

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Evaluating the efficiency of transcranial direct current stimulation on hand motor function in healthy individuals.

Protocol summary

Study aim

Determining the level of hand function in the intervention group (transcranial direct current stimulation) before and after the study. Determining the level of hand function in the control group (sham transcranial direct current stimulation) before and after the study

Design

In this randomized controlled clinical trial study (double-blind), 54 samples of healthy individuals aged 45-20 years will be assigned. The researcher will use the Randomization Allocation Software for randomization.

Settings and conduct

The volunteers will be assigned to intervention and control groups through given numbers 0001 to 0054. The placement of the electrodes, the intervention time, the session intervals, and the sensation caused by the stimulation, which is in the form of itching or burning in the stimulated area will be the same in the two intervention and control groups. The statistical analyser will be unaware of how the candidates are grouped. (two-way blinded). The study is carried out in the physical medicine and rehabilitation department of the AJA University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy individuals aged 45-20 years who are willing to participate in the study and consent to the study objectives. exclusion criteria: Severe, persistent migraine headaches; chronic skin problems; metal plates on the head; use of stimulators or implants; history of epilepsy or head trauma; not tolerating the adverse effects of tDCS.

Intervention groups

The intervention group includes 27 individuals with stimulation protocol (anodal) transcranial stimulation with direct current on the primary non-dominant motor cortex (M1) in 20-minute sessions. The volunteers will participate in 5 consequent sessions in three weekly sessions. In this case, the cathode is placed on the

supraorbital area of the opposite side.

Main outcome variables

hand grip hand dexterity

General information

Reason for update

Acronym

tDCS

IRCT registration information

IRCT registration number: **IRCT20221106056413N2**

Registration date: **2023-06-12, 1402/03/22**

Registration timing: **prospective**

Last update: **2023-06-12, 1402/03/22**

Update count: **0**

Registration date

2023-06-12, 1402/03/22

Registrant information

Name

Tayebeh Sadat Salehi Rihani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficiency of transcranial direct current stimulation on hand motor function in healthy individuals.

Public title

Effects of direct current stimulation on hand function.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy individuals in the age range of 20-45 years

Exclusion criteria:

persistent and severe migraine headaches. Chronic skin problems. presence of metal plates on the head. the use of any stimulators or implants. history of epilepsy or serious or recent head trauma. any musculoskeletal or nerve disease affecting the hand function.

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible candidates to enter the study were assigned by random allocation using block randomization method. The recruited individuals were randomly assigned to one of the two groups of (intervention with tDCS) and a control group (sham tDCS), which will use block randomization with different block sizes. The size of the blocks will be a multiple of 2 and a divisor of 54 (2, 4, and 6). Initially, the block sizes are chosen randomly. Then for each block, different permutations are randomly determined by the Randomization Allocation Software. In each block, the number of people in the groups is equal, and blinding is used to not reveal the permutations in the last people of each block.

Blinding (investigator's opinion)

Double blinded

Blinding description

A direct current stimulator (Neurostim2., Medina Teb, Iran) was used to deliver anodal tDCS in accordance with the current safety limitations with the same protocol and a stimulation intensity of 1-2 mA based on the volunteers tolerance. The volunteers will be assigned to the intervention and control groups through given numbers

0001 to 0054. Also, the placement of the electrodes, the intervention time, the session intervals, and the sensation caused by the stimulation, which is in the form of itching or burning in the stimulated area (the device will not stimulate muscle twitching), will be the same in the two intervention and control groups. In this study, the person who will perform the statistical analysis will be unaware of how the candidates are grouped. (two-way blinded)

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Department of Physical & Rehabilitation Medicine, Faghihi Hospital, Zand Street

City

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Province

Tehran

Postal code

7134846114

Approval date

2023-06-10, 1402/03/20

Ethics committee reference number

IR.SUMS.MED.REC.1402.092

Health conditions studied**1****Description of health condition studied**

Hand function

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Hand grip

Timepoint

Before the intervention and at the end of the intervention.

Method of measurement

dynamometer

Secondary outcomes

1

Description

Hand dexterity

Timepoint

Before and after the intervention.

Method of measurement

Purdue Pegboard test

Intervention groups

1

Description

Intervention group: The intervention group includes 27 people with stimulation protocol (anodal) transcranial stimulation with direct current on the non-dominant primary motor cortex in 20-minute sessions, 5 sessions, three sessions per week for volunteers. In this case, the cathode will be placed on the (M1) supraorbital area of the opposite side. Each session includes 20 minutes of transcranial direct current stimulation. Immediately before the start of the first session and immediately after the fifth treatment session, the grip strength of the hand will be measured by a dynamometer, as well as the force measurement of the hand by the pegboard test as the results of the study.

Category

Rehabilitation

2

Description

Control group: Including 27 people, which sham protocol with a maximum current of 2 mA that will be applied to the patient's head for 30 seconds. Electrodes on the non-dominant primary cortex will be performed in 20-minute sessions, 5 sessions, three sessions per week, and then the current will be halted. Electrodes on the non-dominant primary cortex will be done for them in three sessions a week. In this case, the cathode will be placed on the supraorbital area of the opposite side. Immediately before the start of the first session and immediately after the fifth therapeutic session, the grip strength of the hand will be measured by a dynamometer, as well as the strength of the hand the hand dexterity will be measured by the purdue pegboard test as the results of the study.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

501 AJA Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Memarpour

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Tayebeh Sadat Salehi Rihani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Position

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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