Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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, lever 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

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Name of organization / entity

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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, lever 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Zahedan University of Medical Sciences
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Dr Hooshang Rafighdoost
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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
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

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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