NEUROMODULATION OF THE PRIMARY MOTOR CORTEX BY RTMS AND TREADMILL TRAINING IN CHILDREN WITH SPASTIC CEREBRAL PALSY: A RANDOMIZED, DOUBLE-BLIND, CONTROLLED CLINICAL TRIAL

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ABSTRACT

The objective of this study is to compare the effects of ten sessions of treadmill training performed after 20 minutes of rTMS application on the active primary motor cortex and placebo in the domain of Activity (walking, functional mobility, functional balance, and gross motor function) and Participation of the ICF in children with spastic CP. This is a randomized, placebo-controlled, double-blind clinical trial involving 34 children diagnosed with spastic CP. Participants will be assessed one week before, one week and one month after the end of the intervention using the Modified Ashworth Scale, Tardieu Scale, Muscle Strength Assessment, motor evoked potential, Timed Up and Go, Walk Test, Berg Balance Scale, Gross Motor Function Measurement, and Participation and Environment Measure - Children and Youth. The experimental group will perform gait training on a treadmill after active rTMS application to the primary motor cortex, and the control group will perform gait training after placebo rTMS application. 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 rTMS and 20 minutes of treadmill training). Considering the potential effect of rTMS on the primary motor cortex, the intervention is expected to increase the effect size of gait training in children with CP.

Keywords: cerebral palsy, gait, balance, child, physical therapy, transcranial magnetic stimulation.

INTRODUCTION

Cerebral palsy (CP) is a developmental disorder that affects neurological processes related to movement control and the execution of gross motor functions, such as walking (JACKMAN et al., 2022; ROSENBAUM et al., 2007).

Treadmill training is recognized as an effective physical therapy intervention for promoting functional mobility improvement in children with CP (JACKMAN et al., 2022).

Repetitive transcranial magnetic stimulation (rTMS) is proving to be an effective therapeutic tool for optimizing motor training outcomes. Its

neurophysiological effects are triggered by the use of electrical fields, generated non-invasively in the brain, to increase the excitability/activity of key brain regions that contribute to relevant neurological processes (ROSSI et al., 2021).

Currently, rTMS is increasingly used in the rehabilitation of children with CP, proving to be a safe method with significant therapeutic potential in this population. It is an intervention that can provide promising results on gross motor functions and brain function by modulating developmental plasticity (NARDONE et al., 2021).

In addition, the International Classification of Functioning, Disability, and Health (ICF) is a biopsychosocial model that focuses on interactions between body functions and structures, activities and participation, and contextual factors. Health researchers use the ICF model to report their research results and guide professionals in selecting outcome measures and planning specific interventions for their patients (DOS SANTOS et al., 2012; FRANKI et al., 2012). The literature presents limitations in studies that use this model to report the effectiveness of rTMS-based interventions. Likewise, most clinical trials present results of interventions on the Activity domain.

Participation can be considered under-explored to date. Considering that treadmill training improves corticospinal tract function and that rTMS, through its neurophysiological effects on the primary motor cortex, also results in increased activation of this important structure of the central nervous system, the study hypothesis is that when treadmill training is performed after rTMS, the excitation promoted by transcranial stimulation will result in an increase in the effect size obtained by gait training in the Activity and Participation domains of the ICF.

Thus, the objective of the project is to compare the effects of ten sessions of treadmill training performed after 20 minutes of rTMS application on the active primary motor cortex and placebo in the domains of Activity (walking, functional mobility, functional balance, and gross motor function) and Participation of the ICF in children with spastic CP.

METHODOLOGY

This is a randomized, placebo-controlled, double-blind clinical trial involving 34 children diagnosed with spastic CP, aged between six and twelve 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 Modified Ashworth Scale, Tardieu Scale, Muscle Strength Assessment, motor evoked potential, *Timed Up and Go*, *Walk Test*, Berg Balance Scale, Gross Motor Function Measurement, and Participation and Environment Measure - Children and Youth.

The experimental group will perform treadmill training after active rTMS application to the primary motor cortex. The control group will perform treadmill training after placebo rTMS application to the primary motor cortex. The speed of the treadmill training will be established according to the child's performance in each session. rTMS will be applied with the coil properly positioned over the primary motor cortex at a frequency of 5Hz. 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 rTMS and 20 minutes of treadmill training). The results will be analyzed statistically.

EXPECTED RESULTS

Considering the potential effect of rTMS on the primary motor cortex, it is expected that the intervention will increase the effect size of gait training in children with CP, in addition to optimizing the effects of neurofunctional training on the ICF Activity and Participation domains, with only ten intervention sessions. The therapeutic approach studied may represent a paradigm shift in the neurofunctional rehabilitation of children with CP 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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