Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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
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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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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