Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 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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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
Tehran
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 m/A 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
Tayebeh Sadat Salehi Rihani
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Web page address
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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
Street address
7th Floor, Central Building, Shiraz Medical University, Zand Street
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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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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