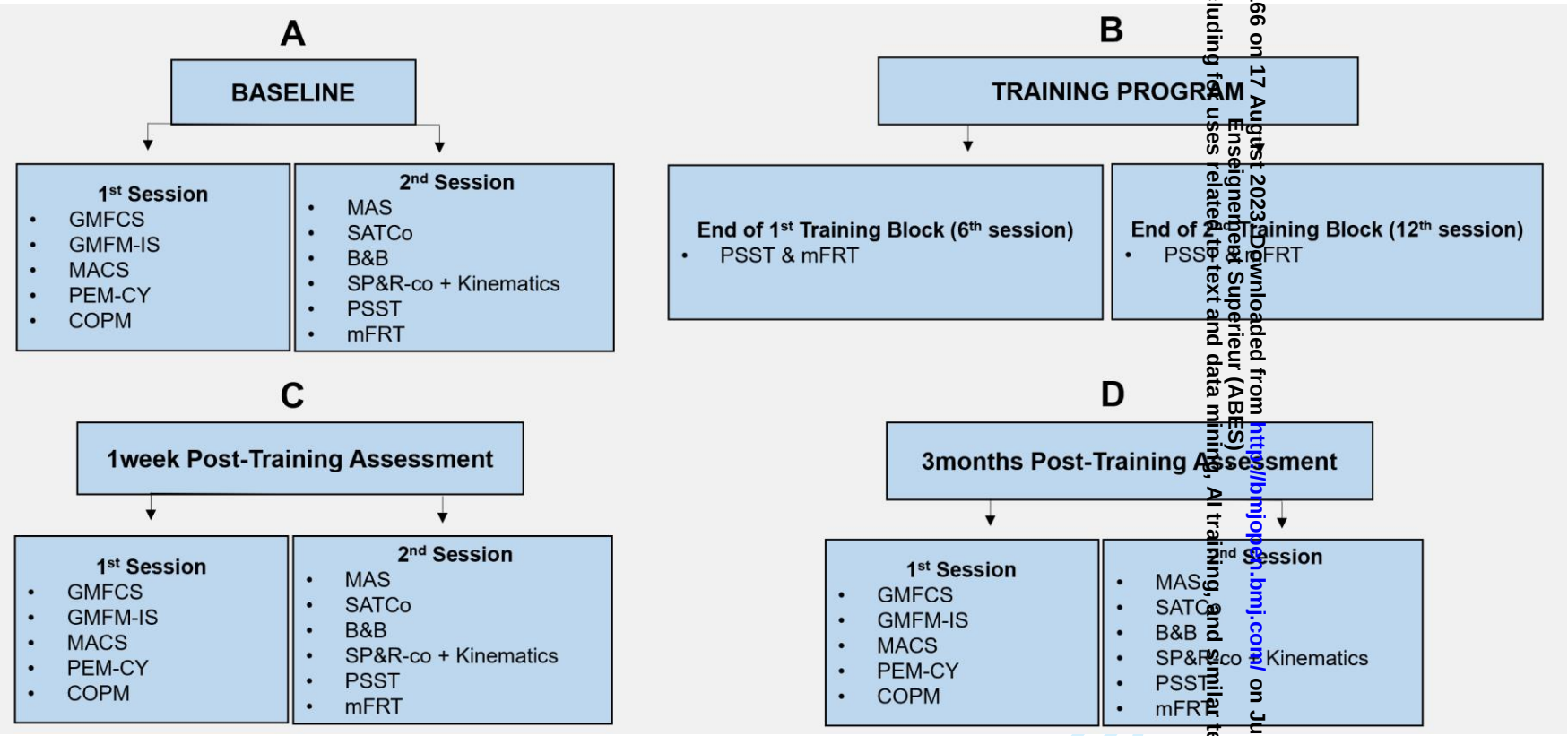


Figure 2



SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

Study Title:

Study protocol for a randomized controlled trial to determine the efficacy of an intensive seated postural intervention delivered with robotic and rigid trunk support systems

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Manuscript Page (lines)
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p.1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Abstract (p.2, line 62) and p.5 (line175)
	2b	All items from the World Health Organization Trial Registration Data Set	Clinicaltrials.gov includes all WHO items.
Protocol version	3	Date and version identifier	Abstract (p.2, line 59)
Funding	4	Sources and types of financial, material, and other support	p.19 (line 511-513)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	p.19 (lines 504-510)
	5b	Name and contact information for the trial sponsor	p.19 (line 511-513)

	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	p.19 (line 512)
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Some of the roles are N/A. An independent researcher will test training effectiveness (p.15 lines 323-337); Data management plan (p.18, lines 427-442); Formal training/supervising plan of research personnel (p. 15-16, lines 322-336); and Data monitoring (p.15-16, lines 337-349)
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	p. 4 (lines 103-119)
	6b	Explanation for choice of comparators	p. 4 (lines 123-132)
Objectives	7	Specific objectives or hypotheses	p. 5 (lines 145-163)
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	p. 5 (lines 149-160, 165-171)

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	p.7 (lines 203-208)
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Table 1: Inclusion/Exclusion criteria (p.6); Personnel delivering the intervention: p.13 (lines 238-243, and Table 2);
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Tables 2-3, Figure 1, and p.7-14 (lines 209-310)
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	p.14 (lines 283-288) and p. 16 (lines 348-349).
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	p.5-6 (lines 172-183), p.15-16 (lines 323-349), p.18 (lines 427-441)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	p.7 (line 210).
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	p. 16-18 (lines 353-426)

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 2 and p. 5 (lines 167-170).
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	p.18 (lines 443-450)
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	p.5-6 (lines 172-183), p.15-16 (lines 323-349), p.18 (lines 427-441)
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	p. 6 (lines 186-195)
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	p.6 (lines 192-194)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	p.6 (lines 192-194) & p.6-7 (lines 200-204)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	p.7 (lines 198-202)

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	p.7 (lines 198-202)
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	p. 5 (lines 168-170); and p. 16-17 (lines 372-426).
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	p. 5 (lines 178-183); and p. 18 (lines 432-441).
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	p.18 (lines 428-431)
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	p. 16 (lines 347-349); p.18 (lines 451-458)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	p.18-19 (lines 459-467)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	p.18-19 (lines 459-467)
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	p. 15 (lines 337-349)
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	p. 16 (lines 345-349)
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	p. 14 (lines 313-321) and p. 15 (line 328)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	p. 19 (lines 468-484)
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	p. 15 (line 328)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	p. 5-6 (lines 178-183)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	p. 18 (lines 428-431)

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	p. 20 (line 514)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	p. 20 (line 511)
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	p. 15 (line 314-315)
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	p.19 (lines 480-484)
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	p. 20 (line 513)
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Added as supplementary material
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Study protocol for a randomized controlled trial to determine the efficacy of an intensive seated postural intervention delivered with robotic and rigid trunk support systems.

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Study protocol for a randomized controlled trial to determine the efficacy of an intensive seated postural intervention delivered with robotic and rigid trunk support systems.

Victor Santamaria[1], Xupeng Ai[2], Karen Chin[3], Joseph P. Dutkowsky[4], Andrew M. Gordon[3], Sunil K. Agrawal[2,5].

Affiliations

[1] Rehabilitation Sciences Department: Physical Therapy Division, New York Medical College, NY, USA
[2] Mechanical Engineering Department, Columbia University, NY, USA
[3] Biobehavioral Sciences Department, Teachers College, NY, USA
[4] Orthopaedic Surgery Department, Columbia University, NY, USA
[5] Rehabilitation and Regenerative Medicine Department, Columbia University, NY, USA

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Address correspondence to:
Victor Santamaria, PT, MSc, PhD, PCS.
Department of Physical Therapy
New York Medical College, School of Health Sciences and Practice
Valhalla, NY, USA
vsantama@nymc.edu

ABSTRACT

Introduction: Children with cerebral palsy (CP) classified as Gross Motor Function Classification System (GMFCS) levels III-IV demonstrate impaired sitting and reaching control abilities that hamper their overall functional performance. Yet, efficacious interventions for improving sitting-related activities are scarce. We recently designed a motor learning-based intervention delivered with the robotic Trunk-Support-Trainer (TruST-intervention), in which we apply force field technology to individualize sitting balance support. We propose a randomized controlled trial to test the efficacy of the motor intervention delivered with robotic TruST compared to a static trunk support system.

Methods and analysis: We will recruit 82 participants with CP, GMFCS III-IV, and aged 6-17yrs. Randomization using concealed allocation to either the TruST- or static trunk-support intervention will be conducted using opaque sealed envelopes prepared by someone unrelated to the study. We will apply an intention-to-treat protocol. The Interventions will be provided 2H/sessions, 3/week, for 4 weeks. Participants will start both interventions with pelvic strapping. In the TruST-intervention, postural task-progression will be implemented by a progressive increase of the force field boundaries, and then by removing the pelvic straps. In the static trunk support-intervention, we will progressively lower the trunk support and remove pelvic strapping. Outcomes will be assessed at baseline, the training midpoint, 1week post-intervention, and a 3month follow-up. Primary outcomes will include the modified functional reach test, a kinematic evaluation of sitting workspace, and the Box & Block test. Secondary outcomes will include: The Segmental Assessment of Trunk Control test, Seated Postural & Reaching Control test, Gross Motor Function Measure-Item Set, Canadian Occupational Performance Outcome, The Participation and Environment Measure and Youth, and postural and reaching kinematics.

Ethics and dissemination: The study was approved by the Columbia University Institutional Review Board (AAAS7804). This study is funded by the National Institutes of Health (1R01HD101903-01) and is registered at clinicaltrials.gov (NCT04897347).

Strengths and limitations of this study

- This RCT investigates an understudied sub-population of individuals with CP.
- The methodology details our novel seated motor and postural control intervention in CP.
- The methodology maximizes the motoric benefits for both the experimental and control groups and will elucidate the active training ingredient.
- The participation of children with CP and severe intellectual deficits will be limited.

INTRODUCTION

Cerebral palsy (CP) is the most common life-long childhood physical disability with 2.0-3.5 per 1000 births, and a lifetime cost per person of $921,000 in the US.[1], [2] Approximately 29% of these children have moderate-to-severe bilateral CP (BCP)—Gross Motor Function Classification System (GMFCS) levels III-V.[3]–[5] Abnormal posture and motor deficits are some of the most disabling impairments.[3], [5], [6] Yet, efficacious therapies targeting sitting postural control that result in long-lasting functional benefits are scarce.[7] This is particularly problematic for children with BCP, GMFCS III-IV, who require sitting abilities for wheeled mobility, activities of daily living (ADLs), an active physical life, and community participation.[8]–[12] Sitting control deficits are commonly resolved by assistive systems and by modifying contextual factors (i.e., power wheelchairs, head and lateral trunk supports, seating adaptations, and personal assistance).[13], [14] This assistive approach facilitates participation; however, these children may not be performing at their maximal independent motor potential. Thus, promoting postural and reaching abilities during independent sitting are essential to enhance the functional life of these children. Nonetheless, what is the best evidence-based therapeutic strategy to target seated functions in children with BCP?

Children with GMFCS III-IV show segmental trunk control deficits at the middle or lower thorax levels, and reaching impairments—as determined by the Segmental Assessment of Trunk Control (SATCo) and Seated Postural & Reaching Control (SP&R-co) Tests.[15], [16] Consequently, changing an external support from mid-ribs to pelvis significantly decreases sitting and reaching control.[17] This suggests the potential application of external support at specific trunk levels to deliver seated postural interventions.[18], [19] A recent randomized controlled trial (RCT) in CP, GMFCS III-V, compared conventional therapy with a home-based activity training delivered with external support at the impaired trunk segment. The intervention resulted in significant short-term postural improvements (i.e., sway) but not in long-term motor benefits.[20] The absence of long-term effects may be because the intervention was not structured around motor learning and control principles, which is essential for inducing neural plasticity and lasting functional outcomes.[21]–[25]

In the present study, we have developed a robotic Trunk-Support-Trainer (TruST) to evaluate seated balance and implement a motor learning-based postural intervention (TruST-intervention).[26], [27] TruST is a motorized-cable driven belt that applies force field technology. A key factor is that the force field matches the participants' sitting stability trunk region and supplements their motor efforts when their trunk is beyond such postural limits. Thus, force fields are tailored to the ability of the participants as their postural control improves across intervention sessions (i.e., postural task-progression). Moreover, TruST displays real-time feedback about the trunk's location with respect to the stability boundaries, which allows the clinician to target postural strategies within, at, or beyond sitting control boundaries. The current RCT investigates the efficacy of TruST-intervention

compared to the same motor intervention implemented with a static trunk support system in children with BCP, GMFCS III-IV.

AIMS AND HYPOTHESES

Overall Aim

We will test whether a motor learning-and-control-based intervention can improve seated postural and reaching abilities in children with BCP, GMFCS III-IV.

Primary Hypotheses

We expect improvements with TruST and the static trunk support system. However, we hypothesize greater improvements for the TruST-intervention. These will be seen by larger improvements in a customized postural-star sitting test (PSST), the modified functional reach test (mFRT) and in upper extremity control in both groups, as determined by the Box and Block (B&B) test and video-coding analysis.

Secondary Hypothesis

We expect improvements in both intervention groups. However, we expect a greater improvement rate with TruST-intervention in segmental trunk control (SATCo), postural sitting and reaching control (Seated Postural & Reaching Control Test, SP&R-co), gross motor function (Gross Motor Function Measure-Item Set, GMFM-IS), child- and family-centered functional and participation outcomes (Canadian Occupational Performance Outcome, COPM, The Participation and Environment Measure and Youth, PEM-CY), as well as in postural and reaching kinematics.

METHODS

Study design

This is an explanatory parallel RCT conducted at Columbia University (NY) in 82 children with BCP, GMFCS III-IV, aged 6-17yrs. The study timeline is from February 2022 to December 2026. After baselines, we will test improvements at mid-point of the intervention (6th session), 1 week post-intervention, and 3 months follow-up. The Consolidated Standards of Reporting Trials (CONSORT) will be followed.[28], [29] A patient or family advisory board did not particpiate during the planning of our RCT study.

Recruitment

Participants will have a confirmed medical diagnosis of BCP. They will be recruited by advertising on our and other websites, social media platforms, clinicaltrials.gov (NCT04897347), various local clinics and through NYC area school districts. Testing and training sessions will be adjusted to the family's schedule before starting the study. During initial pre-screening, a phone survey will be scheduled to interview families, caregivers, or legal guardians by KC or VS. We will obtain information beforehand on participants' eligibility criteria and discuss our study design, research goals, potential risks, and

reciprocal commitment with participants and families. We expect that our recruitment strategies will maximize retention and intervention benefits.

The participants will meet the following inclusion criteria to participate in our study: 1) age 6-17 years; 2) medical diagnosis of BCP (diplegia, triplegia, or quadriplegia); 3) GMFCS levels III or IV; 4) ability to sit 5s with manual support provided to any trunk region at or between mid-ribs and pelvis (SATCo = 3-7); and 5) cognitive capacity to follow basic verbal instructions (e.g., "do not put your hands on your lap", “keep your hands up in the air”, or "follow and reach or touch the toy"). Exclusion criteria include: 1) absent head control (SATCo = 1); 2) current medical illness unrelated to CP at the time of the study; 3) severe dyskinesia that impedes the child to sit and/or perform postural and/or reaching movements; 4) history of recurrent seizures (daily) or refractory epilepsy; 5) severe structural deformities of the spine (scoliosis >40° and/or kyphosis >45°); 6) orthopedic surgery of the spine, and/or upper and/or lower extremities in the last 6 months before the study onset; 7) severe spasticity of biceps/triceps in both upper extremities that prevent reaching movements (Modified Ashworth Scale = 4); 8) chemodenervation or neurolysis (e.g., botulinum toxin or phenol/ethyl alcohol injections) in the upper or lower extremity muscles 3 months before the study or planned during the duration of the study; and 9) major surgeries in the previous 6 months (only if medically contraindicated).

Randomization and Participant Allocation

A researcher blinded to our study will create computer-generated lists of random numbers assigned to seven blocks with 10 participants and to one block with 12 participants (n = 82). To prevent selection bias, the allocation sequence will be concealed from the research team. After randomization to either the TruST- or static trunk support-intervention group, an independent researcher will communicate to the research team the assigned group by opaque, sealed envelopes. Carbon paper inside the envelope will be used to transfer the information onto an allocation card that will be kept with the participant’s record. The envelopes will be opened after the consent of the enrolled participant and completion of baseline assessments.

Blinding

All assessments will be videotaped and scored by clinical evaluators with expertise in CP. The evaluators will be blinded to group allocation and testing sessions. Blinding of families and children to the intervention will not be possible due to equipment characteristics—i.e., robotic-TruST versus static trunk support system.

Study Locations

Both intervention arms will be delivered at Columbia University (NY, US). The TruST-intervention will take place at the Robotics and Rehabilitation (ROAR) Laboratory; whereas, the static trunk support-intervention will be carried at the Center for Cerebral Palsy, Teachers College. The same research personnel will collect data and deliver the motor interventions. However, clinical evaluators will be blind to participant allocation.

Study Interventions

Participants will concurrently follow their regular therapeutic care during the study, which will be documented. The TruST- and static trunk support-interventions are detailed in table 1, following the Template for Intervention Description and Replication (TIDieR) Checklist.[30], [31] The same motor learning and control principles, and activities will be applied to both interventions.[26]

Table 1. TiDiER checklist for comparison between TruST-intervention and static trunk support-interventions

Name	Trunk-Support-Trainer Intervention (Experimental)	Static Trunk Support-intervention (Control)
Why	Motor learning principles and motor-task progression implemented. Postural task-progression is objectively tailored to the child's sitting balance status and systematically progressed in each training session.	The therapeutic elements and intervention protocol are the same. However, the postural task-progression is implemented by lowering the static trunk support as the child improves in segmental trunk control stability across sessions.
What: Equipment	Toys, balloons, balls, cups, blocks, board games, buzzers, white board and colors. A bench with adjustable height and straps to support the pelvis is fixed to a mechanical lifter. The robotic TruST dynamically controls the trunk in sitting; and thus, the entire upper body moves within the pre-defined sitting stability boundaries.	Same equipment and bench. However, the bench is integrated with a rigid apparatus to adjust the level of support at the specific sub-region of the torso where the child loses sitting balance control. Thus, only the upper body region above the rigid support can freely move during the motor intervention.
What: Procedures	Age-appropriate discrete, serial, and continuous motor tasks, including: reaching (pointing and grasping with whole hand and fingers), catching, throwing, punching, hitting (or tapping), and lifting. Motor activities will be practiced along 8 star-radiated directions that are	Same intervention structure and procedures.

	approximately spaced 45° apart and have their center at the child's pelvis. Motor practice will be within and beyond reaching distance in each one of the 8 directions covering the full child's peripersonal space (360°). A total of 30-50 repetitions will be trained in a clockwise and counterclockwise fashion to train the more- and less-impaired upper limbs.	
Providers	Two researchers with clinical/kinesiology knowledge and a bioengineer will participate in each session. The assignment of the personnel providing the intervention will be counterbalanced.	Same providers and counterbalance design.
How	A one-on-one intervention delivery. Motor learning-based intervention that is task-oriented (predefined motor goal), age-appropriate (engaging practice), intensive mass practice (training > resting, high number of trials, and reduced performance time), sequential skill progression (part-task training), and motor randomization (variability during task practice). Motor control parameters modulated to challenge motor performance. TruST via visual feedback on a screen guides the clinician to train two distances: "within boundaries" (maximum active reaching	Same therapeutic program, clinical delivery, and motor learning and control principles will be applied. The motor tasks are equally practiced at two distances: "within maximum active reaching distance" and "beyond active reaching distance". The rigid trunk support system assists the postural trunk movements by statically holding the sub-region of the child's torso where the loss of sitting balance is found.

	distance) and "beyond boundaries" (beyond active reaching distance"). TruST-force fields assist the child in performing postural trunk movements.	
Where	Laboratory setting	Same setting
When and how much: **a) Intensity** **b) Frequency** **c) Session Time** **d) Overall Duration**	The training dosage and schedule will be 2hour-sessions, 3 X week, over 4 weeks, with an estimated overall duration of 24 hours of training.	Same intervention schedule and dosage.
Tailoring	Postural task-progression will be implemented via *assist-as-needed* force fields that are equivalent to 10% of the child's body weight. These force fields will be determined by the area and boundaries of stable sitting control measured by a customized postural star-sitting test (i.e., a trunk control-based kinematic measurement). Force fields are re-adjusted at the beginning of each training session to maintain the postural and motor challenge at a maximum level during the motor intervention.	The static support will be placed at the trunk region at which the child loses sitting balance, as determined by the SATCo. Postural task-progression will be implemented by lowering the rigid support, as the child acquires greater trunk control. The SATCo, starting at the most-impaired trunk segment, will be systematically used prior to starting the motor intervention to re-adjust the support system and ensure the maximum level of postural challenge during the intervention.
Modifications	Games and motor activities will be selected based on the child's preferences. Otherwise, no modifications are expected to occur.	Same method for the selection of games and motor activities.
How Well: **Planned** **a) Fidelity strategies** **b) Fidelity assessment**	Videos and logs to monitor: i) study attendance, ii) visual analogue scale (VAS) for discomfort/pain (Wong-Baker FACES),[32] iii) perceived physical exertion	Same procedure to monitor study attendance, child's discomfort/pain, and motor learning/control modulation for ensuring intervention fidelity.

	(OMNI),[26] iv) motor control parameters used and modulated during training. Video-coding of training session recordings to determine effectiveness of training (i.e., performance of active movements without considering breaks, setup, transfers time between activities, toilet use), type of motor activity and practice time, and motor capacity (e.g., successful trials).	
How Well: Actual	We will determine whether the study and intervention plans are achieved based on attendance to measure participation, data from the customized postural star-sitting test (i.e., increases in force fields boundaries will indicate improved sitting workspace area), and video-coding data to measure motor capacity improvements. The presence of unexpected accidents or therapeutic adverse effects together with the level of fatigue and discomfort or pain will determine intervention safety and feasibility in a large scale of children with BCP.	Similarly, we will determine whether the study and intervention plans are achieved based on attendance to measure participation, data from the SATCo across sessions to determine enhanced trunk control, and video-coding data about the type of motor activity to study improved motor capacity. The presence of unexpected accidents or therapeutic adverse effects together with the level of fatigue and discomfort or pain will inform on intervention safety and feasibility in a large scale of children with BCP.

Common Intervention Procedures: TruST- & Static Trunk Support-Interventions

Dosage

The dosage for both interventions will be identical, 2H/session, 3x/week, for 4 weeks (12 training sessions). In our previous study,[26] we found the proposed intervention

schedule and dosage to be effective in promoting short- and long-term improvements in seated postural and reaching abilities and gross motor functions.

Therapeutic Approach

In both intervention groups, all motor activities will be trained along 8 star-radiated directions spaced at 45° and with the center at the participant's pelvis. The goal of this postural intervention scheme is to cover the 360° peripersonal space around the participant in sitting while being trained at different reaching distances (Fig 1A).

Activities will be practiced under moderate-high intensity but never beyond extreme fatigue, as reported by the child or by the presence of clinical signs such as muscle trembling. Any potential pain or discomfort will be monitored with the Wong-Baker Faces pain scale during and after the intervention.[33]

Parameterization of the Motor Intervention

The motor intervention parameters were investigated in previous studies in preliminary studies (Table 2).[26], [34] A subset of modified motor parameters defined by Fleishman (1972) will be used to modulate postural and reaching control strategies during the motor intervention.[35] Motor learning-based interventions depend upon participants' own preference, motivation, and cognitive-motor abilities. Thus, these parameters will be adjusted across participants and intervention sessions.[21], [23], [36]

Table 2. Activities & Motor Learning and Control Parameters

Motor Activity	Descriptors
Hand Actions	Reaching, grasping, catching, throwing, drawing, punching, or coloring
Games	Connect Four®, Jenga®, white board and pens
Toys and Objects	Balloons, punching bag, balls, marbles, cars, bowling pins, strings, light- and sound-emitting buzzers, constructions blocks, small cups, and shape-like puzzles
Motor Learning Parameters	**Descriptors**
Task nature	Discrete: Task characterized by a defined start and end. Continuous: Motor task that stops arbitrarily. Serial: An orderly sequence of discrete tasks
Movement Repetitions	30-50 trials
Motor skill progression	50% success required to progress the complexity of the motor task: object features (size, shape, or weight) and task constraints (pointing versus grasping)

Motor practice	First practice without objects. Then, objects are incorporated. Whole-task training is emphasized. However, in case of learning deficits, a part-task training following a segmentation method is applied (i.e., splitting the motor activity into components so that the first component is trained first, and then this component is combined with the second, and set forth)
Sequence skill progression	Motor task variations are progressively trained in a sequence from less to more complex
Verbal feedback	In case of learning deficits of the task goal or how to perform it, verbal feedback is incorporated. Knowledge of results (action outcomes) is prioritized over knowledge of performance (movement-based information). A bandwidth mode with a 50% acceptable performance error will be delivered as terminal feedback after motor practice of a block of trials (e.g., in 10 trials, feedback delivered after a block of 5 unsuccessful trials).
Motor randomization	Motor variability (e.g., object location or moving versus stationary targets) and motor parameters (control strategies) are addressed during postural and reaching tasks performed beyond maximum reaching distance.
Motor Control Parameters	**Descriptors**
Control precision	Ability to perform rapid and precise movements to control devices, games, or toys.
Response orientation	Ability to move to specific direction/s.
Arm movement speed	Ability to perform rapid arm movements.
Rate control	Ability to time continuous anticipatory and compensatory movements in response to speed/directional changes.
Multilimb Coordination	Ability to move and coordinate upper extremities to achieve symmetrical/asymmetrical bilateral tasks.
Manual dexterity	Ability to perform skillful in-hand movements.
Finger dexterity	Ability to perform skillful finger movements with small objects such as coins.
Arm-hand steadiness	Ability to maintain steady hand-arm and/or postures during an interval of time.
Wrist, finger speed	Ability to perform rapid and repetitive wrist and finger movements.
Aiming and accuracy	Ability to move the hand or finger to static and/or moving targets of different dimensions; or throwing tasks that demand visual accuracy.
Reaction time	Ability to respond as quick as possible and with rapid movements to external visual/auditory cues.

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Mode of Intervention Delivery and Setting

One-to-one interventions will be delivered in a lab setting by a physical or occupational therapist. All research personnel will be trained and supervised. A physical therapist and researcher (VS) will provide direct supervision every two intervention sessions. Also, a bioengineer (XA) will operate TruST while another researcher/clinician collects kinematic data or deliver the motor intervention.

Postural-Task Progression Procedures

TruST-Intervention: Postural Assistive-Force Fields

The TruST-belt will be placed on lower ribs ($T_{9\text{-}12}$) to provide *"assist-as-needed"* forces. The PSST will be used to match the assistive force-tunnel to the participant's sitting control boundaries and measure sitting workspace (cm^2).[26], [37] This test is based on the Star Excursion Balance Test; in which the person displaces the foot along eight directions, following the shape of a star during one leg stance.[38] Similarly, the PSST is a game-oriented test in which the seated participant performs maximal trunk excursions. A large ball is presented nearby the participant's face to guide the 8 trunk movements that radiate in a star-like fashion. After each maximum trunk displacement, the participant needs to recover upright sitting posture without using the hands for support.

During the TruST-intervention, the assistive-force field intensity equals 10% of the child's body weight (Fig 1B). These forces assist sitting balance toward the pre-defined stability boundaries and not to the center of the star-shaped region. Moreover, assistive forces are only provided when the trunk is beyond the boundaries to supplement the participant's motor efforts. This configuration promotes continuous active sitting control without hand support to practice goal-oriented tasks. As the participant expands the sitting control boundaries across intervention sessions, the assistive-force field areas are increased to the new sitting control boundaries (i.e., postural-task progression).

Another critical parameter to the achievement of independent sitting will be the removal of pelvic strapping (i.e., unsupported sitting). We will follow one of two criteria to remove the straps. The child shows a pre-training sitting workspace area above two standard errors (SE) of the mean from the two, or more, previous pre-training sessions; or pelvic strapping is removed after the 6th session. Our previous study suggests that participants will likely acquire unsupported sitting (unstrapped) by the 6th intervention session.

Static Trunk Support-Intervention: Segment-by-Segment Approach

The static trunk support system (Figure 1C) design follows engineering principles, kinematic and electromyographic data in sitting and reaching control that apply to healthy adults, developing infants, and children with CP.[17], [19], [20], [39]–[43] As determined by the SATCo, we will follow a top-down segment-by-segment approach to evaluate trunk control in sitting at the beginning of each intervention session. We will define the most-impaired trunk segment, place the support, and deliver the motor intervention. The constraint of caudal trunk segments to the one being trained might

help to reduce the overload of sensorimotor information to process and to control the body dynamics during seated motor activities.[39], [43]

For postural task-progression, when there is an improvement in the SATCo—i.e., improved sitting balance at a lower trunk segment—the support is lowered one level. The trunk support system will offer a firm support for a systematic, objective, and reliable SATCo evaluation across participants and sessions.

Discontinuation Criteria for Motor Interventions

We will discontinue the TruST-intervention if postural detriments are observed—i.e., workspace area decreases during 3 consecutive days and below 2SE of the averaged pre-intervention sessions before the detriment onset. Static trunk control-intervention will be discontinued if the SATCo score decreases 1 level, or more, for 3 consecutive days. Any intervention will stop if the participants report excessive pain (VAS ≥ 7).

Motor-Task Progression Procedure

In the TruST-intervention, motor training will be progressed as follows:

1. *Within sitting boundaries (inactive TruST-force field):* The participant performs 30-50 simple reaches (i.e., pointing) with the less- and more-impaired upper extremities. The target is placed at maximum active reaching distance without eliciting additional trunk movements on the right and left sides of the body, following the 8 star-like directions—as we follow in the postural star-sitting test. If 60% of attempts are successful in a minimum of 5 out of the 8 directions (clockwise or counterclockwise), the participant progresses to stage 2.
2. *Beyond sitting control boundaries (active TruST-force field):* The target is placed beyond stability boundaries (~120% active reaching distance) along the 8 directions to elicit trunk movements. In this stage, the participant relies on assistive-force fields to complete the motor activity and return to sitting posture without using the hands to recover sitting stability. As in stage 1, the participant can progress to stage 3 when 60% of attempts are successful at least in 5 out of the 8 directions (clockwise or counterclockwise).
3. *Beyond sitting control boundaries under challenging motor conditions:* The training procedure is like stage 2. However, in stage 3, the clinician modulates specific motor control parameters (see table 2 above), adds practice variability—movement distance and directionality—and introduce diverse goal-oriented activities (i.e., contextual interference) to address maximum motor complexity.

In the static trunk support-group, we will follow the same sequential motor skill training. However, in stage 2 and 3, the participants will rely on a static trunk support to perform the postural and reaching activities without the additional use of the hands for support.

Adverse events and safety

As per our IRB-protocol, major risks or serious long-term harm are not expected. Thus, pre-established compensation has not been determined. Major falls from the bench will be prevented with a slacked harness—to avoid weight support during the intervention. Minor equipment- or intervention-related injuries that do not require medical attention are muscle fatigue, minor dermic abrasions, and localized erythema or petechiae under the belt or trunk support. If adverse events such as muscle or articular pain, excessive physical or cognitive fatigue, musculotendinous strains, or ligament sprains occur, these will be reported in our study protocols (see "Fidelity" section) and study IRB.

Fidelity

Supervisory team: researchers attributes, scientific documentation, and personnel training.

We will have a Manual of Procedures (MOP) in place that covers each treatment arm. The MOP will describe the study design, personnel roles, experimental procedures, interventions, data analyses, precautions and safety measures, and how to handle blinded and private data. It will register adverse events, and protocol or procedure modification logs.

All research personnel (including volunteers) in direct contact with participants will receive training in ethical, safety, experimental, and intervention protocols to achieve optimal ethical and professional attributes to perform the study. This training will include IRB-related coursework (e.g., "Good Clinical Practice"), basic first aid and CPR training, communication skills to interact with participants and families, information on RCT designs—ensuring internal and external validity of the study—and a two-hour in-person training seminar to learn about postural- and reaching-related deficits in CP, motor intervention design, and basic operations of TruST and static trunk support systems.

Data Monitoring during the Study

Attendance will be used to measure participation and monitor potential dropouts, including if the reason is internal or external to our study. Video footage of training sessions will be video-coded to determine training effectiveness (i.e., time-on-task), type and frequency of motor activities practiced, toys or objects used, and motor capacity (e.g., success to achieve the goal, time to achieve the task, and repetitions). An external researcher with expertise in video-coding analyses, who is independent to our study team, will analyze masked video data with Datavyu software (https://datavyu.org/).

A data monitoring committee has not been established. In weekly meetings, we will monitor if all study protocols are implemented as planned. Aside from an external statistical analysis, interim statistical analyses will be carried to monitor the progression of the two study arms. If 50% of the projected sample size does not improve in either intervention, we will inform the funding agency and discontinue our RCT.

Participant's Data

Using the ICF framework, we will collect data within the body structure and function, activity, and participation domains.[14] Figure 2 depicts the study outline and data collections.

Medical, Demographic, and Concurrent Therapy Data

NIH questionnaires will be used to gather demographic data, sex, age, race, and ethnicity. This data will be used to ensure cultural diversity. Medical information such as CP diagnosis and subtype, brain injury, and other comorbidities will be obtained from medical records. We will record the current medical and therapeutic regimens—type, schedule, and intensity—of participants for further interpretation of our study outcomes. Any communication that involves personal or medical information will follow the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[44]

Screening and descriptive measures

GMFCS: The GMFCS comprises five levels of severity. It categorizes functional abilities such as sitting, walking, running or jumping while considering the need for assistive equipment (postural support, wheeled mobility, or walkers).[45]

Manual Ability Classification System (MACS): The MACS categorizes how children manipulate objects during ADL depending on their functional independence.[46]

Spasticity will be measured with the Modified Ashworth Scale (MAS): The MAS can be used to assess spasticity in CP. [47], [48] It scores the increase in muscle resistance through passive limb movements. The score ranges from 0 (no increase in muscle tone) to 4 (limb rigid in flexion or extension). We will be cautious interpreting spasticity as MAS scores depend upon joint and muscle features, and examiners.[48]

Primary Outcomes

mFRT: The mFRT measures proactive postural control during maximum reaching distance. It is reliable tool in CP (r = 0.42 to 0.77) and discriminates GMFCS levels (GMFCS III = 10.8cm ± SD: 3.8).[49], [50] Test responsiveness is unknown in CP, however.

PSST: It will be performed before and after interventions to monitor sitting control progression in both TruST- and static trunk control-intervention groups. The investigators have several motivations that rationalize this customized measurement. It: 1) is age-appropriate, 2) is goal-oriented, 3) directly measures sitting based on trunk control improvements, 4) is responsive to capture sitting workspace area increases, and 5) offers data with a straightforward functional interpretation.

B&B: It examines manual dexterity. The child moves a maximum number of blocks (block size = 2.5cm^2), one at a time, between the compartments of a partitioned box in 60s.[51] In BCP, B&B shows a strong association ($r \geq 0.7$) with self-care, mobility, and social function.[52] B&B is responsive to motor interventions that include more- and less-affected hands with a minimal clinically important difference (MCID) of 1.9 and 3.0 blocks, respectively.[53], [54] Arm displacement and grasping will be analyzed with Datavyu.[55] An instruction manual has been created to standardize video-coding procedures and define the reaching variables. Grasping is defined as the moment the hand contacts the block to the time the block is lifted from the surface. Arm displacement is defined from end of

grasping to block release. Reaching performance is the summation of grasping and arm displacement. Two, or more, coders will determine video-coding reliability ($r \geq 0.7$).

Secondary Outcomes

GMFM-IS: The GMFM-IS determines the gross motor function of children with CP—A: lying and rolling, B: sitting, C: crawling, D: standing and E: walking, running & jumping. It is an abbreviated and validated version of the GMFM-66. It includes an algorithm with three critical items to decide which one of four item sets is most appropriate to assess motor function and obtain a GMFM-66 score.[56] GMFM shows strong interrater reliability ($\kappa = 0.75$) for 2-12yrs and strong inverse correlation with GMFCS ($r = -0.91$).[57], [58] Moreover, it is responsive to change with an MCID of 0.8-1.6 (medium effect size) and 1.3-2.6 (large effect size).[59]

COPM: It will be used to measure parent- and child-centered functional goals and preferences specific to seated posture and reaching impediments that restrict participation.[60] COPM has high interrater agreement in prioritizing problems (80%) and it can detect clinical important differences across time (MCID above 2-point change).[61]–[63]

PEM-CY: It measures participation—12 home items, 17 school items and 16 community items—including environmental factors (reliability: home = 0.71, school = 0.76, and community = 0.69).[64], [65] A study on environmental-based intervention showed that PEM-CY can capture improvements in children with physical disabilities. We will explore if PEM-CY can capture post-intervention changes in our study.[66]

SP&R-co test: The theoretical play-oriented framework and metrics of the SP&R-co test have been validated in children with CP who have moderate-to-severe motor conditions. It shows good-excellent interrater and intrarater reliability (ICCs = 0.68–0.86, and 0.64–0.95, respectively). As the SATCo, the SP&R-co follows a segment-by-segment trunk approach to assess quantitatively sitting control across static, active, proactive (via bimanual and unimanual reaches), and reactive dimensions. Responsiveness has not been addressed, but the standard error measurements for each seated postural dimension of the SP&R-co test are available.[15]

Postural and reaching kinematics: We will follow the seated postural framework validated in the SP&R-co to capture motor improvements in the next tasks:

Static Seated Task: Postural orientation and balance in sitting during 20s.

Active Seated Task: Simultaneous control of the trunk and head rotations when the child visually follows an object 90° to the right and left (i.e., chin over shoulder).

Proactive Seated Task: Seated anticipatory and compensatory postural control during direction-specific reaches performed straight, and 45° to the right and left.

SATCo: It is validated in children with CP and shows excellent interrater and intrarater reliability (ICCs > 0.84 and 0.98, respectively). The evaluator offers support at various trunk segments (shoulders, axillae, inferior angle of scapulae, on lower ribs, below lower ribs, and pelvis) to measure trunk control across 3 dimensions: static (during 5s), proactive (visually following an object to the right and left), and reactive (postural responses to nudges). The score is from 1 (no head control) to 8 (full trunk control).[16]

Test responsiveness has not been established but studies show potential to identify trunk balance improvements in each of the tested trunk segments.[19], [43]

Data Management and Data Collections

After the subject eligibility is confirmed, we will assign a code to each participant only accessed by the PIs (SKA and AMG), co-investigator (VS), and research coordinator (KC). All data collections will be digitized and saved in encrypted endpoint hard drives. Paper forms will be collected as safe copies in a private locked cabinet in the PI's office.

To keep young children informed and engaged during the study, each one will receive a personalized fun "Research Passport" that lists each study stage and explains the purpose of each visit. Upon completion of each procedure, the child will earn a stamp on each page. Additionally, we will offer families the possibility of receiving a brief clinical informative report with the functional status of the child after the study by VS—who is a board-certified pediatric and licensed physical therapist in NY.

We will divide our three main data collection events (baseline, 1-week post-training, and 3-mos follow-up) into two sub-sessions to reduce the burden and physical fatigue that the evaluations may cause (Fig 2). We will empower participants with the ability to stop any study session and request breaks verbally or with a laminated red stop sign.

Data Analysis

Sample size estimation

We used preliminary data from our previous study and literature to estimate sample and effect sizes.[17], [26] *G-Power* (version 3.1.9.4., Dusseldorf University) and SPSS (version 25, IBM) were applied. Our primary outcome was upper body balance during seated reaching (Pilot average = 30˚ ± SD = 22˚, partial η^2 = 0.10, n = 11). With a mixed Analysis of Variance (ANOVA), we estimated 68 subjects to achieve a power = 0.8, considering a two-tailed α rate = 0.01. We will recruit an additional 20% of participants (a total of 82 participants) to account for potential group heterogeneity and dropouts.

Statistical Procedures

An alpha rate = 0.01 will be used for statistical analyses. The effect of interventions on primary and secondary outcomes will be analyzed with a two-factor mixed ANOVA, including groups as a between-subjects factor (TruST- and static trunk support groups), and testing sessions as a repeated measures factor (baseline, mid-point training, 1week post-training, and 3mos follow-up). The group X testing session interaction will be used to test the hypothesis that TruST-intervention is superior to static trunk support-intervention. If the ANOVA model is significant, we will perform *post-hoc* comparisons with Holm-Bonferroni procedure to control familywise error.

Statistical Handling of Non-Normally Distributed and Missing Data

In the event that participants miss sessions for unpredicted reasons (e.g., illness) or drop the study, we will apply a Generalized Estimating Equations (GEE) as an alternative statistical plan. In this way, we will account for missing data and follow an *intent-to-treat* principle. The GEE will analyze events-in-trials following a repeated-measures procedure with subjects as clusters, test session as the within-subject variable, and intervention groups as the between-subject variable. A linear model will be selected, and the covariance structure will be specified as correlation matrix based on the quasi-likelihood under independence criterion (QIC) goodness of fit coefficient.[67]

Ethics, Resource Sharing Plan, and Dissemination

The present RCT has been registered in clinicalgov.org (#NCT04897347). The study protocol, recruitment materials, and assent and consent forms have been approved by the Columbia University Institutional Review Board (IRB AAAS7804). Study information, assent, and informed consent forms will be signed by all participants and caregivers prior to requesting medical records and starting the study. Participants will be verbally reminded they can withdraw consent at any time without penalty. All de-identified data will be stored for 3 years after study completion in password protected computers. We will store de-identified data in an online HIPAA-compliant database (REDCap). The study protocols follow standardized procedures in RCT such as CONSORT and TIDieR to facilitate appropriate scientific, ethical, and safety assessments and to increase the likelihood of research success.[28], [30], [31]

We will make available the study data via the Data and Specimen Hub (DASH)—a data sharing platform of the Eunice Kennedy Shriver National Institute of Child Health and Development. Findings will be disseminated through peer-reviewed publication and national and international conferences. Participants and families will be informed on the study progress via newsletters and meetings.

Discussion

We are expanding on our previous small feasibilty study in which we did not include a control group (i.e., static trunk support-intervention).[26] We expect our motor learning-based postural interventions to induce postural and reaching improvements. Nonetheless, we expect that postural-task progression tailored to the participant's postural sitting control via TruST-force fields will have a synergistic effect during motor trainig that may lead to greater improvements. As shown in our previous studies, we will apply motor-task progression to challenge the child via specific motor parameters in age-approriate and goal-oriented activities that maximize engagement. Tailored postural support that is progressively lowered allows participants to experience a full motor repertoire based on self-initiated movements and trial and error. We do not expect safety concerns during the motor interventions but physical fatigue is highly plausable due to the motor- and postural-task progression nature. If our hypothesis is supported, a critical point will be knowledge translation of TruST-intervention. Valid static trunk support systems are accessible in most rehab settings and special education schools. Regarding TruST, the team will investigate its development into a versatile and

affordable equipment with an user-friendly interface for clinical use. Regarding our intervention, we will also study whether a distributed motor practice, more similar to regular therapy schedules (30-60min versus 120min), would be equally effective. Finally, if participants acquire unsupported sitting, further studies will be necessary to objectively address how to modify the child's context (physical barriers) to fully transfer and retain their functional gains to everyday ADLs.

Contributors: SKA and AMG are the principal investigators. VS is a co-investigator. SKA, AMG, JD, and VS have designed the RCT and standardized study procedures and training personnel documentation. VS trains research personnel in motor intervention protocols. SKA, AMG, and VS supervises data collections. KC is the research coordinator. XA is a PhD candidate and bioengineer during data collections. SKA, AMG, JD, VS, and XA will process, analyze, and interpret the data. SKA, AMG, VS, XA, and KC will collaborate in the final scientific write-up of the research work.

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Competing interests: None declared.

Patient and public involvement: Participants and families participate in the study and offer valuable insights about it. However, they are not directly involved in the conducting, reporting, or dissemination plans of this research.

Patient consent for publication: Not required.

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Figure Captions

Figure 1

Fig 1. Figure A depicts the star-shaped scheme applied during the motor intervention with TruST and rigid trunk support systems. The postural star-sitting test follows the same scheme to compute sitting workspace area (cm^2). Figure B shows a model of TruST with a child. The main components are numbered: motors (1), pulleys and cable tension sensors (2), cables (3), mechanical lifting platform (4), bench with pelvic

strapping (5), and ball used during the postural star-sitting test (6). The arrow depicts the active trunk excursion. Figure C depicts the static trunk support system and the main components: principal rigid column (1), U-shaped trunk support that slides along the vertical column (2), trunk support adjustments in the frontal and sagittal planes (3), base of the frame with wheels that can be locked (4). Note that the frontal belt and bench are not shown in this model.

Figure 2

Fig 2. Diagram depicting the timeline data collections and type of data gathered during the study.

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Figure 1

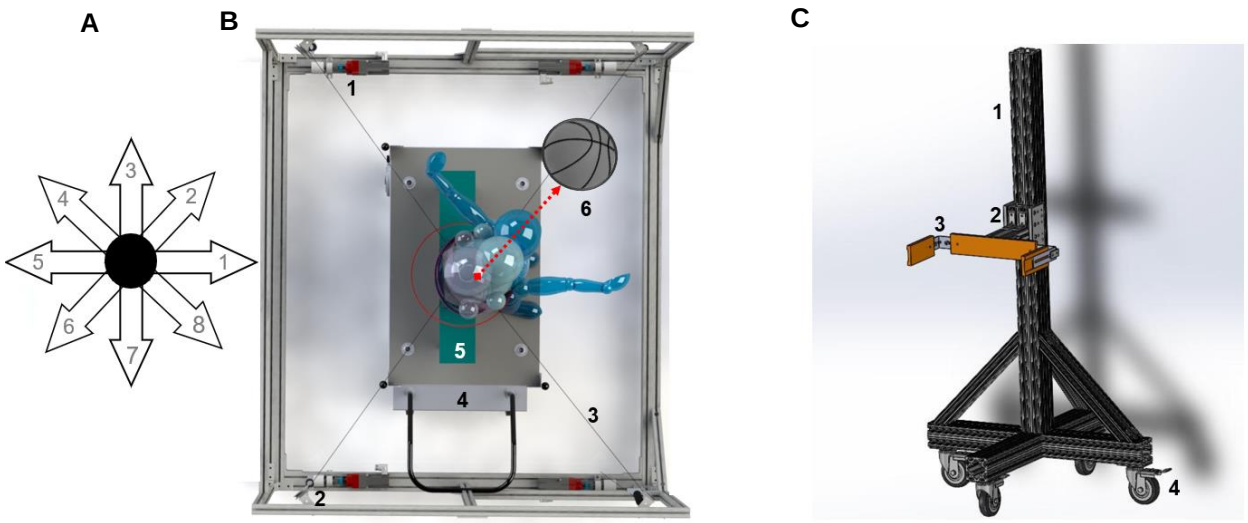
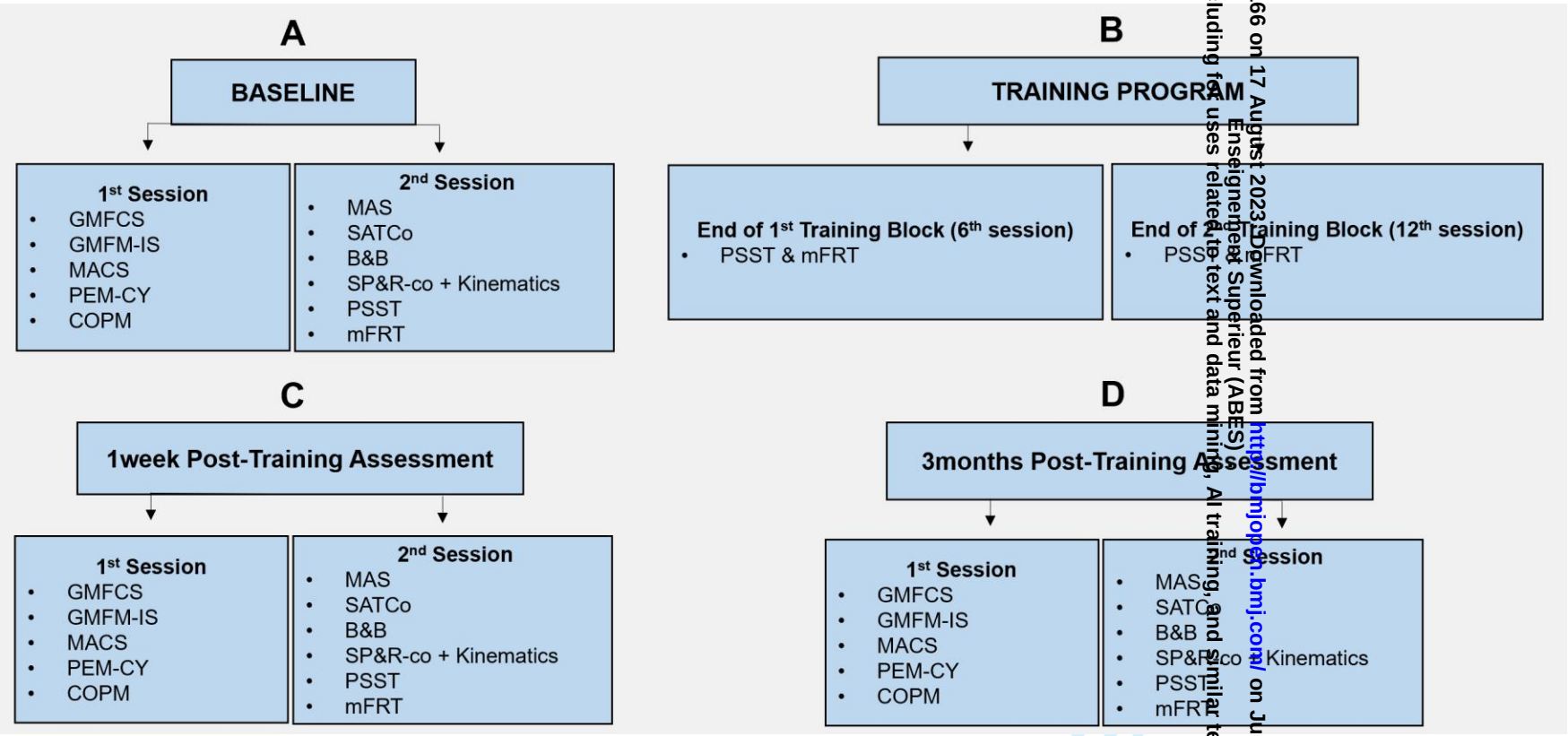


Figure 2



Study Title:

Study protocol for a randomized controlled trial to determine the efficacy of an intensive seated postural intervention delivered with robotic and rigid trunk support systems.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Manuscript Page (lines)
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p.1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Abstract (p.2, line 62-63) and p.5 (line173)
	2b	All items from the World Health Organization Trial Registration Data Set	Clinicaltrials.gov includes all WHO items.
Protocol version	3	Date and version identifier	Abstract (p.2, line 61-63)
Funding	4	Sources and types of financial, material, and other support	p.20 (lines 536-538)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	p.20 (lines 529-535)
	5b	Name and contact information for the trial sponsor	p.20 (line 536)

	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	p.20 (line 536)
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Some of the roles are N/A. An independent researcher will test training effectiveness (p.15 lines 349-354); Data management plan (p.18, lines 445-4459); Formal training/supervising plan of research personnel (p. 15, lines 339-346); and Data monitoring (p.15, lines 347-359)
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	p. 4 (lines 103-131)
	6b	Explanation for choice of comparators	p. 4 (lines 119-141)
Objectives	7	Specific objectives or hypotheses	p. 5 (lines 144-161)
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	p. 5 (lines 164-169)

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	p.6 (lines 211-216)
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Inclusion/Exclusion criteria p.6 (lines 180-195); Personnel delivering the intervention: table 1 and p.12-13 (lines 247-252);
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Tables 1-2, Figure 1, and p.7-14 (lines 217-291)
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	p.14 (lines 292-297)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	p. 16 (lines 348-349), p.5-6 (lines 171-179) and p.18 (lines 450-455)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	p.16 (lines 368-369).
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	p. 16-17 (lines 364-444)

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 2 and p. 5 (lines 165-169).
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	p.18 (lines 461-468)
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	p.5-6 (lines 176-179) and p.18 (lines 450-455)
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	p. 6 (lines 196-200)
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	p.6 (lines 200-205)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	p.6 (lines 199-200)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	p.6 (lines 206-210)
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	p.6 (lines 206-210)

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	p. 15 (lines 344-346) and p. 16-17 (lines 384-444).
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	p. 5 (lines 178-183); and p. 18 (lines 450-458).
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	p.18 (lines 446-449) and p. 19 (line 495).
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	p. 15 (lines 357-358); p.18 (lines 469-477)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	p.18-19 (lines 478-486)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	p.18-19 (lines 478-486)

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	p. 15 (lines 337-349)

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	p. 15 (lines 347-359)
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	p. 15 (lines 334-338) and p. 15 (line 355-359)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	p. 19 (lines 487-498)
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	p. 15 (line 355-359)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	p. 5-6 (lines 174-178)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	p. 16 (lines 370-371) and p. 18 (lines 446-449)
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	p. 20 (line 539)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	p. 19 (lines 499-503)

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	p. 15 (line 323-324)
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	p.19 (lines 499-503) and p. 20 (537-538)
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	p.19 (lines 499-503) and p. 20 (537-538)
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	See supplementary material
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.