

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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

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## Person responsible for scientific inquiries

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#### Name of organization / entity

School of Public Health

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Dr Mahboobeh Firoozkoohi Moghadam

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Infant Psychiatrist

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## 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

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**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*