

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of High Definition-transcranial Direct Current Stimulation (HD-tDCS) on Cognitive Problems and Mood of Shiraz Elderly

Protocol summary

Study aim

The present study seeks to investigate high definition-transcranial direct-current stimulation (HD-tDCS) on cognitive and depression symptoms of the elderly.

Design

This is a clinical trial research with pre-test, post-test, one-month follow-up and control group. There are parallel groups of 30 participants that We will randomly divide the clients into two groups (experimental and control).

Settings and conduct

This is a randomized clinical trial study in which the double blind method will be used. Therefore we refer to Shiraz geriatric research center and by using the convenience sampling method, people with discomfort and complaints of depression are suggested to participate in the study. We offer neurotherapy to satisfy the clients to participate in the research.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of the disorder by a psychiatrist, Rejecting differential diagnosis by a neurologist, Aged between 50 to 75 years, Not suffering from cardiovascular disease and diabetes, Not Smoking. Exclusion criteria: Dissatisfaction to participate in the research, Having a type of motor or cognitive disabilities, Receiving simultaneous psychiatric treatment, History of seizure disorders, Having a pacemaker.

Intervention groups

The intervention group received high definition-transcranial direct-current stimulation (HD-tDCS) at 2 mA (positive stimulation) over 10 consecutive sessions. Ten sessions of HD-tDCS without electricity flow (sham mode) will be used for the control group.

Main outcome variables

Cognitive Symptoms, Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190708044138N2**

Registration date: **2020-05-18, 1399/02/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-18, 1399/02/29**

Update count: **0**

Registration date

2020-05-18, 1399/02/29

Registrant information

Name

Mohammad Hossein Sorbi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3621 1306

Email address

sorbi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-12, 1398/08/21

Expected recruitment end date

2020-08-10, 1399/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of High Definition-transcranial Direct Current Stimulation (HD-tDCS) on Cognitive Problems and Mood of Shiraz Elderly

Public title

Effectiveness of High Definition-transcranial Direct Current Stimulation (HD-tDCS) on the mental health of elderly

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Gaining mild to moderate depression score (scores from 14 to 30) in the Beck depression inventory Rejecting differential diagnosis of neuro-motor disorder by a neurologist and absence of neurological disorder Aged between 50 to 75 years Not suffering from cardiovascular disease, kidney disease and diabetes (getting information by asking from participants and get help from a physician) Not Smoking and not taking painkillers, sedatives and hypnotics.

Exclusion criteria:

Dissatisfaction to participate in the research Having a type of motor or cognitive disabilities that interferes working with computer Receiving simultaneous psychiatric treatment or other psychotherapies to relieve depression disorder History of seizure disorders in individuals having a pacemaker, having a metal object in the head and neck or any other obstacle to do electrical stimulation

Age

From **50 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: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be done using www.randomization.com to assign equal participants in each group (1:1 allocation). An independent researcher will make random allocation cards using computer-generated random numbers. he will keep the original random allocation sequences until analysis time. Another researcher will measure the patients outcome and he will not know the allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

The neuroscientist of geriatric research center will be aware of the research topic and will perform therapeutic interventions. He codes the patients and refers them to a psychologist to check the patient's mental state and record the relevant criteria based on the same code. The patients will be tested in the same condition in the neurotherapy room and the electrodes of the device will be connected to their, but they will not be aware of the

real or sham stimulation. Accordingly, this study will be a double-blind study.

Placebo

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

Zand St, Central building of Shiraz University of Medical Sciences, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-08-07, 1398/05/16

Ethics committee reference number

IR.SUMS.REC.1398.746

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

Major depressive disorder, single episode, moderate

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

Primary outcomes**1****Description**

Cognitive Symptoms

Timepoint

Cognitive Symptoms was measured at the beginning of the study (before the intervention), after the last treatment session, and 30 days (one month) after the last treatment session.

Method of measurement

The Integrated Visual and Auditory (IVA-2)

2**Description**

Depression

Timepoint
Depression was measured at the beginning of the study (before the intervention), after the last treatment session, and 30 days (one month) after the last treatment session.

Method of measurement
Beck depression inventory (BDI-II)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group received high definition-transcranial direct current stimulation (HD-tDCS) at 2 mA (positive or anode stimulation) over 10 consecutive sessions (25 minutes per session)

Category
Treatment - Devices

2

Description
The control group received high definition-transcranial direct current stimulation (HD-tDCS) with sham mode over 10 consecutive sessions.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz Geriatric Research Center

Full name of responsible person
Dr. Mohammad Ali Nazarinia

Street address
Zand St, Shiraz Geriatric Research Center, Shiraz University of Medical Science

City
Shiraz

Province
Fars

Postal code
7134814336

Phone
+98 71 3612 2203

Email
nazariniam@sums.ac.ir

Web page address
<http://sgrc.sums.ac.ir/en/index.html>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Younes Ghasemi

Street address
Zand St, Central building of Shiraz University of Medical Sciences, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7134814336

Phone
+98 71 3212 2884

Email
gsia@sums.ac.ir

Web page address
<https://www.sums.ac.ir/>

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
Urmia University

Full name of responsible person
Mohammad Hossein Sorbi

Position
Instructor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Eleven kilometers of University Boulevard

City
Urmia

Province
West Azarbaijan

Postal code
5756151818

Phone

+98 44 3275 2741

Email

Sorbih@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Ali Nazarinia

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

Street address

Zand St, Shiraz Geriatric Research Center

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3212 2283

Email

nazariniam@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Urmia University

Full name of responsible person

Mohammad Hossein Sorbi

Position

Instructor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Eleven kilometers of University Boulevard

City

Urmia

Province

West Azarbaijan

Postal code

5756151818

Phone

009832752741

Email

Sorbih@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Participant Data File: Because the individual data of the study participants are considered, this study shares some of the data such as information about the main outcomes of the study.

When the data will become available and for how long

The access period starts 9 months after the results are published.

To whom data/document is available

The data obtained from this study are only available to researchers working at Urmia University and Shiraz University of Medical Sciences.

Under which criteria data/document could be used

The data of this research are only permitted for review and meta-analysis studies.

From where data/document is obtainable

Visit Mr. Mohammad Hossein Sorbi from Urmia University, or contact him by email or phone. Phone: 09131560290, Email: Sorbih@gmail.com

What processes are involved for a request to access data/document

Applicants are required to submit a written request to Mr. Sorbi by email (9 months after the publication of the research results). After reviewing the request, the data will be sent to the applicant online via email.

Comments