

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Name

Kambiz Rohampour

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3369 0884

Email address

rohampour@gums.ac.ir

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

Alia Saberi

Street address

Namjou street, Emam Blvd

City

Rasht

Province

Guilan

Postal code

41937-13194

Phone

+98 13 3332 2444

Fax

+98 13 3333 9842

Email

poursina@gums.ac.ir

Web page address

<http://www.gums.ac.ir/poursina>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

Street address

Shahid Beheshti Blvd.(west), opposite of Sepah Bank, vice-chancellor for Research Building

City

Rasht

Province

Guilan

Postal code

4193853948

Phone

+98 13 3336 2889

Fax

+98 13 3336 2842

Email

research@gums.ac.ir

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

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Kambiz Rohampour

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

Guilan University Complex, 6th km of Tehran road,

City

Rasht

Province

Guilan

Postal code

4193853948

Phone

+98 13 3369 0884

Email

rohampour@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Alia Saberi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Namjou street, Poursina Hospital

City

Rasht

Province

Guilan

Postal code

41937-13194

Phone

+98 13 3369 0884

Fax

+98 13 3369 0036

Email

Alia.saberi.1@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Kambiz Rohampour

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

Guilan University Complex, 6th km of Tehran road,

City

Rasht

Province

Guilan

Postal code

4193853948

Phone

+98 13 3369 0884

Email

rohampour@gmail.com

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