

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of trans-cranial direct current stimulation with and without mirror therapy on neuromuscular development and mental health in children with spastic quadriplegic cerebral palsy

Protocol summary

Study aim

To determine the combined effects of trans-cranial direct current stimulation and mirror therapy on neuromuscular development and mental health in children with spastic quadriplegic CP

Design

Single centered double blinded Randomized clinical trial

Settings and conduct

Study setting will be Department of Physical Therapy and Rehabilitation, Ghurki Trust & Teaching Hospital, Lahore. A 30-minute session of TDCS will be administered, with 15 minutes dedicated to the upper extremity and 15 minutes to the lower extremity. The overall duration of mirror therapy will be 30 minutes: 15 minutes for the upper extremity and 15 minutes for the lower extremity. There will be a total of 10 sessions (5 times a week for 2 weeks), both for TDCS and mirror therapy treatment. While undergoing routine physical therapy five days a week for 30 minutes each from the beginning of treatment to the completion of the treatment that is follow-up (weeks 1-10). The outcome measures will be taken at baseline (Pre-I), after two weeks (Post-I), and again after ten weeks of standard of care physical therapy treatment (Post-II) which is routine physical therapy.

Participants/Inclusion and exclusion criteria

inclusion Criteria Diagnosed patients of spastic quadriplegic CP via physical examination aged from 3-7 years from both genders having Level-I, II & III GMFCS who can walk with or without assistance, respectively Tone less than or equal to 2 on the modified Ashworth scale Exclusion criteria: Athetoid CP, ataxic and mixed variety, Monoplegia, diplegic hemiplegic CP patients or History of any neurosurgery or neurolytic block

Intervention groups

Group-A (TDCS, MT with routine Physical Therapy) Group-B (TDCS with routine Physical Therapy) Group-C (MT with

routine Physical Therapy)

Main outcome variables

Motor Development & Control, Muscle performance, Anthropometry (Height, Weight, Circumference), Mental Health

General information

Reason for update

Acronym

TDCS, MT, CP

IRCT registration information

IRCT registration number: **IRCT20231227060542N1**

Registration date: **2024-01-26, 1402/11/06**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-26, 1402/11/06**

Update count: **0**

Registration date

2024-01-26, 1402/11/06

Registrant information

Name

Shoaib Waqas

Name of organization / entity

The University of Lahore

Country

Pakistan

Phone

+92 302 4552109

Email address

drshoaibwaqas@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-08, 1402/10/18

Expected recruitment end date

2024-10-31, 1403/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of trans-cranial direct current stimulation with and without mirror therapy on neuromuscular development and mental health in children with spastic quadriplegic cerebral palsy

Public title

To determine the combined effects of trans-cranial direct current stimulation and mirror therapy on neuromuscular development and mental health in children with spastic quadriplegic cerebral palsy.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosed patients of spastic quadriplegic cerebral palsy via physical examination aged from 3-7 years from both genders , Level-I and II patients on the Gross Motor Function Classification System (GMFCS) who can walk with or without assistance, respectively , Tone less than or equal to 2 on the modified Ashworth scale Having good understanding for the commands

Exclusion criteria:

Athetoid cerebral palsy, ataxic an mixed variety will be excluded• Monoplegia, diplegic hemiplegic cerebral palsy patients will be excluded• History of any neurosurgery or neurolytic block (botulinum toxin and phenol) in the previous 6 months or any cancerous history or orthopedic deformity Any integumentary condition, seizure history or metal implant especially in the skull or use of hearing aids

Age

From **3 years** old to **7 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling technique will be simple random sampling and allocation to different groups will be via random number table. Subjects will be evaluated for eligibility before allocation to one of three groups: Group-A (TDCS, MT with routine Physical Therapy), Group-B (TDCS with routine Physical Therapy) and Group-C (MT with routine Physical Therapy)

Blinding (investigator's opinion)

Double blinded

Blinding description

participant and Outcome assessor was blinded

Placebo

Not used

Assignment

Parallel

Other design features

Nil

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee (REC)

Street address

The University of Lahore, Bhobhatian Chowk

City

Lahore

Postal code

55150

Approval date

2023-10-05, 1402/07/13

Ethics committee reference number

REC-UOL-626-12-2023

Health conditions studied**1****Description of health condition studied**

Cerebral Palsy

ICD-10 code

G80.0

ICD-10 code description

Spastic quadriplegic cerebral palsy

Primary outcomes**1****Description**

Motor development, Motor control, muscle performance, anthropometry, mental health

Timepoint

Before treatment, after two weeks and after 10 weeks

Method of measurement

Shoaib motor development tool, Fugal Mayer, isokinetic Dynamometer, Tape, stadiometer and weight machine, SDQ questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

before treatment, after 6months

Method of measurement

SF-36

Intervention groups

1

Description

Subjects will be evaluated for eligibility before allocation to one of three groups: Group-A (TDCS, MT with routine Physical Therapy), Group-B (TDCS with routine Physical Therapy) and Group-C (MT with routine Physical Therapy). Group A, which is the experimental group, will be treated for a 30-minute session of TDCS, with 15 minutes dedicated to the upper extremity at a 1 mA intensity and 15 minutes to the lower extremity at a 2 mA intensity in a comfortable seated position (Radwan et al., 2023) with routine physical therapy five days a week for 30 minutes each from the beginning of treatment to the completion of the treatment that is follow-up (weeks 1-10).

Category

Rehabilitation

2

Description

Group B, which is also a treatment group included in mirror therapy, will be 30 minutes: 15 minutes for the upper extremity and 15 minutes for the lower extremity. There will be a total of 10 sessions (5 times a week for 2 weeks), both for TDCS and mirror therapy treatment with routine physical therapy five days a week for 30 minutes each, from the beginning of treatment to the completion of the treatment that is follow-up (weeks 1-10).

Category

Rehabilitation

3

Description

Control group: Combinations of goal-directed functional training and reflex inhibitory patterns will be used under the umbrella of routine Physical Therapy. Goal-directed functional training, focusing on rehabilitation to help CP children perform functional activities and tasks for better quality of life, independence, and overall well-being that may have been compromised due to their neurological condition. Whatever the functional level of the patient in terms of motor development (gross motor, fine motor, communication, social interaction, and balance), muscle performance and control will be targeted, and activities will be planned as per the patient's capability and strength. Reflex inhibitory patterns are a set of neurological responses that help control and regulate reflex actions in the body, which are automatic, involuntary responses to stimuli in nature. They play a

crucial role in protecting the body, feeding, initiating movement, and maintaining balance. In CP children, either reflexes are diminished or exaggerated, like the Moro and protective extension reflex (protective reflexes), rooting and sucking reflex (feeding reflexes), symmetrical tonic neck reflex, asymmetrical tonic neck reflex, tonic labyrinthine reflex (postural reflex), equilibrium reactions, head of body, body on head, or body on body reactions (righting reactions). For integration or inhibition of these reflexes, repeated stimuli and special postures will be adapted for better neuromuscular development.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Physical Therapy & Rehabilitation
Ghurki Trust & Teaching Hospital, Lahore

Full name of responsible person

Shoaib Waqas

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

nil

Full name of responsible person

Research Ethics Committee (REC)

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Nil

Proportion provided by this source

1

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

The University of Lahore

Full name of responsible person

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Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Other areas of specialty/work

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Latest degree

Master

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

EFFECTS OF TRANSCRANIAL DIRECT CURRENT STIMULATION WITH AND WITHOUT MIRROR THERAPY ON NEUROMUSCULAR DEVELOPMENT AND MENTAL HEALTH IN CHILDREN WITH SPASTIC QUADRIPLLEGIC CP

When the data will become available and for how long

After Analysis till the publication of my work

To whom data/document is available

drshoaibwaqas@gmail.com

Under which criteria data/document could be used

Confidential

From where data/document is obtainable

Department of Physical Therapy And Rehabilitation GTTH Lahore

What processes are involved for a request to access data/document

