

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Email address

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

##### Province

Alborz

##### Postal code

3133654689

##### Phone

+98 26 3421 7494

##### Email

amirabas5465@gmail.com

### 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

##### City

Kasraj

##### Province

Alborz

##### Postal code

3133654689

##### Phone

+98 26 3271 5709

##### Email

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

##### Street address

Damavand street

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 7754 2057

##### Email

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

**City**

Karaj

**Province**

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**Postal code**

3133654689

**Phone**

+98 26 3271 5709

**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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**Email**

behnamgh7491@gmail.com

**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