Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of bihemispheric transcranial direct current stimulation on memory abilities and parameters of quantitative electroencephalography (qEEG) in mild cognitive impairment patients

Protocol summary

Study aim
Determining the effect of transcranial direct current stimulation on memory abilities in mild cognitive impairment patients

Design
A parallel, randomized, double-blinded, clinical trial with a control group

Settings and conduct
This clinical trial will be performed in Poursina Hospital in Rasht (Iran). 36 patients with mild cognitive impairment will be randomly divided into two groups: active and sham stimulation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: clinical diagnosis of mild cognitive impairment; MMSE score between 19 and 24; age 50-80 years old; literacy in Persian; being right-handed. Exclusion criteria: history of dementia or mental disability; consumption of cognitive enhancers; reversible medical conditions associated with a potential cognitive impairment; recent diagnosis of alcoholism or alcohol-based disorders based on DSM-V; epilepsy; severe clinical diseases including cardiovascular, gastrointestinal, respiratory, endocrine and CNS diseases; history of cerebrovascular surgery; patients who have participated in another clinical study in the last 30 days; contraindications to brain stimulation with tDCS.

Intervention groups
Active tDCS: bihemispheric tDCS with 2 mA intensity will be applied for 30 minutes. Anodal stimulation will be applied to the left hemisphere F3 region, - Sham tDCS: Both electrodes will be placed as in active group, but current will be applied for 30 seconds (10 seconds ramp-up, 10 seconds 2 mA and 10 seconds ramp-down).

Main outcome variables
Improvement of general memory; verbal memory; visual and working memory and delayed recall based on Wechsler memory scale (WMS) questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190522043673N2**
Registration date: **2021-03-02, 1399/12/12**
Registration timing: **prospective**

Last update: **2021-03-02, 1399/12/12**
Update count: **0**

Registration date
2021-03-02, 1399/12/12

Registrant information

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Kambiz Rohampour

Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-21, 1400/02/31

Expected recruitment end date
2022-07-22, 1401/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of bihemispheric transcranial direct current stimulation on memory abilities and parameters of quantitative electroencephalography (qEEG) in mild cognitive impairment patients

Public title
The effect of tDCS on memory in mild cognitive impairment patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Clinical diagnosis of mild cognitive impairment (MCI) performed by a neurologist based on criteria revised by the National Institute on Aging and Alzheimer's (NIA-AA) in 2012. MMSE score between 19 - 24 age of 50 to 80 years Literacy in Persian Being right-handed

Exclusion criteria:
History of dementia or mental retardation Consumption of cognitive enhancers Reversible medical conditions associated with potential cognitive impairment Recent diagnosis of alcoholism or alcohol-based disorders based on the DSM-V Epilepsy Severe clinical conditions include cardiovascular, gastrointestinal, respiratory, endocrine, and CNS diseases History of cerebrovascular surgery Patients who have participated in another clinical study in the last 30 days Contraindications to brain stimulation with tDCS

Age
From **50 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization will be used; with a block size of 4; Allocation concealment will be performed using sealed envelope software. The participants will be allocated to group A or B, using blocked randomization (Block size: 4). One of the groups receive active tDCS, while the other is sham stimulated, neither the participants nor the allocator is not aware that which group will be the treatment group. The physiotherapist, applying the tDCS, is the only researcher who knows the treatment and the sham group. After treatment (or sham stimulation), the data will be analyzed by the statistician, who is either blind to the data groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants will be allocated to group A or B, using blocked randomization. Neither the participants nor the allocator is not aware that which group will be the treatment group. The physiotherapist, applying the tDCS, is the only researcher who knows the treatment and the sham group. After treatment (or sham stimulation), the data will be analyzed by the statistician, who is also blind to the treatment/sham groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
Poursina Hospital, Namjou street, Emam blvd.

City
Rasht

Province
Guilan

Postal code
41937-13194

Approval date
2021-02-17, 1399/11/29

Ethics committee reference number
IR.GUMS.REC.1399.596

Health conditions studied

1

Description of health condition studied
Mild cognitive impairment

ICD-10 code
G31.84

ICD-10 code description
Mild cognitive impairment, so stated

Primary outcomes

1

Description
Wechsler Memory Scale (WMS)

Timepoint
Before intervention - After intervention - 3 month after intervention

Method of measurement
Wechsler Memory Scale (WMS) questionnaire

Secondary outcomes

1

Description
Absolute power in different band frequencies in EEG
Timepoint
Before intervention - immediately after intervention - 3 month after intervention
Method of measurement
EEG recording and qEEG analysis with Matlab software

Intervention groups

1

Description
Active tDCS group; the anodal electrode will be placed on the left dorsolateral prefrontal cortex (DLPFC), which is equivalent to F3 zone according to the standard 10-20 electrode placement system. The cathodal electrode will be placed on the opposite side (F4 zone). Stimulation with a current intensity of 2 mA will be applied for 30 min for ten consecutive sessions.
Category
Treatment - Devices

2

Description
Sham tDCS; Both electrodes will be placed as in active group. Current will be applied for 30 seconds (10 seconds ramp-up, 10 seconds 2 mA and 10 seconds ramp-down). The electrodes remain in place for 30 minutes but no current will be applied to assess the placebo effect of the intervention.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Mohammadreza Naghipour
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Web page address
http://www.gums.ac.ir/research
Grant name
Grant code / Reference number
2724
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan 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
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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
Not applicable
Data Dictionary
Not applicable