

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The impact of transcranial electrical stimulation over the doroslateral and ventromedial prefrontal cortices on reduction of social anxiety symptoms

#### Protocol summary

2019-12-16, 1398/09/25

#### Study aim

Determining the the impact of transcranial electrical stimulation over the doroslateral and ventromedial prefrontal cortices on reduction of social anxiety symptoms

#### Design

The present study is a clinical trial with pre-test, post-test and follow-up design with control group.

#### Settings and conduct

This study was performed in Ardabil city and among those referred to psychiatric clinics with diagnosis of social anxiety disorder and will be randomly assigned to study groups.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: ages 18 to 45 years old; diagnosis of social anxiety disorder based on DSM5 criteria and exclusion criteria: diagnosis of bipolar mood disorder or psychotic disorder based on DSM5 criteria; intracranial implants and a history of epilepsy and seizures.

#### Intervention groups

Two intervention groups and one control group

#### Main outcome variables

Symptoms of social anxiety disorder, attention bias, depression, quality of life

#### General information

##### Reason for update

Modify the sample collection place

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181013041327N2**

Registration date: **2019-12-16, 1398/09/25**

Registration timing: **prospective**

Last update: **2021-04-02, 1400/01/13**

Update count: **2**

##### Registration date

#### Registrant information

##### Name

jaber Alizadehgoradel

##### Name of organization / entity

The University of shahid beheshti

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3325 0055

##### Email address

j.alizadeh45@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2019-12-22, 1398/10/01

#### Expected recruitment end date

2020-05-09, 1399/02/20

#### Actual recruitment start date

2020-01-05, 1398/10/15

#### Actual recruitment end date

2020-03-15, 1398/12/25

#### Trial completion date

2020-07-05, 1399/04/15

#### Scientific title

The impact of transcranial electrical stimulation over the doroslateral and ventromedial prefrontal cortices on reduction of social anxiety symptoms

#### Public title

Transcranial direct current stimulation and social anxiety disorder

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age range from 18 to 45 years old Diagnosis of social

anxiety disorder based on DSM5 criteria

**Exclusion criteria:**

Diagnosis of bipolar mood disorder or psychotic disorder based on DSM5 criteria Intracranial Implants History of epilepsy and seizures

**Age**

From **18 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **36**

Actual sample size reached: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

For small studies, random numbers can be used to sort individuals into groups. Persons participating in the research will be given a code or machine number in order to use the random or random numbers table. Since the number of people we want will be selected from 80 people, so the assigned codes and numbers will be double digits. To select sample people from the table, it will randomly start from a table point in the row or column direction. Subjects are then randomly assigned to one of four study groups using the random number table and receive intervention in the same group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, both the participant and the performer are blinded by electrical stimulation and do not know which stimulus is real and which is artificial.

**Placebo**

Used

**Assignment**

Crossover

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Ardabil University of Medical Sciences

**Street address**

End of University Street, Ardabil University of Medical Sciences Administrative Complex

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5618985991

**Approval date**

2019-12-01, 1398/09/10

**Ethics committee reference number**

IR.ARUMS.REC.1398.478

**Health conditions studied**

**1**

**Description of health condition studied**

Social anxiety disorder

**ICD-10 code**

F40.1

**ICD-10 code description**

Social phobias

**Primary outcomes**

**1**

**Description**

Symptoms of social anxiety disorder

**Timepoint**

Before the intervention, after the intervention and three months after the intervention

**Method of measurement**

Social Anxiety Disorder Questionnaire

**2**

**Description**

Attention bias

**Timepoint**

Before the intervention, after the intervention and three months after the intervention

**Method of measurement**

Dot probe test

**3**

**Description**

Quality of Life

**Timepoint**

Before the intervention, after the intervention and three months after the intervention

**Method of measurement**

Quality of Life Questionnaire

**4**

**Description**

Depression

**Timepoint**

Before the intervention, after the intervention and three months after the intervention

**Method of measurement**

Beck Depression Inventory

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Electrical stimulation of the dorsolateral prefrontal cortex (DLPFC) area with an intensity of 1 mA

#### Category

Rehabilitation

### 2

#### Description

Intervention group 2: Electrical stimulation of the dorsolateral prefrontal cortex (DLPFC) area with an intensity of 2 mA

#### Category

Rehabilitation

### 3

#### Description

Control group: Mock stimulation of dorsolateral prefrontal cortex (DLPFC)

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

University of Mohaghegh Ardabili

##### Full name of responsible person

Eisa Jafari

##### Street address

University Street - University of Mohaghegh Ardabili

##### City

Ardabil

##### Province

Ardabil

##### Postal code

5619911367

##### Phone

+98 45 3150 5000

##### Email

jafari.esa60@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Payame Noor University of Ardabil

##### Full name of responsible person

Esac Jafari

#### Street address

Janabazan Square - University Street - Next to Shorabil Recreation Complex - Payame Noor University of Ardabil

#### City

Ardabil

#### Province

Ardabil

#### Postal code

5619913115

#### Phone

+98 45 3351 3002

#### Email

jafari.esa60@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Payame Noor University of Ardabil

#### Proportion provided by this source

100

#### Public or private sector

Private

#### 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

Beautiful Mind Psychology Clinic

##### Full name of responsible person

Jaber Alizadehgoradel

##### Position

PhD in Clinical Psychology

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Psychology

##### Street address

Moallem Street - Amin Doctors Building

##### City

Ardabil

##### Province

Ardabil

##### Postal code

5619163111

##### Phone

09804533250055

##### Email

j.alizadeh45@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Beautiful Mind Psychology Clinic

**Full name of responsible person**

Jaber Alizadehgoradel

**Position**

PhD in Clinical Psychology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Moallem Street - Amin Doctors Building

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5619163111

**Phone**

+98 45 3325 0055

**Email**

j.alizadeh45@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Beautiful Mind Psychology Clinic

**Full name of responsible person**

Jaber Alizadehgoradel

**Position**

PhD in Clinical Psychology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Moallem Street - Amin Doctors Building

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5619163111

**Phone**

+98 45 3325 0055

**Email**

j.alizadeh45@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is 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**

Behavioral data files, study protocols, informed consent forms, and clinical trial reports after identifiable individuals are shared.

**When the data will become available and for how long**

The access period starts 5 years after the results are published.

**To whom data/document is available**

Behavioral data for this study will only be available to researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Use of data is permitted only for articles related to the field of addiction.

**From where data/document is obtainable**

Jaber Alizadehgoradel - j.alizadeh45@gmail.com

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

Researchers who want to access the data should receive a letter from their workplace university and send it to the responsible person's email address, and the data will be available in less than 1 month.

**Comments**