

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of Transcranial Directed Current Stimulation on upper limb function in children with unilateral cerebral palsy

Protocol summary

Study aim

Determining the effect of transcranial direct electrical stimulation technique on upper limb function of children with hemiplegic cerebral palsy

Design

Randomized clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients, lottery was used for randomization.

Settings and conduct

This study is conducted in the occupational therapy clinics of Karaj city. This study is a double-blind study in which the evaluator, the participants, and the statistician are unaware of the grouping. At first, preliminary tests are taken from all the samples by the evaluator. . Then the intervention sessions in such a way that one group called the control group did routine occupational therapy exercises for forty-five minutes in each session and the other group called the intervention group did occupational therapy exercises for forty-five minutes along with the technique of transcranial direct electrical stimulation of the area. An initial movement with a current intensity of 1.5-2 mV for twenty minutes in each session and for twenty sessions is started by the researcher and at the end the initial tests are taken again by the evaluator and then analyzed.

Participants/Inclusion and exclusion criteria

Subjects must have a diagnosis of hemiplegic cerebral palsy at the age of 5-10 years, have no unstable medical conditions such as seizures, and receive no other adjuvant treatment during the intervention.

Intervention groups

The intervention group receives 20 sessions of routine occupational therapy exercises for 45 minutes along with 20 minutes of electrical stimulation, and routine occupational therapy exercises are performed for 45 minutes in control group

Main outcome variables

motor function of the upper limb, dexterity of the upper limb, coordination of the upper limb-speed of the upper

limb

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220725055552N1**

Registration date: **2022-07-27, 1401/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-27, 1401/05/05**

Update count: **0**

Registration date

2022-07-27, 1401/05/05

Registrant information

Name

Behnam Ghaderian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3224 7828

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behnamgh7491@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-26, 1401/05/04

Expected recruitment end date

2022-08-01, 1401/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The effect of Transcranial Directed Current Stimulation on upper limb function in children with unilateral cerebral palsy
Public title	The effect of electrical stimulation in the treatment of upper limbs of cerebral palsy
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	The person must be a hemiplegic cerebral palsy The person must be 5-10 years old The person without unstable medical conditions such as seizures
Exclusion criteria:	Failure to attend more than one meeting. Non-cooperation of children and their families until the end of the regular study period
Age	From 5 years old to 10 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Outcome assessor • Data analyser
Sample size	Target sample size: 50
Randomization (investigator's opinion)	Randomized
Randomization description	To select the sample, we refer to Tanin and Nikan Karaj clinics, and fifty people will be sampled according to the conditions of inclusion in the study, but the samples will be divided into two intervention and control groups in a simple randomization using the coin toss method. In this way, we consider one of the groups to be the lion and the other group to be the line, and based on the desired sample size, the same number of coins are tossed.
Blinding (investigator's opinion)	Double blinded
Blinding description	The evaluator, the participants and the statistician are unaware of the grouping, and also to blind the participants, devices and electrodes are placed for both groups, but stimulation is not done for the control group.
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Damavand street

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-05-15, 1401/02/25

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.061

Health conditions studied

1

Description of health condition studied

Hemiplegia cerebral palsy

ICD-10 code

G80.2

ICD-10 code description

Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description

Motor function of the upper limb

Timepoint

At the beginning of the intervention and after the end of the intervention

Method of measurement

Fugl-Meyer test

Secondary outcomes

1

Description

Upper limb coordination

Timepoint

The beginning and end of the intervention

Method of measurement

Bruininks-Oseretsky test

2

Description

Upper limb Integration

Timepoint

The beginning and end of the intervention

Method of measurement

Bruininks-Oseretsky test

3

Description

Precision of fine movement

Timepoint

The beginning and end of the intervention

Method of measurement

Bruininks-Oseretsky test

4

Description

Upper extremity speed

Timepoint

The beginning and end of the intervention

Method of measurement

Box and block test

5

Description

Dexterity of Upper extremity

Timepoint

The beginning and end of the intervention

Method of measurement

Bruininks-Oseretsky test

Intervention groups

1

Description

This group performed routine occupational therapy exercises for 45 minutes along with transcranial direct electrical stimulation technique, in which a low direct electric current with an intensity of 1.5-2 mV is injected into the primary motor area of the healthy hemisphere with a tDCS device. They receive for twenty minutes in each session and for twenty sessions in a period of one month.

Category

Rehabilitation

2

Description

Control group: This group receives routine occupational therapy exercises for forty-five minutes in each session and twenty sessions in a one-month period, and also to blind the participant, an electrical stimulation device is placed on the primary motor area of the healthy hemisphere for twenty minutes in each session. It can be done, but the stimulation does not take place.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikan Karaj Occupational Therapy Clinic

Full name of responsible person

Amir Abbas Parnoun

Street address

Republic Square, Amirkabir St

City

karaj

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3133654689

Phone

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2

Recruitment center

Name of recruitment center

Tanin Karaj Occupational Therapy Center

Full name of responsible person

Hirash ghaderian

Street address

Haft Tir Street, Ghasemi Street

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hirashybg87@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehdi Rezai

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rehabilitation.sbmu@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

no

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Behnam Ghaderian

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

Street address

Seventh Floor, Haft Tir Crossroad, the beginning of Student Blvd., in front of the police station clinic, Ghasemi Alley, Arad Doctors Building, 7th floor

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Other areas of specialty/work

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Person responsible for updating data

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Position

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available