

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 83 3845 8428

##### Email address

pfarzam76@yahoo.com

##### 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

**Age**

From **6 years** old to **12 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target 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](http://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-offline-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.

**City**

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**Province**

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6714734439

**Phone**

+98 903 250 7110

**Email**

Sedighi-mostafa@yahoo.com

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

**Name of organization / entity**

razi university

**Full name of responsible person**

vorya tahmasbi

**Street address**Taghebstan, Daneshgah Street, Razi University,  
Faculty of Sport Sciences**City**

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**Province**

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**Email**

worya2626@gmail.com

**Grant name**Vice 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

**Street address**Taghebstan, Daneshgah Street, Razi University,  
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**Province**

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

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**Full name of responsible person**

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

razi university

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**Latest degree**

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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**