Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Name of organization / entity
The university of Razi

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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
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. 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
razi university
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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
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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