# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jul 2026

## Investigating the effect of transcranial direct current stimulation before and during mirror visual feedback on the sensory and motor performance of the upper limb in children with spastic hemiplegia cerebral palsy

## Protocol summary

**Study aim**

Investigating the effect of transcranial direct current stimulation before and during mirror visual feedback on the Sensory and Motor performance upper limb in Children with spastic hemipelgia cerebral palsy

**Design**

In the present study, with within-subjects design, counterbalanced and double-blind design, 12 subjects will be randomly exposed to four different conditions.

**Settings and conduct**

This research will be done in Medical clinic under the supervision of a neurologist. After selecting the subjects and familiarizing themselves with the research process, each subject will be exposed to four different conditions of electrical stimulation of the brain with a random combination.The principal investigator and subjects will not be aware of the type of stimulation received in each session.

**Participants/Inclusion and exclusion criteria**

Criteria for entering the research: Children with SHCP based on neurologist diagnosis،Having levels 1 and 2 of manual ability classification system (MACS), cognitive and verbal abilities،Being able to sit unsupervised،Having normal or corrected vision.Criteria for not entering the research: Having the experience of this training program،Having a history of seizures، severe pain in the affected limb، Using drugs that affect the central nervous system، Having any kind of metal implant in the brain

**Intervention groups**

This study is an intra-group and counterbalanced study in which the subjects are exposed to four different conditions of brain stimulation including: 1) sham stimulation before mirror visual feedback; 2) sham stimulation during mirror visual feedback; 3) Anodal stimulation before mirror visual feedback, 4) Anodal stimulation during mirror visual feedback will be placed.

**Main outcome variables**

Sensory and Motor performance

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20230728058946N1**
Registration date: **2023-11-09, 1402/08/18**
Registration timing: **prospective**

Last update: **2023-11-09, 1402/08/18**
Update count: **0**

**Registration date**

2023-11-09, 1402/08/18

**Registrant information**

**Name**

Pegah Farzamfar

**Name of organization / entity**

The university of Razi

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-11-21, 1402/08/30

**Expected recruitment end date**

2023-12-01, 1402/09/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

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

**Public title**

Transcranial direct current stimulation before and during mirror visual feedback on the Sensory and Motor performance upper limb

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Children with SHCP based on neurologist diagnosis Having levels 1 and 2 of manual ability classification system (MACS), cognitive and verbal abilities Being able to sit unsupervised Having normal or corrected vision

**Exclusion criteria:**

Having the experience of this training program Having a history of seizures Having untreated attention deficit hyperactivity disorder suffering from genetic psychiatric diseases,Metabolic and diseases such as epilepsy and cardio-respiratory, vision and sleep disorders, severe pain in the affected limb Using drugs that affect the central nervous system Having any kind of 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: **12**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, in order to randomize the order of subject exposure to four different conditions (4 different types of electrical stimulation of the brain), the Latin square method will be used. For this purpose, first, using the website www.random.org, each subject will be randomly assigned a number between 1 and 12 as an identification code. Then, the English letters A, B, C, D are assigned to four intervention conditions and a Latin square will be created with four rows and four columns. After creating the Latin square, participants number 1 to 3 in the sequence of the first row, participants 4 to 6 in the sequence of the second row, participants 7 to 9 in the sequence of the third row and participants 10 to 12 in the sequence of the fourth row will be placed.

**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 and the location of stimulation in each session. In the present study, the Neurostim stimulation device was used to induce direct current electrical stimulation in four separate sessions and four different modes including: 1) sham stimulation before mirror visual feedback; 2) sham stimulation during mirror visual feedback; 3) Anodal stimulation before mirror visual feedback, 4) Anodal stimulation during mirror visual feedback will be used. For this purpose, a person outside the research team will be responsible for applying electrical stimulation in four experimental sessions. In order to blind the participants, after they sit on a special chair, the electrical stimulation device of the brain is hidden from their sight and covered by a cover completely, and the electrodes will be placed on the desired areas by the examiner. In order to blind the researcher, before the intervention, the researcher leaves the laboratory and returns to the test site after the stimulation period has passed and the electrodes are removed and the stimulation device is turned off. Also, in the sham stimulation mode, according to standard protocols, the active current is induced on the head for 30 seconds to induce the same sensation as the active stimulation mode, and then the current is cut off and the stimulation is deactivated.

**Placebo**

Used

**Assignment**

Crossover

**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**

2023-07-17, 1402/04/26

**Ethics committee reference number**

IR.RAZI.REC.1402.049

## Health conditions studied

**1**

**Description of health condition studied**
The participants are spastic hemiplegic cerebral palsy children.
**ICD-10 code**
G80.2
**ICD-10 code description**
Spastic hemiplegic cerebral palsy

## Primary outcomes

**1**

**Description**
Fine Finger Dexterity
**Timepoint**
before the beginning of the intervention and after the end of the intervention in each session
**Method of measurement**
Purdue Pegboard Test

**2**

**Description**
Hand-eye coordination
**Timepoint**
before the beginning of the intervention and after the end of the intervention in each session
**Method of measurement**
Frostig's Advanced Perceptual-Visual Test

**3**

**Description**
Range of motion of wrist and elbow joints
**Timepoint**
before the beginning of the intervention and after the end of the intervention in each session
**Method of measurement**
goniometer

**4**

**Description**
gross hand movements
**Timepoint**
before the beginning of the intervention and after the end of the intervention in each session
**Method of measurement**
Box and Block Test

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group 1: Before mirror visual feedback, they will receive 20 minutes of anodal stimulation at 2 mA intensity. In order to stimulate, the Neurostim stimulation device manufactured by Medina Teb Company will be used. The target area in the brain is identified using the 10-20 international brain mapping system and stimulation is performed using special stimulation electrodes and a special electroencephalogram cap.
**Category**
Treatment - Devices

**2**

**Description**
Intervention group 2: During mirror visual feedback, they will receive 20 minutes of anodal stimulation at 2 mA intensity. In order to stimulate, the Neurostim stimulation device manufactured by Medina Teb Company will be used. The target area in the brain is identified using the 10-20 international brain mapping system and stimulation is performed using special stimulation electrodes and a special electroencephalogram cap.
**Category**
Treatment - Devices

**3**

**Description**
Intervention group 3: Before mirror visual feedback, they will receive 20 minutes of sham (control) stimulation at 2 mA intensity. In order to stimulate, the Neurostim stimulation device manufactured by Medina Teb Company will be used. The target area in the brain is identified using the 10-20 international brain mapping system and stimulation is performed using special stimulation electrodes and a special electroencephalogram cap.
**Category**
Placebo

**4**

**Description**
Intervention group 4: During mirror visual feedback, they will receive 20 minutes of sham (control) stimulation at 2 mA intensity. In order to stimulate, the Neurostim stimulation device manufactured by Medina Teb Company will be used. The target area in the brain is identified using the 10-20 international brain mapping system and stimulation is performed using special stimulation electrodes and a special electroencephalogram cap.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Clinic Mostafa Sedighi
**Full name of responsible person**
Mostafa Sedighi
**Street address**

Shir Khursheed Crossroads. In front of Mohammad Kermanshahi Hospital. Khurshid 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**
Farzaneh Gandomi

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**Email**
gandomif@razi.ac.ir

**Grant name**
Deputy of Research and Technology of 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**
Master

**Other areas of specialty/work**
Sport Medicine

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**
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## Person responsible for updating data

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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 subjects.

**When the data will become available and for how long**
6 months after printing the results

**To whom data/document is available**
Researchers

**Under which criteria data/document could be used**
For meta-analytic research

**From where data/document is obtainable**
If you need to receive documents, email Pegah Farzamfar, the main investigator, with the email address: pfarzam76@yahoo.com.

**What processes are involved for a request to access data/document**
In case of an official request, stating the relevant reasons and mentioning the complete details, the data will be sent via email after 72 hours.

**Comments**