

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative effect of anodal and cathodal transcranial direct current stimulation (tDCS) over the motor cortex with different stimulation intensity on motor learning in healthy young adults

Protocol summary

Study aim

To determine the comparative effect of anodal and cathodal electrical brain stimulation of the motor area of the brain with currents of 1 and 2 milliamperes on the motor learning of healthy young people during the serial motor cognitive task (SRTT).

Design

A randomized double-blind clinical trial using coding method containing 4 intervention groups and a control group on 100 healthy young people.

Settings and conduct

In order to participate in the project, the volunteers go to the neuromuscular rehabilitation research center of Semnan University of Medical Sciences and then are randomly divided into 5 different groups that are the same in terms of age and gender. Subjects are then asked to perform a serial task with the CMT software with their right hand (dominant hand).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Young people with an age range of 18-35 years and right handed; Exclusion criteria: being exposed to currents affecting the CNS during the last two weeks, presence of psychological or neurological diseases.

Intervention groups

Current is applied by a pair of electrodes (cathode and anode) at the same time as SRTT is performed for 20 minutes. In two anodal groups, in order to stimulate the motor area of the brain using anodal TDCS, the anode active electrode is placed on the left motor area of the brain (C3) and the cathode electrode is placed on the right side of the forehead area. Electrical stimulation is applied in one group with an intensity of 1 and in another with an intensity of 2 mA. When using TDCS cathodal, all the above steps are done by replacing the electrodes. In the Sham group, electrodes are placed randomly, and the device is off. The SRTT test is repeated for all people

within 72 hours after the first session without applying TDCS.

Main outcome variables

One block time (SRT) and the number of errors with CMT software

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221023056277N2**

Registration date: **2023-02-24, 1401/12/05**

Registration timing: **prospective**

Last update: **2023-02-24, 1401/12/05**

Update count: **0**

Registration date

2023-02-24, 1401/12/05

Registrant information

Name

Amin Mottahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-02, 1402/01/13

Expected recruitment end date

2023-06-03, 1402/03/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of anodal and cathodal transcranial direct current stimulation (tDCS) over the motor cortex with different stimulation intensity on motor learning in healthy young adults

Public title

The comparative effect of anodal and cathodal electrical brain stimulation of the motor area of the brain with different intensity of currents on motor learning of healthy young people

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Young people with an age range of 18-35 years The dominant hand of people should be the right hand

Exclusion criteria:

Report any history of neurological diseases such as Parkinson's, Alzheimer's, schizophrenia and dyslexia, so that the disease affects people's ability to learn. Report any history of psychological diseases Report of exposure to currents affecting the central nervous system during the last two weeks Report the use of any sedative drugs in the past two days Report any symptoms of forgetfulness and depression Memory disorders with a score less than 21 through the MMSE test The presence of any symptoms of movement disorders in the upper limb of the right hand, which, based on the researcher's assessment and diagnosis, causes movement restriction in the joints of the upper limb. The presence of any symptoms of radiculopathy, carpal tunnel syndrome in the right hand as diagnosed by the researcher Report uncorrected vision and hearing impairments Report dizziness Users of pacemaker

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Numbers 1 to 100 are written on paper and all of them are placed in closed envelopes. Then the patients are asked to choose one envelope each. Patients whose envelope numbers are 1-20 in intervention group 1,

40-21 in intervention group 2, 41-60 in intervention group 3, 61-80 in intervention group 4, and patients whose envelope numbers are 81-100 in the control group will be placed.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Outcome assessor and analyzer and participant will be blind (double blind) and will not be aware from grouping. Definition of groups A, B and C will be available to analyzer and outcome assessor.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Semnan University of Medical Sciences

Street address

Basij Blvd., Semnan University of Medical Sciences

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2023-02-07, 1401/11/18

Ethics committee reference number

IR.SEMUMS.REC.1401.284

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

Investigating the comparative effect of anodal and cathodal electrical brain stimulation of the motor area of the brain with different current intensities on the motor learning of healthy young people

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

One block time (SRT)

Timepoint

The reaction time of performing each sequence in all five groups is measured and recorded before applying the current, 35 minutes after TDCS and 72 hours after applying this current.

Method of measurement

The time of one block (SRT) is measured with CMT software.

2

Description

Number of errors

Timepoint

The number of errors in people of all five groups is measured and recorded before applying the current, 35 minutes after TDCS and 72 hours after applying this current.

Method of measurement

The number of errors is measured by CMT software.

Secondary outcomes

empty

Intervention groups

1

Description

first intervention group: To use the TDCS tool in the intervention groups, a direct stimulation current will be used by a pair of electrodes (cathode and anode). The current is controlled by an ammeter. Stimulating electrodes are 5x7 cm in size and are made of sponge soaked in saltwater solution. When using TDCS, a current of 1 mA is applied to the skull for a maximum of 20 minutes. Electrical brain stimulation will be used for 20 minutes at the same time as SRTT cognitive motor task. In two anodal groups, in order to stimulate the motor area of the brain using anodal tDCS, the anode active electrode is placed on the left motor area of the brain (C3) and the cathode electrode is placed on the right side of the frontal area. Electrical stimulation with an intensity of 1 mA and with a gradual slope is applied for 20 minutes.

Category

Diagnosis

2

Description

second intervention group: To use the TDCS tool in the intervention groups, a direct stimulation current will be used by a pair of electrodes (cathode and anode). The current is controlled by an ammeter. Stimulating electrodes are 5x7 cm in size and are made of sponge soaked in saltwater solution. When using TDCS, a current of 2 mA is applied to the skull for a maximum of 20 minutes. Electrical brain stimulation will be used for 20 minutes at the same time as SRTT cognitive motor task. In two anodal groups, in order to stimulate the motor area of the brain using anodal tDCS, the anode active electrode is placed on the left motor area of the brain

(C3) and the cathode electrode is placed on the right side of the frontal area. Electrical stimulation with an intensity of 2 mA and with a gradual slope is applied for 20 minutes.

Category

Diagnosis

3

Description

third intervention group: When using TDCS cathodal on the motor area of the brain, in the cathodal group, the cathode active electrode is placed on the motor area on the left side of the brain (C3) and the anode electrode is placed on the right side of the forehead area. In the group, a cathodal with an intensity of 1 milliamperere is placed. It is applied with a gradual gradient for 20 minutes

Category

Diagnosis

4

Description

fourth intervention group: When using TDCS cathodal on the motor area of the brain, in the cathodal group, the cathode active electrode is placed on the motor area on the left side of the brain (C3) and the anode electrode is placed on the right side of the forehead area. In the group, a cathodal with an intensity of 2 milliamperere is placed. It is applied with a gradual gradient for 20 minutes

Category

Diagnosis

5

Description

Control group: In the Sham tDCS group, the anode and cathode electrodes will be selected randomly, and like the previous groups, the active electrode will be placed in the motor area of the brain and the inactive electrode will be placed on the right frontal area. The current will increase up to the first 45 seconds, and then it will reach zero again in 60 seconds, and like the previous groups, the electrodes will remain without current on the respective areas for up to 20 minutes. The motor serial task test for the people of all five groups within 72 hours after The test of the first session will be repeated again. Electrical stimulation of the brain will not be used in this session. Finally, the reaction time and the number of errors regarding the task sequences will be recorded and analyzed before using the main test and during two intervention sessions.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center,
Semnan University of Medical Sciences

Full name of responsible person

Shida Mousavi and Amin Mottahedi

Street address

Quds Boulevard, Neuromuscular Rehabilitation
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Fatemeh Ehsani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No - there are no plans to publish it

Study Protocol

Undecided - It is not yet known if there will be 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

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