

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

Sensory and Motor performance

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 hemiplegia 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

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

Country

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University

Full name of responsible person

Farzaneh Gandomi

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Taqbestan, University St., Razi University, Faculty of Sports Sciences

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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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Position

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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