

EVALUATING THE IMPACT OF TRANSCRANIAL DIRECT CURRENT STIMULATION COMBINED WITH MIRROR THERAPY ON MOTOR AND MENTAL DEVELOPMENT IN CHILDREN WITH SPASTIC QUADRIPELEGIC CEREBRAL PALSY: A RANDOMIZED CLINICAL TRIAL PROTOCOL

Original Research

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ABSTRACT

Background: Cerebral palsy (CP) is a non-progressive neurological disorder resulting from damage to the immature brain, often leading to significant delays in motor and cognitive development. Spastic quadriplegic CP represents one of the most severe forms, involving all four limbs and the trunk. Despite advances in rehabilitation, effective interventions remain limited. Emerging techniques such as transcranial direct current stimulation (tDCS) and mirror therapy (MT) have shown potential in promoting neuroplasticity and enhancing neuromuscular function in pediatric neurorehabilitation.

Objective: This study aims to evaluate and compare the individual and combined effects of tDCS and MT on motor development and mental health in children with spastic quadriplegic CP, under the framework of neuroplastic adaptation.

Methods: *Design:* A single-center, double-blinded, randomized clinical trial.

Setting: Department of Physical Therapy and Rehabilitation, Ghurki Trust and Teaching Hospital, Lahore, Pakistan.

Participants: A total of 105 children aged 3–7 years, diagnosed with spastic quadriplegic CP, will be recruited using simple random sampling. Participants will be allocated equally into three groups (n=35 each):

- **Group A:** tDCS + MT + Routine Physical Therapy (RPT)
- **Group B:** MT + RPT
- **Group C:** tDCS + RPT

Interventions: Group-specific interventions will be delivered five times per week over two weeks (10 sessions of tDCS and/or MT).

RPT will continue throughout the 10-week study period.

Outcome Measures: The primary outcomes include motor development (Shoaib Sensorimotor Development Tool), motor control (Fugl-Meyer Assessment), muscle performance (isokinetic dynamometer), anthropometric measures (height, weight, and head circumference), mental health (Strengths and Difficulties Questionnaire) and Dopamine level (Plasma Lab Test). Data will be collected at baseline, after two weeks, and at the tenth-week post-intervention.

Trial Registration: This trial has been prospectively registered on the Iranian Registry of Clinical Trials under registration number IRCT20231227060542N1, dated January 26, 2024.

Ethics and Dissemination: Ethical approval was obtained from the Research Ethics Committee (REC), Faculty of Allied Health Sciences, The University of Lahore under reference number REC-UOL-185-12-2023, dated December 20, 2023. Informed consent will be obtained from all participants' legal guardians. Study findings will be disseminated through publication in peer-reviewed journals and presentations at national and international conferences to inform clinical practice in pediatric rehabilitation.

Keywords: Cerebral Palsy, Cognitive Development, Mirror Therapy, Motor Skills Disorders, Neuromodulation, Transcranial Direct Current Stimulation.

INTRODUCTION

Cerebral palsy (CP) is a non-progressive neurodevelopmental disorder resulting from early brain injury or malformation, commonly leading to impairments in movement, posture, sensation, perception, communication, and behavior. Among the various subtypes, spastic quadriplegic CP represents one of the most severe forms, affecting all four limbs and the trunk due to motor cortex involvement (1). Its manifestations include spasticity, poor motor coordination, abnormal reflexes, and delayed or impaired developmental milestones. These children often struggle with fine and gross motor skills, leading to functional limitations in everyday tasks such as walking, eating, speaking, and self-care (2,3). The prevalence of CP varies globally, estimated at approximately 2 per 1000 live births in most countries (4,5), though regional variations exist—such as a higher rate reported in India (6) and a lower rate in Pakistan's Khyber Pakhtunkhwa province (7). Risk factors contributing to the development of CP span prenatal, perinatal, and postnatal events, including hypoxic-ischemic injury, neonatal seizures, respiratory distress, and delivery complications such as cesarean or breech presentation (8). The resultant neuromuscular deficits manifest as abnormal tone, poor balance and coordination, muscular weakness, and persistent primitive reflexes, all contributing to a compromised functional capacity (9). Furthermore, children with CP often experience delays in mental development and face challenges in learning, social interactions, and emotional regulation. Anthropometric indicators such as reduced height, weight, and head circumference are also commonly observed, highlighting compromised physical growth and neurological development (10-12).

Traditional rehabilitation approaches for CP include physical therapy interventions such as bimanual training, constraint-induced movement therapy, reflex-inhibiting patterns, and goal-directed functional training (13). While effective, these interventions often rely on peripheral stimulation and are limited by the extent of motor dysfunction in severely affected individuals. To enhance therapeutic outcomes, modern strategies have introduced central nervous system stimulation techniques such as transcranial direct current stimulation (tDCS), which modulates cortical excitability and facilitates neuroplasticity. tDCS is a non-invasive, affordable, and user-friendly neuromodulatory intervention that applies low-intensity electrical currents to targeted brain regions to enhance motor learning and functional recovery in neurological conditions, including CP and stroke (12, 14). Mirror therapy, another innovative technique, utilizes the brain's mirror neuron system by engaging visual feedback to stimulate motor cortex activity. Initially designed for hemiplegic children, it has demonstrated promising outcomes in children with quadriplegia as well, promoting both unilateral and bilateral motor recovery (14, 15). When combined, tDCS and mirror therapy potentially offer a dual mechanism—direct cortical stimulation and peripheral visual-motor engagement—to maximize neuroplastic adaptation and motor improvement.

The theoretical underpinnings of both techniques are rooted in the concept of neuroplasticity—the brain's ability to reorganize itself functionally and structurally in response to training or injury. While tDCS represents a top-down approach influencing cortical excitability, mirror therapy serves as a bottom-up mechanism enhancing motor recovery through sensory-motor integration (12, 15). Despite the individual efficacy of these modalities, limited evidence exists regarding their combined application in spastic quadriplegic CP, especially in terms of both motor and mental development. Furthermore, the literature lacks robust clinical trials exploring the synergistic effects of tDCS and mirror therapy within this population, particularly in resource-limited settings such as Pakistan (16-18). Considering these gaps, this randomized clinical trial protocol is designed to evaluate the combined impact of transcranial direct current stimulation and mirror therapy on neuromuscular and mental development in children with spastic quadriplegic CP. Specifically, the study aims to: (1) determine the combined effects of tDCS and mirror therapy on neuromuscular development, mental health, and dopamine; (2) compare the individual and combined efficacies of these interventions; (3) assess the standalone effect of tDCS; and (4) assess the standalone effect of mirror therapy in this pediatric population (19-22).

METHODS

Trial Design

This study is designed as a single-center, double-blinded, randomized clinical trial with a parallel group allocation model. The study follows the Consolidated Standards of Reporting Trials (CONSORT) guidelines and has been prospectively registered in the Iranian Registry of Clinical Trials under reference number IRCT20231227060542N1, dated January 26, 2024. Participants will be randomly assigned to one of three groups receiving either transcranial direct current stimulation (tDCS), mirror therapy (MT), or a combination of both, along with routine physical therapy.

Study Setting

The study is being conducted at the Department of Physical Therapy and Rehabilitation, Ghurki Trust and Teaching Hospital, Lahore, Pakistan. This facility provides specialized pediatric neurorehabilitation services and houses trained staff and equipment necessary for delivering all study interventions and assessments. A dedicated therapy room with ambient lighting and a soundproof environment is used for intervention sessions to ensure patient comfort and adherence.

Eligibility Criteria

Children aged between 3 to 7 years of either gender, clinically diagnosed with spastic quadriplegic cerebral palsy through physical examination, will be included in the study (6). Eligible participants must have Gross Motor Function Classification System (GMFCS) levels I to III, with a Modified Ashworth Scale tone ≤ 2 (23-26), and cognitive ability to follow instructions or use augmentative communication (27). Participants not currently receiving treatment at the study center but applying spontaneously will also be considered. Exclusion criteria include patients with athetoid, ataxic, or mixed CP types, as well as monoplegic, diplegic, or hemiplegic presentations. Additionally, children with a history of neurosurgery or neurolytic block in the last six months, orthopedic deformities, integumentary issues, cancer, skull metal implants, or those using hearing aids will be excluded (6, 24).

Interventions

All participants will receive routine physical therapy, while the three groups will additionally receive:

Group A – Transcranial Direct Current Stimulation (tDCS): Participants will be seated in a CP chair with proper postural alignment following the 90-90-90 rule (28). Using the international 10–20 EEG system, the anodal electrode will be placed over the primary motor cortex (M1) and the cathodal electrode over the contralateral supraorbital area. The stimulation will alternate for the right and left extremities using a wireless Segal Stim SG-2023004 device with saline-soaked sponge electrodes (6, 29–31). Sessions will last 30 minutes (15 minutes per side), conducted five times per week for two weeks (10 sessions total) at an intensity of 2 mA (24).

Group B – Mirror Therapy (MT): The participant will perform limb-specific motor activities in front of a mirror measuring 35x35 cm, observing the reflected movement of their active extremity while the contralateral limb is hidden behind the mirror (27). Exercises include wrist/finger flexion-extension, pronation/supination, elbow movement (upper limbs), ball rolling, rocker board, and pedaling exercises (lower limbs) (32, 33). Each session will last 30 minutes (15 minutes per side), five times per week for two weeks (10 sessions total). Each movement will be repeated 20 times across 10 sets with 2-minute rest intervals, incorporating visual feedback after each set to enhance engagement and performance (34).

Group C – Combination Therapy: Participants will receive both tDCS and MT in the same session as per the protocols described above.

Routine Physical Therapy for All Groups: Each session includes 10 minutes of goal-directed functional training and 10 minutes of reflex inhibitory pattern exercises. These continue five days per week for the full 10-week duration of the study. The goal-directed component focuses on enhancing muscle performance and control through task-specific activities, while the reflex inhibitory component targets the modulation of exaggerated or diminished reflexes, such as the Moro, rooting, and tonic neck reflexes, thereby supporting improved neuromotor development.

Outcomes

Primary outcomes include motor development, muscle performance, motor control, anthropometry (height, weight, head circumference), mental health, and dopamine level.

- **Motor development** is measured by the Shoaib Sensorimotor Development Tool (SSDT), integrating domains like gross and fine motor skills, social interaction, balance, reflexes, and tone, with a high-reliability coefficient of 0.977.
- **Motor control** will be assessed using the Fugl-Meyer Assessment (FMA) for the upper and lower extremities with internal consistencies of 0.86 and 0.935 respectively (35–38).
- **Muscle performance** is evaluated using an isokinetic dynamometer, with a reliability of 0.94 (39-41).
- **Anthropometric measurements** will be recorded using reliable tools: stadiometer for height (0.998), measuring tape for head circumference (0.99), and calibrated scale for weight (0.99) (42–44).
- **Mental health** will be assessed using the Strengths and Difficulties Questionnaire (SDQ), with a reliability of 0.80 (45, 46).
- **Dopamine level** will be assessed by a plasma lab test.

Assessments will be conducted at three-time points: baseline (Pre-I), after 2 weeks (Post-I), and after 10 weeks (Post-II).

Participant Timeline

Recruitment commenced in January 2024 and will continue through mid-2025. Interventions will last two weeks, with additional follow-up therapy continuing until week 10. Assessments will be conducted at baseline, 2 weeks, and 10 weeks. The timeline aligns with clinical observations that neurodevelopmental and psychological improvements typically manifest between weeks 2 and 12 in rehabilitation settings.

Sample Size

Based on pilot data from 10 participants per group, the sample size was calculated using OpenEpi. Group I had a mean (SD) of 19 (6.93), while Group II had 23.87 (6.17), providing 80% power at a 95% confidence interval (23). A minimum of 29 participants per group was needed. After accounting for a 20% potential dropout rate, each group will enroll 35 participants, totaling 105 (23).

Randomization

Participants will be randomly allocated to one of three groups using a computer-generated random sequence. Allocation concealment will be ensured using sealed, opaque envelopes opened only after enrollment. Simple random sampling will be applied to maintain equal allocation probability.

Blinding

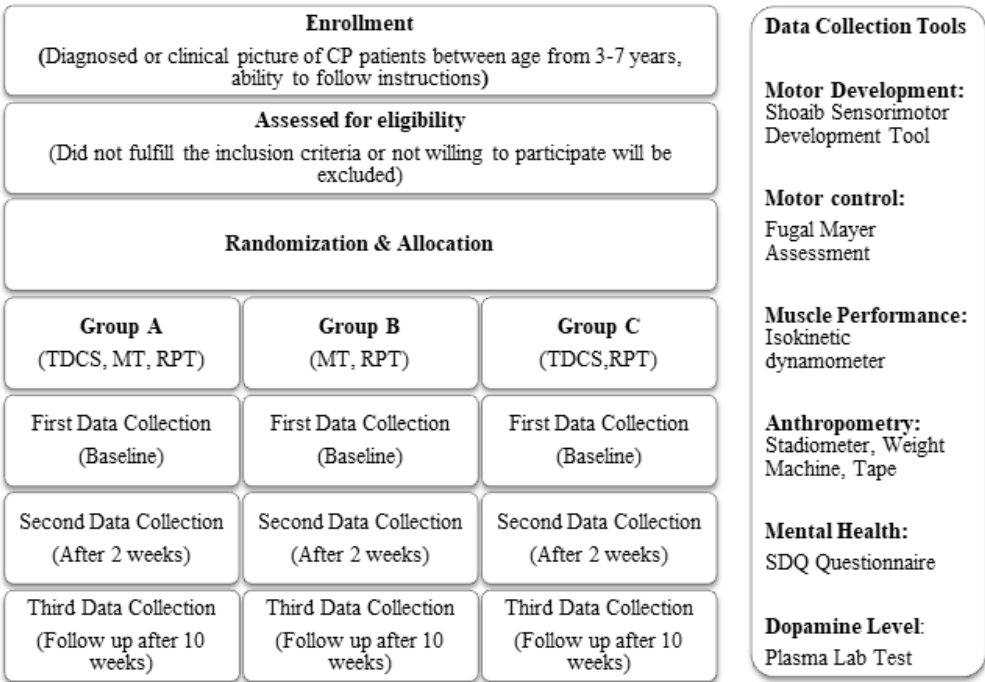
This is a double-blinded trial. Participants and the outcome assessors will remain blinded to group allocations. Group codes will be anonymized and linked to participant IDs via a master sheet maintained by an independent third party. This ensures unbiased data collection, analysis, and reporting.

Data Collection Methods

Data will be gathered using standardized clinical tools and measurement instruments described in the outcomes section. All assessors will be trained in data collection procedures to minimize inter-rater variability. Data will be stored securely, and confidentiality will be maintained. Participants will be informed of their right to withdraw at any time without penalty.

Statistical Methods

All data will be analyzed using SPSS version 26. Descriptive statistics and visual graphs will be used to assess completeness and variability. The normality of data distribution will be tested using the Shapiro-Wilk or Kolmogorov-Smirnov tests. If data are normally distributed, parametric tests such as ANOVA and linear regression will be used. For non-normal data, non-parametric tests like Kruskal-Wallis and Spearman correlation will be applied. A *p*-value <0.05 will be considered statistically significant. Analyses will include adjustments for demographic and clinical confounders, and an intention-to-treat approach will be followed, retaining outcome data from participants who discontinue intervention mid-study.



ETHICS AND DISSEMINATION

Ethical Approval

This clinical trial protocol received ethical approval from the Research Ethics Committee (REC), Faculty of Allied Health Sciences, The University of Lahore, under reference number REC-UOL-185-12-2023, dated December 20, 2023. The study was designed by the Declaration of Helsinki and national ethical guidelines, ensuring the protection of participants' rights, safety, and well-being throughout the research process.

Informed Consent

Before participation, written informed consent will be obtained from the legal guardians of all children enrolled in the study. The consent process will include a detailed explanation of the study's purpose, procedures, benefits, risks, and the voluntary nature of participation. Participants will also be informed of their right to withdraw from the study at any point without any penalty or impact on their clinical care. All personal data will be handled with strict confidentiality and stored securely in password-protected systems accessible only to authorized personnel.

Dissemination Plans

The results of this study will be disseminated through multiple channels to ensure a broad academic and clinical impact. Findings will be submitted for publication in peer-reviewed national and international journals. Additionally, results will be presented at regional and global conferences focused on pediatric neurology, rehabilitation, and physical therapy. The research team also plans to share summarized findings with participating institutions and families involved in the study to contribute to awareness and evidence-based clinical practice in cerebral palsy management.

TRIAL STATUS

Recruitment for this clinical trial commenced in January 2024 and is projected to continue until June 2025, or until the required sample size is achieved. Data collection and intervention phases will occur concurrently during this period. This document reflects Protocol Version 1.0, finalized and approved on December 20, 2023. Any subsequent amendments to the protocol will be submitted for ethical review and updated in the clinical trial registry accordingly.

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