Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparative effects of bilateral and unilateral transcranial direct current stimulation (tDCS) over the motor cortex on motor learning in healthy older adults

Protocol summary

Study aim

the comparative effect of unilateral and bilateral anodal tDCS electrical brain stimulation of the brain's motor area with a current intensity of 1 mA on motor learning of healthy elderly people.

Design

A randomized and parallel-group clinical trial study on 54 patients. The randomization is simple, which was done in a block method with the help of a random table of numbers.

Settings and conduct

The following study has been conducted at the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences, with the voluntary participation of healthy young elderly people. It involves 3 groups, each required to complete a movement task using the Color Matching Test (CMT) software. The first group receives unilateral anodal tDCS. the second group receives bilateral tDCS in the M1 region. The third group receives a sham tDCS. The reaction times are recorded for all participants, before the application, immediately after the application, and 72 hours post-application of the current. The participants and the evaluator are blinded to ensure objective and unbiased results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy young elderlies (60-75 years), right-handed, willing to participate after studying the conditions. Exclusion criteria: history of neurological/psychological diseases, forgetfulness/depression symptoms, recent CNS exposure to currents in two weeks, pacemaker use, electrical stimulation contraindications.

Intervention groups

Group 1: anodal tDCS unilaterally for 20 minutes with an intensity of 1 milliamp. Group 2: bilateral tDCS with the same duration and intensity as the first group. Group 3 (Sham tDCS): random electrode placement. The current will be cut off after a certain period and the electrodes will remain without current on the respective areas for 20 minutes.

Main outcome variables

reaction time; Number of errors

General information

Reason for update

This update is intended to clarify and correct the description of the study blinding procedures. The term “double-blind” was used in the original registration; however, during the actual conduct of the study, participants, outcome assessors, and the data analyst were blinded to group allocation, whereas the researcher responsible for administering transcranial direct current stimulation (tDCS) was aware of the assigned intervention because the device had to be configured according to the allocated treatment. Therefore, this amendment is intended to describe the blinding procedures more accurately and align the trial registration with the methods actually implemented. It does not reflect a change in the study procedures.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240312061271N1**
Registration date: **2024-04-02, 1403/01/14**
Registration timing: **prospective**

Last update: **2026-10-11, 1405/07/19**
Update count: **1**

Registration date

2024-04-02, 1403/01/14

Registrant information

Name

yaghoubali shourvarzi

Name of organization / entity

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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-04-20, 1403/02/01
Expected recruitment end date
2024-07-21, 1403/04/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
comparative effects of bilateral and unilateral transcranial direct current stimulation (tDCS) over the motor cortex on motor learning in healthy older adults

Public title
comparative effects of bilateral and unilateral transcranial direct current stimulation (tDCS) over the motor cortex on motor learning in healthy older adults
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy young elderly people with an age range of 60-75 years. The dominant hand of the participants should be the right hand. Willingness to participate in the study and sign the informed consent form.
Exclusion criteria:
Reporting any history of neurological diseases such as Parkinson's, Alzheimer's, schizophrenia and dyslexia in such a way that the disease has affected the person's ability to learn. Report any history of psychological illness Report exposure to currents affecting the central nervous system during the last two weeks Report on the use of any type of sedative medication during the last two days Report any symptoms of forgetfulness and depression Memory disorders with a score of less than 21 through the MMSE test The presence of any symptoms of movement disorders in the upper limb of the right hand, which, according to the researcher's evaluation and diagnosis, has caused movement restrictions in the joints of the upper limb. Observing any symptoms of radiculopathy and carpal tunnel syndrome in the right hand with the researcher's diagnosis Report uncorrected vision and hearing impairments Report dizziness Pacemaker users Contraindications to the use of electrical stimulation Inability to understand or follow the study process Reluctance to participate in the study
Age
From **60 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
For this study, a simple and easily accessible sampling method will be used. Individuals will be divided into three groups completely at random. To ensure randomization, the block method will be used along with random tables to select numbers between 1 and 6. A treatment allocation list will then be created based on each number. Boxes will be numbered in a random sequence and each box will contain either the desired intervention or a sheet with random allocation written on it. These boxes will be completely sealed and given to the administrator and researcher based on the order of arrival of the patients. Using the aforementioned items, the standard intervention and treatment group for each person will be determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
To minimize bias in the study, all treatment steps will be performed by the main researcher, while the evaluation steps before and after the intervention will be carried out by a research assistant who is a physiotherapist. Participants in each group will not be informed about the treatment of the other group, and the evaluator will not be aware of which group each participant belongs to.
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
Semnan University of Medical Sciences and Health Services Headquarters, Basij Blvd, Semnan
City
Semnan
Province

Semnan

Postal code

3519618375

Approval date

2024-03-12, 1402/12/22

Ethics committee reference number

IR.SEMUMS.REC.1402.314

Health conditions studied

1

Description of health condition studied

Motor learning of the healthy young elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Number of errors

Timepoint

Before, immediately after, and 72 hours post tDCS application

Method of measurement

Color matching test software

2

Description

Reaction time

Timepoint

Before, immediately after, and 72 hours post tDCS application

Method of measurement

Color matching test software

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: receiving unilateral anodal tDCS. The active anode electrode is placed on the left M1 area of the brain (C3) and the cathode electrode is placed on the right side of the forehead area for 20 minutes with an intensity of 1 mA.

Category

Treatment - Devices

2

Description

The second intervention group: received bilateral tDCS. The anode electrode is placed on the left M1 area, and the cathode electrode is placed on the right M1 area for 20 minutes with an intensity of 1 mA.

Category

Treatment - Devices

3

Description

Control group: will receive a simulated electrical stimulation of the motor area of the brain, known as sham tDCS. The placement of the electrodes will be chosen randomly. The current will increase for the first 45 seconds and then remain constant for 60 seconds, before being turned off completely. Similar to the other groups, the electrodes will remain inactive for up to 20 minutes after the procedure.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan University of Medical Sciences, Neuromuscular Rehabilitation Research Center

Full name of responsible person

Fatemeh Ehsani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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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 additional information 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