

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effects of trans cranial direct current stimulation on brain through skull on somatic and psychiatric symptom of elderly women with fibromyalgia

#### Protocol summary

##### Summary

**Objectives:** The current study would be carried out to determine the effects of trans-cranial direct current stimulation on brain through skull on somatic and psychiatric symptoms of elderly women with fibromyalgia. **Participants:** Among the attendants of rheumatology clinic of Rasool Akram hospital, Tehran, Iran; 50 elderly female volunteers with fibromyalgia would be selected. **Design and Setting:** The participants will be randomly divided into 2 groups, 25 of active stimulation and 25 of sham stimulation by the secretary of the clinic. The patients would be recognized by a code. The patients would receive the primary evaluation and tDCS intervention or placebo-therapy. Not the divider nor the patient and the analyzer would be aware of belonging of the patient to these two groups. Only the operator is aware of this, and after the finishing of the study, he will reveal the codes. The patients would be divided into A and B groups randomly, a group would receive active stimulation and the other would receive sham stimulation. Both groups would be compared. **Interventions:** The stimulation's characteristics are 2 mA, for 20 minutes, anode on M1 and cathode on right supra-orbital in active group and simulated condition in sham group are 2mA for 30 seconds. **Main outcome:** All will pass BECK, HAM, FIQ, VAS, SF36 test, before, after 10 session of tDCS or sham stimulation and after 1 month. The outcomes of both active and sham groups will be compared. The analysis and interview would be performed by blinded operators.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201606091959N8**  
Registration date: **2017-01-15, 1395/10/26**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-01-15, 1395/10/26

##### Registrant information

###### Name

Seyed Kazem Malakouti

###### Name of organization / entity

Iran University of Medical Science - Tehran Psychiatric Institute

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6655 0200

###### Email address

malakouti.k@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Science

##### Expected recruitment start date

2016-11-20, 1395/08/30

##### Expected recruitment end date

2017-03-20, 1395/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of trans cranial direct current stimulation on brain through skull on somatic and psychiatric symptom

of elderly women with fibromyalgia

### Public title

The effects of trans cranial direct current stimulation on brain through skull on somatic and psychiatric symptom of elderly women with fibromyalgia

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: patients with fibromyalgia according to ACR-90; older than 50 years and female; Medications the patient has not changed during the 8 weeks ago and medically was stable. Exclusion criteria: psychiatric disease or chronic pain disorder in medical evaluation; history of substance abuse; history of Neurological diseases; cardiac pace maker; history of deep brain stimulation surgery.

### Age

No age limit

### Gender

Female

### Phase

2

### Groups that have been masked

No information

### Sample size

Target sample size: 50

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical committee of Iran University of Medical Sciences

##### Street address

Hemmat Highway

##### City

Tehran

##### Postal code

1449614535

#### Approval date

2015-11-22, 1394/09/01

#### Ethics committee reference number

IR.IUMS.REC.1394.9211497002

## Health conditions studied

### 1

#### Description of health condition studied

fibromyalgia

#### ICD-10 code

M79.7

#### ICD-10 code description

fibromyalgia

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

before, after and 1 months after interventions

#### Method of measurement

Visual Analogue Scale questionnaire

## Secondary outcomes

### 1

#### Description

function

#### Timepoint

before, after and 1 months after interventions

#### Method of measurement

FIQ Questionnair

### 2

#### Description

depression

#### Timepoint

before, after and 1 months after interventions

#### Method of measurement

BDI Questionnair

### 3

#### Description

quality of life

#### Timepoint

before, after and 1 months after interventions

#### Method of measurement

SF36 Questionnair

### 4

#### Description

anxiety

#### Timepoint

before, after and 1 months after interventions

#### Method of measurement

HAM Questionnair

## Intervention groups

### 1

#### Description

In the active group, 20 minutes, 2mA direct current stimulation, Anode at primary motor cortex and cathode at right supra-orbital is given.

#### Category

Treatment - Other

### 2

#### Description

In the control group, 30 seconds, 2mA stimulation with 5 seconds RAMP-UP and RAMP-Down current is given to make the patient have a similar emotion to active group at the skull

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rhomatologic Clinic of Rasoole Akram hospital

##### Full name of responsible person

Zhale Zandie

##### Street address

Rasoole Akram hospital, Sattar Khan, Tehran

##### City

Tahran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

vice chancellor for research, Iran University of Medical Sciences

##### Full name of responsible person

Dr. Seyed Kazem Malakouti

##### Street address

Iran University of Medical Science, shahid Hemmat highway, Tehran

##### City

Tehran

#### 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, Iran 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

Iran University of Medical Science

##### Full name of responsible person

Dr Zhale Zandie

##### Position

resident of geriatric medicine

##### Other areas of specialty/work

##### Street address

Rasoole Akram hospital, Sattar khan, Tehran

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zhzandie@gmail.com

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Iran university of medical science

##### Full name of responsible person

Dr Seyed Kazem Malakouti

##### Position

Phd in psychaitry

##### Other areas of specialty/work

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## Person responsible for updating data

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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*