

# CEREBELLAR TRANSCRANIAL DIRECT CURRENT STIMULATION AND GAIT TRAINING IN CHILDREN WITH DOWN SYNDROME: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED CLINICAL TRIAL

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## ABSTRACT

The objective of this research project is to compare the effects of ten sessions of treadmill training combined with active cerebellar transcranial direct current stimulation (tDCSa) and placebo on the Activity (mobility and functional balance) and Participation domains of the ICF of children with Down syndrome (DS). This is a randomized, placebo-controlled, double-blind clinical trial involving 30 children diagnosed with DS, aged between 3 and 8 years, who meet the eligibility criteria. Participants will be assessed one week before, one week and one month after the end of the intervention, using the Timed Up and Go, 10-meter walk test, Pediatric Balance Scale, and Measure of Participation and Environment - Children and Youth. The experimental group will perform treadmill training combined with active cerebellar tDCSa application. The control group will perform treadmill training combined with placebo tDCS application. The speed of the gait training will be established according to the child's performance in each session. tDCS will be applied with the anode electrode positioned over the cerebellar region and the cathode electrode over the central supraorbital region. The intervention will consist of ten sessions, with a frequency of five sessions per week, conducted over two consecutive weeks, each lasting 20 minutes. Considering the potential effect of cerebellar tDCSa, it is expected that the intervention will enhance the effect size of treadmill training in children with DS.

**Keywords:** Down syndrome, gait, balance, child, physical therapy, transcranial direct current stimulation.

## Introduction

Down syndrome (DS) is a genetic condition characterized by a chromosomal abnormality caused by an extra copy of chromosome 21, which

leads to specific characteristics in those affected. It is recognized as the leading cause of cognitive impairment and is considered one of the most frequent numerical abnormalities of the autosomal chromosomes. In this population, we can observe a variety of deficits in the learning and development process, directly impacting selective motor control and compromising motor acquisition and functional independence (JAIN et al., 2022; KARIMI; NELSON, 2023; KIM et al., 2017).

In relation to movement, and especially walking, children with DS have difficulty with motor coordination. Neuropsychomotor developmental delay present from birth and reduced cerebellar volume cause children to develop compensatory patterns and strategies, including impairments in movement timing and adaptation to movement changes, postural and balance deficits, co-contraction of agonist and antagonist muscles, spinal abnormalities, and joint instability, especially in the hip, knee, and ankle (KAMIŃSKA et al., 2023; VALENTÍN-GUDIOL et al., 2017).

Improvements in gait and postural control are considered fundamental therapeutic goals for the rehabilitation of children with DS. Physical activity programs can contribute to achieving these goals, in addition to promoting a better lifestyle and delaying the development of diseases related to age and a sedentary lifestyle (KAMIŃSKA et al., 2023; VALENTÍN-GUDIOL et al., 2017).

Properly performed treadmill training results in improved functional mobility, static and dynamic balance, gross motor functions, physical conditioning, and gait pattern. These results are related to treadmill training providing practice of a specific task, with multiple repetitions of walking steps, facilitating motor learning due to repetitive practice of this function, thereby stimulating the processing and responses of the central nervous system (KAMIŃSKA et al., 2023; VALENTÍN-GUDIOL et al., 2017)

Transcranial direct current stimulation (tDCS) has been known to induce lasting changes in cortical excitability. Cortical modulation is dependent on the polarity of the applied current. tDCS allows two types of stimulation: anodic current, which increases cortical excitability, favoring neuronal membrane depolarization, or cathodic current, where the stimulus has an inhibitory effect

due to neuronal membrane hyperpolarization (FREGNI et al., 2021; THIBAUT et al., 2013).

Considering the prospect of optimizing the effect size of treadmill training, and given the complexity and intensity of DS's negative impact on neuropsychomotor development, understanding the effects of tDCS in this population appears promising. As it is considered a safe, inexpensive, and easy-to-apply resource, tDCS may contribute positively to the rehabilitation of children with DS, if it is scientifically demonstrated that its neurophysiological effects are capable of promoting the improvement of learning new motor strategies that result in improved performance in activities (mobility and functional balance) and participation.

The study hypothesis is that ten sessions of treadmill training combined with anodal tDCS on the cerebellum will result in clinically relevant effects on the Activity (mobility and functional balance) and Participation domains of the International Classification of Functioning, Disability, and Health (ICF) in children with DS.

Thus, the objective of the project is to compare the effects of ten sessions of treadmill training combined with active anodal tDCS on the cerebellum and placebo on the Activity domain (functional mobility and functional balance) and the Participation domain of the ICF in children with Down syndrome.

## **Methodology**

This is a randomized, placebo-controlled, double-blind clinical trial involving 30 children diagnosed with DS, aged between three and eight years, who meet the eligibility criteria.

Participants will be assessed one week before, one week and one month after the end of the intervention. The assessment will consist of measuring functional mobility (*Timed Up and Go* and 10-meter walk test), functional balance (Pediatric Balance Scale) and social participation (Measure of Participation and Environment - Children and Youth).

The experimental group will perform treadmill training after active tDCS application on the cerebellum. The control group will perform treadmill training after placebo tDCS application on the cerebellum. The speed of the treadmill training will be established according to the child's performance in each session. tDCS will be applied to the cerebellum at an intensity of 1mA (GRECCO et al., 2015). The intervention will involve ten intervention sessions, with a frequency of five sessions per week, carried out over two consecutive weeks and lasting 40 minutes each (20 minutes of tDCS and 20 minutes of treadmill training). The results will be analyzed statistically.

### **Expected results**

Considering the potential effect of anodal tDCS on the cerebellum, it is expected that the intervention will increase the effect size of gait training in children with DS, in addition to optimizing the effects of neurofunctional training on the ICF Activity and Participation domain, with only ten intervention sessions. The therapeutic approach studied may represent a paradigm shift in the neurofunctional rehabilitation of children with DS through an effective, low-cost, and short-term intervention.

### **Conclusion**

The research project schedule involves the start of recruitment and assessment procedures in October 2024. The results obtained will be analyzed and presented in scientific articles.

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