Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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The University of Lahore
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Pakistan
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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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The University of Lahore, Bhobhatian Chowk
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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
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Ashfaq Ahmad
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Professor
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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 QUADRIPLEGIC 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

Simply Do an Email

Comments