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

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SUMMARY

The objective of the study project is to compare the effects of ten sessions of treadmill gait training conducted after 20 minutes of rTMS application on the primary motor cortex, both active and placebo, in the domain of Activity (gait, 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. The participants will be evaluated one week before, one week after, 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 Measure, and Participation and Environment Measure - Children and Youth. The experimental group will perform treadmill gait training after the application of active rTMS on the primary motor cortex, and the control group after the application of placebo rTMS. The intervention will involve ten intervention sessions, with a frequency of five sessions per week, conducted over two consecutive weeks and lasting 40 minutes each (20 minutes of rTMS and 20 minutes of treadmill gait training). Considering the potential effect of rTMS on the primary motor cortex, it is expected that the intervention will enhance the effect size of gait training in children with CP.

Keywords: Cerebral palsy; gait; balance; child; physiotherapy; transcranial magnetic stimulation.

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Introduction

Cerebral Palsy (CP) is a motor development disorder, with impairments in the 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 gait training is recognized as an effective physiotherapeutic intervention for promoting the improvement of functional mobility in children with CP (JACKMAN et al., 2022).

Repetitive transcranial magnetic stimulation (rTMS) is proving to be an effective therapeutic tool for optimizing the results of motor training. Its neurophysiological effects are triggered through the use of electric fields, generated non-invasively in the brain, to durably increase the excitability/activity of key brain regions that contribute to relevant neurological processes (ROSSI et al., 2021).

Currently, rTMS is being increasingly used in the rehabilitation of children with CP, demonstrating 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, modulating developmental plasticity (NARDONE et al., 2021).

Moreover, 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-related researchers use the ICF model to report their research findings 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 in the domain of Activity.

Participation can be considered underexplored so far. Considering that treadmill gait training results in an improvement in the function of the corticospinal tract and that

rTMS, through its neurophysiological effects on the primary motor cortex, will also lead to increased activation of this important structure of the central nervous system, the hypothesis of the study is that performing treadmill gait training after rTMS, the excitation promoted by transcranial stimulation will result in an increase in the magnitude of the effect obtained by gait training in the domains of Activity and Participation of the ICF.

Thus, the objective of the project is to compare the effects of ten sessions of treadmill gait training conducted after 20 minutes of rTMS application on the primary motor cortex, both active and placebo, in the domains of Activity (gait, 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.

The participants will be evaluated 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 Measure, and the Participation and Environment Measure for Children and Youth.

The experimental group will perform treadmill gait training after the application of active rTMS on the primary motor cortex. The control group will perform treadmill gait training after the application of placebo rTMS on the primary motor cortex. The speed of the gait training will be set 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 gait 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, as well as optimize the effects of neurofunctional training on the Activity and Participation domains of the ICF, with just ten intervention sessions. The therapeutic approach studied could represent a paradigm shift in the neurofunctional rehabilitation of children with CP, through an effective, low-cost, and short-duration intervention.

Conclusion

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

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