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Study Protocol

# Study protocol: Responsiveness of postural control of children with and without a developmental coordination disorder after Transcranial Direct Current Stimulation

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**ABBREVIATIONS**

| | |
|---|---|
| AF | Assent form |
| AP | Antero-posterior displacement |
| COP | Center of pressure |
| DCD | Developmental coordination disorder |
| DCDQ | Developmental Coordination Disorder Questionnaire (Brazilian version) |
| DSM-5 | Diagnostic and Statistical Manual of Mental Disorders - 5th edition |
| FP | Force plataform |
| FpZ | Central forehead region |
| ICF | Informed consent form |
| MABC-2 | Movement Battery Assessment for Children (Second Edition) |
| ML | Medio-lateral displacement |
| M1 | Primary motor cortex |
| SOT | Sensory organization test |
| TD | Typical development |
| tDCS | Transcranial direct current stimulation |

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**BACKGROUND:** Developmental coordination disorder (DCD) is a neurodevelopmental disorder that affects around 5% of school-age children worldwide. DCD negatively impacts motor repertoire, quality of life, and overall health. One of the main motor impairments affecting activity and participation is poor postural balance. Although the neural basis of DCD is not yet clear, morphological and functional alterations have been found in children with DCD in crucial areas for postural control, such as the cerebellum and the primary motor cortex. Transcranial direct current stimulation (tDCS) is a noninvasive technique for inducing synaptic modulation, promoting neuromodulation that can help in understanding physiopathology and determining therapeutic strategies for people with DCD.
**AIM:** The proposed randomized clinical trial will verify the immediate effects of tDCS in the primary motor cortex and the cerebellum on postural balance in children with and without DCD.
**METHOD:** Fifteen children with DCD and 15 typically developing children will be randomized to receive a single session of anodal cerebellar tDCS, cathodal cerebellar tDCS, anodal primary motor cortex tDCS, or sham tDCS in a crossover design. Postural balance will be assessed by posturography with and without visual and somatosensory system manipulation immediately before and after each tDCS session.
**RESULTS AND INTERPRETATION:** This paper presents a detailed description protocol of a double-blind, placebo-controlled, crossover clinical trial. The results can bolster understanding of the postural control of children with DCD compared to children with typical development as well as knowledge about the possible effects of tDCS on the postural balance of such children.

**KEYWORDS**: Motor skills disorder | Neurodevelopmental disorders | Postural balance | Transcranial direct current stimulation | Child development

## INTRODUCTION

Developmental coordination disorder (DCD) is a neurodevelopmental disorder characterized by difficulties in acquiring and performing motor tasks [1]. DCD can occur in all cultures, ethnicities, and socioeconomic levels, with the most accepted prevalence estimated between 5% and 6% of school-age children worldwide [2,3]. The early motor development of children with DCD may be delayed, and movement execution may appear more clumsy, slow, varied, or less accurate than their peers [2,4]. Alterations in the acquisition and performance of age-related motor skills restrain the activity and participation of these children [5]. The impact on quality of life is even more significant, with psychological and social aspects also compromised [6,7].

The static balance of children with DCD is significantly impaired when visual, somesthetic, and vestibular afferents are manipulated, even if all these sensory modalities are available [8,9] during bipodal side-by-side support [10]. Impaired balance is more evident

in situations of greater sensorimotor demand when there is conflict or reduction in any sensory information [8,11].

Although sensorimotor integration has been investigated to understand altered postural control in children with DCD, discussion about the neural basis of this motor-control deficit is incipient. It is hypothesized that a poor ability to learn and perform motor skills is associated with a delay or dysfunction at the neuro-maturational level [12]. Some studies have pointed to the cerebellum as the core of DCD deficits [5,13], mainly due to the classic signs of uncoordinated and clumsy behavior and altered postural balance [14]. Cortical brain areas also seem to be involved in the etiology of DCD deficits. Children with DCD have impaired anticipatory postural adjustments, interfering in the production of coordinated movements secondary to poor neuromuscular timing [15], which results in slowing down task execution [16]. The primary motor cortex (M1) plays a crucial role in impaired anticipatory postural adjustments and voluntary motor control in DCD. In this context, neuromodulatory strategies targeting cerebellar and cortical motor areas may be useful for improving motor control deficits in children with DCD.

Transcranial direct current stimulation (tDCS) is a low-cost, easy-to-manipulate, noninvasive brain stimulation technique that induces regional changes in cortical excitability dependent on current electric intensity, time of application, and electrode montages. In general, stimulation by direct current through an anode increases cortical excitability, while cathodal stimulation decreases it [17,18], promoting a neural modulation [19]. The safe use of tDCS in children is well established, with the absence of significant adverse effects and good tolerance reported in both clinical trials [20] and computational models [21].

The tDCS technique has been proven to be a very effective tool in motor rehabilitation situations [22], with positive effects on the postural balance of children with spastic [23,24] and ataxic cerebral palsy [25]. In children with DCD, preliminary studies using the M1 [26] and cerebellar anodal tDCS [27] did not improve the learning or execution of fine motor tasks. Nevertheless, the hypothesis of the positive effects of the neuromodulation of the M1 and the cerebellum on postural balance had yet to be tested. Physiological responses to noninvasive neuromodulation in healthy children also had yet to be described. Analyzing the effect of different tDCS montages on static posture oscillation patterns will provide a better comprehension of the neural basis of the deficits of children with DCD, possibly revealing a new technique for the motor rehabilitation of these children.

The primary objective of this study will be to investigate the impact of brain facilitation/inhibition on postural balance in children with DCD and children with typical development (TD). Our secondary objective will be to investigate whether there are significant differences between primary motor cortex facilitation, cerebellar facilitation, and cerebellar inhibition in the postural balance of children with DCD or healthy controls. We hypothesized that tDCS would improve postural balance in children with DCD and those with TD. Comparing all the montages, anodal CE-tDCS may be the most effective way to reduce the sway rates of children with DCD, like that observed in ataxic children [25], based on studies that attributed DCD-children to cerebellar dysfunction.

## METHODS

### Study protocol

A randomized, double-blind, placebo-controlled crossover study will be conducted to evaluate the impact of brain electrical stimulation on postural balance and TD in children with DCD. This study was approved by the research ethics committee of the Faculty of Medicine of the University of São Paulo (CAAE: 39398214.4.0000.0065) and registered at clinicaltrials.gov (NCT03892083), entitled “The effect of tDCS on the postural control of children with DCD”.

Participants will be randomized to receive a single session of four different tDCS protocols: (1) cerebellar anodal stimulation (anodal tDCS-CE), (2) cerebellar cathodal stimulation (cathodal tDCS-CE), (3) M1 anodal stimulation (tDCS-M1), and (4) sham tDCS. Randomization of the sequence of tDCS sessions for all children will be performed by an independent researcher via a randomized generating program (www.randomization.com), using sequential numbers from 1 to 21 (21 children with DCD and 21 children with TD) and including them in sealed opaque envelopes. The “blinding” of the evaluator and the children will be maintained until the end of the research and data processing.

### Study Population, Recruitment, and Inclusion

Participants will be recruited from municipal schools and speech therapy and physiotherapy clinics at public universities in São Paulo, Brazil. Children who meet the following criteria will be eligible: (1) children of both sexes, aged between 7 years and 10 years 11 months, (2) children with indicative of DCD according to the Diagnostic and Statistical Manual of Mental Disorders - 5th edition (DSM -5), with percentile ≤ 5 both in total score as well as in balance domain of the MABC-2 [28,29] (DCD group), (3) by the score indicated for each age by the Developmental Coordination Disorder Questionnaire DCDQ-Brazil [30] or by reports of parents or teachers matching DSM-5 criterion B and (4) children without DCD, matched in age and gender, showing a percentile of ≥ 50 in the MABC-2 Motor Assessment Battery Balance total score and domain, without being indicative of DCD by the DCDQ-Brazil (TD group) or report of parents/teachers with no motor/coordination complaints.

Children will be excluded from the survey under the following conditions: (1) signs of excessive discomfort during or after any procedures or sessions involved in the research, (2) previous tDCS treatment, (3) visual or hearing impairments, heart disease, rheumatologic or orthopedic dysfunctions, neurological or psychiatric problems (except ADHD and language/speech disorders as the

most comorbid disorders with DCD), and (4) tDCS contraindications such as skin problems, the presence of metal plates on the head, or a history of epilepsy.

The sample size was estimated by the analysis of power [31] from our pilot study data involving four children with DCD. Mean differences between the effects of anodal and sham anodal cerebellar tDCS on the center of pressure (COP) oscillation area variable were incorporated into the G*power 3 software, with $\alpha < 0.05$ and a test power of 80%. The children performed the task of remaining in bipodal support, with eyes closed and feet over foam, when data of pre-tDCS was MD = 0.74 ± 5.31 and post-tDCS was MD = -3.85 ± 6.24. The effect size of 0.78 was calculated using the error probability of type 1 (α) and type 2 (β) (0.05, and 0.02, respectively). However, assuming a more conservative estimate of the effect size, we will consider 0.39 or 15% of the variance explained by the tDCS effect. According to the data from the sample calculation, a minimum of 21 children with DCD is required.

### Informed Consent Procedure

To participate in this study, a child has to consent in an assent form (AF) and be accepted by parents and/or guardians for participation by signing an informed consent form (ICF).

### Study Intervention

Both children's groups (DCD and TD) will receive a single session of four brain electrical stimulation protocols, with a minimum interval of seven days [32] and a maximum of 15 days between each intervention, to avoid the cumulative effect of tDCS and minimize the learning effect without interfering with a child's overall physiological development. In each session, the following sequence of procedures will take place: an initial posturography evaluation performed by two researchers; a tDCS session applied in a closed and quiet place by the lead researcher (M.C.D.S.M.), and finally, the child will return for a balance reevaluation (Figure 1).

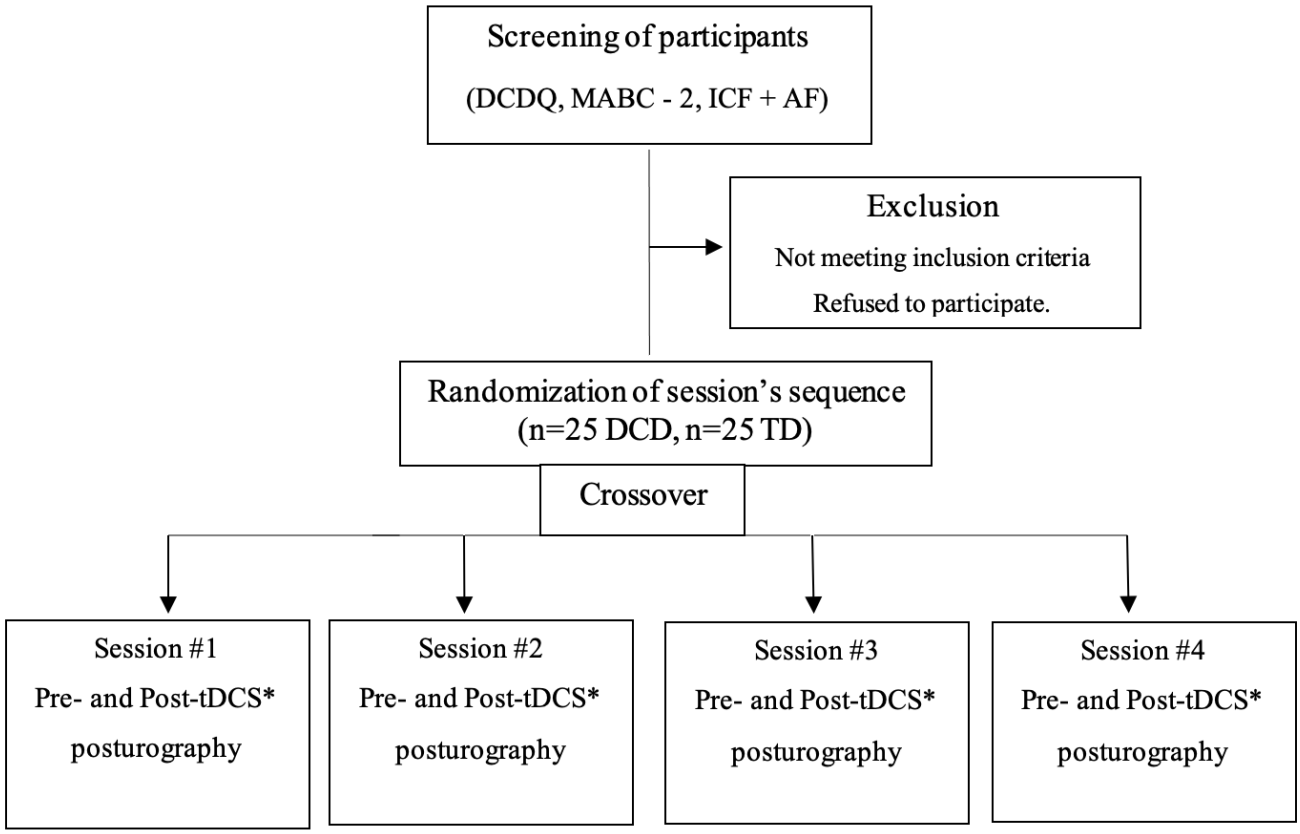


**Figure 1.** Flowchart of the study. DCDQ: Developmental coordination disorder questionnaire; MABC - 2: Movement battery assessment for children - Second Edition. AF: Assent Form, ICF: Informed Consent Form; DCD: Developmental coordination disorder; TD: Typical development; tDCS: Transcranial direct current stimulation. *tDCS intervention will be applied in a random order of the following protocols: tDCS-M1: anodal tDCS over the primary motor cortex; tDCS-CEa: anodal cerebellar tDCS; tDCS-CEc: cathodal cerebellar tDCS; sham tDCS.

### Postural Balance Assessment

The postural balance will be assessed on a force platform immediately before and after the tDCS (anodal tDCS-CE, cathodal tDCS-CE, tDCS-M1, or sham tDCS). The evaluation of static balance involved four conditions of progressive difficulty, triggered by the

manipulation of sensory afferences. The protocol was based on the sensory organization test (SOT) and has already been used in both healthy children [38] and children with DCD [11]. The protocol evaluates a participant's ability to maintain balance by manipulating sensory afferences. To avoid the effects of child fatigue due to the assessment before and after tDCS, we have chosen to manipulate only somatosensory and visual afferences, totaling four conditions.

A portable force platform (FP) (EMG System® - Brazil) will be used to collect body sway data represented by COP parameters. Data acquisition began with the subjects stable in a quiet bipedal posture on the FP. The subjects will be asked to remain barefoot, with their feet facing forward and in a comfortable position. This initial position will be marked on the paperboard and will be reused in all other conditions and sessions until the end of the protocol. Three 30-second repetitions will be acquired with subjects standing in the four test conditions described above, with the sequence always following the one with all available sensory afferences, to the most difficult condition. Thus, the child begins the evaluation of the fixed surface with eyes opened, followed by the fixed surface and eyes closed, the unstable surface and eyes opened, and the unstable surface and eyes closed. The closed eye condition will be ensured using EVA-covered children's swim goggles, and surface instability will be provided by a foam of density 26kg / $m^3$ and size of 50 cm X 50 cm.

During the tests, kinetic data will be acquired through FP output with two orthogonal COP components: medio-lateral displacement (ML) and antero-posterior displacement (AP) sway in centimeters (cm). Also, it will be considered for analysis the total COP displacement (cm), which is the distance travelled by the CoP during the 30-s trial; the mean velocity of COP displacement (cm/sec), and the displacement area ($cm^2$) of the COP. Three experimental trials of 30-s will be recorded, and the mean result will be used for analyses of each parameter.

### tDCS intervention

The tDCS procedure will be delivered by an electric stimulator (TCT Research Limited, Hong Kong, China) [33] and two sponges (nonmetallic) with electrodes measuring 5X7cm [25,34], humidified in saline solution 0.9%. Active electrode positioning will follow guidance according to the 10-20 International EEG System and will be fixed to the head with elastic bands. For anodal tDCS-CE, the anodal electrode will be placed over the central region of the cerebellum (1 cm below the inion), and the cathodal electrode will be placed over the central forehead region (FpZ), following the characteristic of montage described previously for balance outcomes with children [25].

During cathodal tDCS-CE, the electrodes will have the same location as anodal tDCS-CE, but with inverted polarities, with the cathode positioned 1 cm below the inion and the anode over the central supraorbital region. In the condition of primary motor cortex stimulation (tDCS-M1), the anode will be positioned centrally over the Cz, first described as ideal for reaching the lower limb area of the bilateral primary motor cortex [35], with the same area for the reference electrode of cerebellar stimulation (FpZ).

The applied current during the 20 minutes will gradually increase to 1 mA at the beginning of the session and will gradually decrease at the end of the session. For sham stimulation, the same procedures will be applied, but the stimulator remains switched on only for the first 30 seconds when the child experiences the initial sensation of current flow but without receiving electrical stimulation for the rest of the session. To counterbalance the sham condition location, half of the participants will experience the sham condition with the M1 montage and the other half with the cerebellar montage [36].

### Diagnostic Measures Participant Characteristics

The participants' characteristics will be collected through a non-structured interview. DCD and motor impairment will be assessed by the Brazilian version of the Developmental Coordination Disorder Questionnaire (DCDQ) and the Movement Battery Assessment for Children (MABC-2 - Second Edition).

*DCDQ*

The DCDQ is a specific parent questionnaire screening for DCD in children aged 5–15 years, which has been translated and adapted for Brazilian children [30]. It contains 15 items that evaluate a child's performance in different situations in daily life. The questions are divided into three groups: motor control during movement, fine/written motor skills, and general coordination. The questionnaire items were scored on a four-point scale, where the sum of each item resulted in the total score and varied according to age group. Scores below 47 at seven years old, below 56 at eight and nine years old, and 58 at ten years of age indicate children suspected of having DCD [37].

*Motor Impairment*

Motor impairment will be assessed through the Movement Battery Assessment for Children (MABC-2 - Second Edition) [29]. The MABC-2 is a British standardized test used to screen, identify, and describe motor performance impairment in children aged 3 to 16 years. Tasks are divided into three age ranges: 3 to 6 years and 11 months, 7 to 10 years and 11 months, and 11 to 16 years old. It includes eight gross and fine motor tasks, grouped into three categories: manual dexterity (three items), aiming and catching (two items), and balance (one static item and two dynamic items). The raw scores are converted to percentile, where a score ≤ the 5th percentile is indicative of DCD, a percentile between 6 and 15 signals risk/suspicion of DCD, and a percentile ≥16, normal motor performance.

### Adverse Effects

Participants will be instructed to respond for each session to a 4-point scale questionnaire about their perception of any of the adverse effects (headache, cervical pain, scalp pain, burning sensation, tingling sensation, redness, somnolence, concentration difficulty, or mood change). The intensity of each adverse effect score ranged from 1 (absent) to 4 (severe).

### Statistical Analysis and Data Management

The primary outcome will be considered in the COP area. Differences in body sway variables (COP anteroposterior, mediolateral, and total displacement; COP area; and COP anteroposterior and mediolateral velocity and frequency) in time (pre- and post-TDCS), and stimulation condition (anodal tDCS-M1, anodal tDCS-CE, cathodal tDCS-CE, and sham tDCS) will be analyzed by two-way analysis of variance with repeated measures (ANOVA 2 × 4). The sphericity of the data will be verified by a Mauchly´s sphericity test, which considers assumption values above 0.05. In the case of noncompliance, the Greenhouse-Geisser correction will be applied. Post hoc tests with Bonferroni corrections will be used as needed. Significance level will be considered $p < 0.05$. The analysis will be conducted using IBM SPSS v. 20 software for Windows.

Access to data will be limited to the principal investigators and through email registration. All data will be anonymized, added to an Excel worksheet, and transferred to SPSS software (v. 20). Missing data will be handled using the multiple imputation method.

After publication and communication, the data will be made available for free through a formal request. Due to journal rules, data may be added as supplements when possible.

## DISCUSSION

This paper presents a detailed description of a double-blind, placebo-controlled crossover clinical trial that compared the effects of tDCS facilitation/inhibition on postural balance control in children with DCD and with TD.

To our knowledge, this is the first study to verify the effect of tDCS on postural control in children with and without DCD. Studies on motor learning in children with TD have shown positive effects of tDCS [39,40], while in children with DCD, neither M1 stimulation [26] nor cerebellar anodal tDCS [27] has led to improvements in manual task performance.

Neuromodulation research in children is very incipient despite the large amount of evidence produced about adults. Understanding the effects of tDCS on the postural balance of TD children is essential to comprehend adequate motor control and to provide a basis for treatment protocols in different populations with motor impairments.

Modulating cerebral areas involved in the postural control of DCD and TD children may help better understand the impact each controller center (the cerebellum and the motor cortex) may have on the postural control of both populations. This would permit a better comprehension of how both groups differ in their responses to tDCS and assist in decision-making about the best rehabilitation programs for people with DCD. Investigating the different montages of tDCS over DCD children, could let clinics to know how the best area and condition could be used as an auxiliar intervention, helping improving postural balance and reducing the postural instability usually observed in this population.

Some limitations of this study lie in the characteristics of one session design protocol, evaluating only a short-term effect of each stimulating area, and limiting the analysis of the medium-long time effects described in clinical trials with multiple sessions. We believe that a single-session study should precede a study with 10 or more consecutive sessions to allow for verifying which area and condition would bring greater benefits to improving balance when stimulated. Future studies are planned to be developed to verify the real benefits of a tDCS intervention associated with longer motor training. Also, the study design included an initial assessment, tDCS stimulation, and a reassessment at the same moment via a long, tiring session. This did not permit us to include more assessments of clinical outcomes that should be considered in a multisession-design future study.

The results of this randomized controlled trial will be published in open-access, peer-reviewed scientific journals and presented at national and international meetings and conferences. We will leverage our patient and family relationships to maximize dissemination.

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