

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of transcranial direct current stimulation versus no stimulation on working memory in elders with normal cognitive status: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of transcranial direct current stimulation versus no stimulation on working memory in elders with normal cognitive status **Design:** a double blind randomized clinical trial. **Setting and conduct:** The eligible elders who will refer to School of Public Health, Zahedan University of Medical Sciences, during the study period will be enrolled into the trial. **Inclusion criteria:** (a) age above 60 years; (b) score of MMSE less than 25. **Exclusion criteria:** (a) psychological disorders such as schizophrenia, mood disorder, dementia, active psychosis, and stimulant dependent; (b) neurological disorders involving central nerves system such as Alzheimer, Parkinson, stroke, multiple sclerosis; (c) chronic diseases such as diabetes, renal failure, liver failure, and hypo-thyroiditis; (d) history of head trauma during past six months. **Intervention group:** Andean stimulate of the left prefrontal skull with amperage 2 mA for 20 minutes daily for 5 days. **Control group:** Virtual stimulate of the left prefrontal skull for 20 minutes daily for 5 days. **Primary outcome:** Assessing the working memory using n-back test before intervention, before the third stimulation, the day after completion of stimulation and 2 week after intervention; (b) Assessing the verbal working memory using Digit span test before intervention, before the third stimulation, the day after completion of stimulation and 2 week after intervention. **Secondary outcome:** assessing cognitive impairment using MMSE questionnaire before intervention and 2 weeks after intervention. **Randomization:** Random assignment of the patients to the intervention and control groups using drawing lots. **Blinding:** Patients will be unaware of the type of stimulation. The examiner will not be aware of the stimulation. Therefore, the trial will be run as triple blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201605299014N101**

Registration date: **2016-06-05, 1395/03/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-05, 1395/03/16

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Zahedan University of Medical Sciences

Expected recruitment start date

2016-01-05, 1394/10/15

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of transcranial direct current stimulation versus no stimulation on working memory in elders with normal cognitive status: a double blind randomized clinical trial

Public title
Effect of transcranial direct current stimulation versus no stimulation on working memory in elders with normal cognitive status

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: (a) age above 60 years; (b) score of MMSE less than 25. Exclusion criteria: (a) psychological disorders such as schizophrenia, mood disorder, dementia, active psychosis, and stimulant dependent; (b) neurological disorders involving central nerves system such as Alzheimer, Parkinson, stroke, multiple sclerosis; (c) chronic diseases such as diabetes, renal failure, liver failure, and hypo-thyroiditis; (d) history of head trauma during past six months.

Age
From **60 years** old to **100 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization: Random assignment of the patients to the intervention and control groups using drawing lots.
Blinding: Patients will be unaware of the type of stimulation. The examiner will not be aware of the stimulation. Therefore, the trial will be run as triple blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Zahedan University of Medical Sciences, University Ave. Zahedan

City

Zahedan

Postal code

Approval date

2015-12-08, 1394/09/17

Ethics committee reference number

IR.ZAUMS.REC.1394.273

Health conditions studied

1

Description of health condition studied

Working memory

ICD-10 code

R41

ICD-10 code description

Other symptoms and signs involving cognitive functions and awareness

Primary outcomes

1

Description

Assessing the working memory

Timepoint

before intervention, before the third stimulation, the day after completion of stimulation and 2 week after intervention

Method of measurement

using n-back test

2

Description

Assessing the verbal working memory

Timepoint

before intervention, before the third stimulation, the day after completion of stimulation and 2 week after intervention

Method of measurement

using Digit span test

Secondary outcomes

1

Description

assessing cognitive impairment

Timepoint

before intervention and 2 weeks after intervention

Method of measurement

using MMSE questionnaire

Intervention groups

1

Description

Andean stimulate of the left prefrontal skull with amperage 2 mA for 20 minutes daily for 5 days.

Category

Treatment - Devices

2

Description

Virtual stimulate of the left prefrontal skull for 20 minutes daily for 5 days

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Public Health

Full name of responsible person

Dr Mona Kamali

Street address

School of Public Health, Health Ave.

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Zahedan University of Medical Sciences

Full name of responsible person

Dr Hooshang Rafighdoost

Street address

Zahedan University of Medical Sciences, University
Ave.

City

Zahedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor for Research the Technology, Zahedan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Public Health

Full name of responsible person

Dr Mona Kamali

Position

Resident of Psychiatry

Other areas of specialty/work

Street address

School of Public Health, Health Ave.

City

Zahedan

Postal code

Phone

+98 54 3329 5796

Fax

Email

kamali.m40@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Public Health

Full name of responsible person

Dr Mahboobeh Firoozkoobi Moghadam

Position

Infant Psychiatrist

Other areas of specialty/work

Street address

School of Public Health, Health Ave.

City

Zahedan

Postal code

Phone

+98 543430543

Fax

Email

firoozkoobi@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

Street address

School of Public Health, Hamadan University of

Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Fax

Email

poorolajal@umsha.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty