

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Studying the effect of 10 sessions of transcranial direct current stimulation before and after visual mirror feedback treatment on upper limb motor function in children with spastic hemiplegic cerebral palsy

Protocol summary

Study aim

Investigating the effect of of transcranial direct current stimulation before and after mirror visual feedback treatment on motor function of the upper limb in children with spastic hemiplegia cerebral palsy

Design

The present study, with a within-group and between-group, and double-blind design, will randomly assign 18 subjects to three groups.

Settings and conduct

This study will be conducted in a medical clinic under the supervision of a neurologist. After selecting subjects and familiarizing them with the research process, each subject will be randomly assigned to one of three groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with SHCP based on a neurologist's diagnosis, age range 6 to 12 years, having levels 1 and 2 of the Manual Ability Classification System (MACS), cognitive, verbal, and visual abilities, and being able to sit unsupervised. Exclusion criteria: having experience with this type of intervention, having a history of seizures, having untreated attention deficit hyperactivity disorder, having genetic, metabolic, or degenerative psychiatric diseases, and diseases such as epilepsy and cardiorespiratory diseases, visual and sleep disorders, severe pain in the affected limb, using medications that affect the central nervous system, having any type of metal implant in the brain

Intervention groups

The present study is an experimental study in which subjects will be randomly assigned to two experimental groups and a control group. In the control group, MVF treatment and sham brain stimulation will be performed. In experimental group 1, brain stimulation will be applied first and then MVF (tDCS offlin-pre), but in experimental group 2, MVF will be applied first and then brain stimulation (tDCS-offlin-post)

Main outcome variables

Motor function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230728058946N2**

Registration date: **2025-10-17, 1404/07/25**

Registration timing: **prospective**

Last update: **2025-10-17, 1404/07/25**

Update count: **0**

Registration date

2025-10-17, 1404/07/25

Registrant information

Name

Pegah Farzamfar

Name of organization / entity

The university of Razi

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2025-11-22, 1404/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of 10 sessions of transcranial direct current stimulation before and after visual mirror feedback treatment on upper limb motor function in children with spastic hemiplegic cerebral palsy

Public title

Transcranial direct current stimulation before and after visual mirror feedback treatment on upper limb motor function in children with spastic hemiplegic cerebral palsy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Children with SHCP based on neurologist diagnosis 6 to 12 years Possessing Level 1 and 2 of the Manual Ability Classification System (MACS), cognitive, verbal, and visual abilities Being able to sit unsupervised

Exclusion criteria:

Having experience in receiving this type of intervention Having a history of seizures Having untreated attention deficit hyperactivity disorder Having genetic, metabolic or degenerative psychiatric diseases and diseases such as epilepsy and cardiorespiratory, visual and sleep disorders, severe pain in the affected limb Use of medications that affect the central nervous system Having any metal implant in the brain

AgeFrom **6 years** old to **12 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **18****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, the block randomization method was used through the website www.randomization.com. For this purpose, each subject was first assigned a number as a unique identification code and an 18-digit sequence (equal to the sample size) was created. Then, the names of the intervention groups were defined in the relevant section of the website, including: Experimental Group 1, first brain stimulation and then MVF (tDCS offlin-pre), Experimental Group 2, first MVF and then brain stimulation (tDCS-offlin-post), and the control group (sham stimulation group with MVF). After defining the groups and in order to prevent potential problems caused by blocking with fixed-size blocks, the method of randomly selecting blocks of different sizes was used for

blocking. In this case, since the sample size was known, the block sizes were unequal and a multiple of the number of intervention groups (for example, blocks of 2, 4, 6, or 8). The website has the ability to randomly create sequences of blocks of different sizes. In the final step, by executing the Plan Generate command on the website, all subjects were randomly assigned to blocks of different sizes that themselves had a random sequence. Finally, by using the number (code) assigned to each subject and examining the blocks, the group of each subject was determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, the researcher and participants will be blinded to the type of transcranial electrical stimulation used in each session. In the present study, the Neurostim stimulator will be used to induce direct current electrical stimulation. For this purpose, a person outside the research team will be responsible for applying electrical stimulation in the experimental sessions. In order to blind the participants, after they sit on a special chair, the brain electrical stimulation device is hidden from their sight and is completely covered by a cover, and the electrodes will be placed on the desired areas by the test taker. In order to blind the researcher, the researcher also leaves the laboratory before applying the intervention and returns to the testing site after the stimulation period has elapsed, the electrodes are removed, and the stimulator is turned off. Also, in the sham stimulation mode, according to standard protocols, an active current is induced on the head for 30 seconds to induce a sensation similar to the active stimulation mode, and then the current is interrupted and the stimulation is deactivated.

Placebo

Used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Razi University Research Ethics Committee

Street address

Taq Bostan, University St., Razi University

City

kermanshah

Province

Kermanshah

Postal code

6714414971

Approval date

2025-09-22, 1404/06/31

Ethics committee reference number

IR.RAZI.REC.1404.029

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

The participants are children with spastic hemiplegic cerebral palsy

ICD-10 code

G80.2

ICD-10 code description

Spastic hemiplegic cerebral palsy

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

Fine finger dexterity

Timepoint

Before the start of the intervention (pre-test), after the fifth session of the intervention (mid-test), after the end of the 10th intervention session (post-test), and two weeks later (recall).

Method of measurement

Purdue Pegboard Test

2**Description**

Eye-hand coordination

Timepoint

Before the start of the intervention (pre-test), after the fifth session of the intervention (mid-test), after the end of the 10th intervention session (post-test), and two weeks later (recall).

Method of measurement

Beery's Visual-Motor Integration Test

3**Description**

Gross hand movements

Timepoint

Before the start of the intervention (pre-test), after the fifth session of the intervention (mid-test), after the end of the 10th intervention session (post-test), and two weeks later (recall).

Method of measurement

Box and Block Test

4**Description**

Grip strength

Timepoint

Before the start of the intervention (pre-test), after the fifth session of the intervention (mid-test), after the end of the 10th intervention session (post-test), and two weeks later (recall).

Method of measurement

Digital dynamometer device

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Experimental group 1 (first brain stimulation and then mirror visual feedback (tDCS offline-pre))

Category

Other

2**Description**

Intervention group: Experimental group 2 (first mirror visual feedback, then brain stimulation (tDCS-offlin-post))

Category

Other

3**Description**

Control group: Placebo group (first sham stimulation then mirror visual feedback)

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mustafa Seddiqi Clinic

Full name of responsible person

mostafa sedighi

Street address

Shir Khorshid Crossroads. Opposite Mohammad Kermanshahi Hospital. Khorshid Building.

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Sedighi-mostafa@yahoo.com

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

razi university

Full name of responsible person

vorya tahmasbi

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Faculty of Sport Sciences**City**

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Grant nameVice Chancellor for Research and Technology, Razi
University**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

razi university

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

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

Academic

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

razi university

Full name of responsible person

pegah farzamfar

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Sports Medicine

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after de-identifying the subjects.

When the data will become available and for how**long**

6 months after results are published

To whom data/document is available

Researchers

Under which criteria data/document could be used

For meta-analytical research

From where data/document is obtainable

If you need to receive documentation, please send an email to Pegah Farzamfar, research researcher, at the email address: pfarzam76@yahoo.com.

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

Upon formal request, stating the relevant reasons and providing full details, the data will be sent via email after 72 hours.

Comments