Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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
2019-12-16, 1398/09/25

Registrant information

Name
jaber Alizadehgoradel

Name of organization / entity
The University of shahid beheshti

Country
Iran (Islamic Republic of)

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+98 45 3325 0055

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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 orsolateral 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
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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
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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
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Person responsible for scientific inquiries

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Name of organization / entity
Beautiful Mind Psychology Clinic

Full name of responsible person
Jaber Alizadehgoradel

Position
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Person responsible for updating data

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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