Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Synergistic effect of Transcranial direct current stimulation (tDCS) with cognitive behavioral therapy (CBT) on social anxiety, depression, emotion regulation, quality of life, EEG, attention bias in patients with social phobia disorder: randomize clinical trial

Protocol summary

Study aim

Determining the synergistic effect of CBT with tDCS in regulating brain waves and reducing the signs and symptoms of people with social anxiety.

Design

This study includes three groups, two of them are intervention and one of them is sham group. Sample members are randomly assigned to three groups using Excell software. The sample size of this study is 45 people, Considering drop out.

Settings and conduct

This research will be performed in person individually by the therapists in Shahid Beheshti Hospital in Zanjan. This study is one-blind and participants will be blind to the groups.

Participants/Inclusion and exclusion criteria

Suffering social anxiety disorder; willingness to participate in research; age range minimum 18 and maximum 50 years old; non-smoker; at least third junior high school; no severe psychiatric disorders such as psychotic disorders, cognitive disorders and other psychiatric disorders; lack of history of epileptic seizures and history of head injury; no metal device or other electrical device in the head; do not consume drugs and alcohol; not receiving psychological and technological treatments at least one month before entering the research. Exclusion criteria: absence for more than two sessions; suicidal ideation during intervention sessions; the need for crisis-related interventions such as medication during intervention sessions; cancel continuation of intervention sessions.

Intervention groups

Intervention group 1: first receives transcranial electrical stimulation and in the second stage receives cognitive-behavioral therapy. Intervention group 2: will receive only transcranial electrical stimulation. The third group will first receive sham stimulation and then cognitive-behavioral therapy.

Main outcome variables

Social anxiety; depression; emotion regulation; attention bias; worry; quality of life; brainwave

General information

Reason for update

There is reason to doubt, the information is proven and should be corrected

Acronym

IRCT registration information

IRCT registration number: **IRCT20220421054607N1**
Registration date: **2022-05-19, 1401/02/29**
Registration timing: **prospective**

Last update: **2024-02-03, 1402/11/14**
Update count: **2**

Registration date

2022-05-19, 1401/02/29

Registrant information

Name

Parinaz sadat Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5237 0482

Email address

ami.parinaz399@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-05-26, 1401/03/05
Expected recruitment end date
2023-07-21, 1402/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Synergistic effect of Transcranial direct current stimulation (tDCS) with cognitive behavioral therapy (CBT) on social anxiety, depression, emotion regulation, quality of life, EEG, attention bias in patients with social phobia disorder: randomize clinical trial

Public title
The Synergistic effect of Transcranial direct current stimulation (tDCS) with cognitive behavioral therapy (CBT) in patients with social phobia disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering social anxiety disorder Willingness to participate in research Age range minimum 18 and maximum 50 years old Non-smoker At least third junior high school No severe psychiatric disorders such as psychotic disorders, cognitive disorders and other psychiatric disorders Lack of history of epileptic seizures and history of head injury No metal device or other electrical device in the head Do not consume drugs and alcohol Not receiving psychological and technological treatments at least one month before entering the research
Exclusion criteria:
Absence for more than two sessions Suicidal ideation during intervention sessions The need for crisis-related interventions such as medication during intervention sessions Cancel continuation of intervention sessions
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples are assigned after screening using Excell program in three groups of treatment number 1, treatment number 2 and sham so that all participants have an equal chance to participate in the groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
None of the subjects will know about randomization and the group assignment process.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences,12th St.,Karmandan Town
City
Zanjan
Province
Zanjan
Postal code
4513676993
Approval date
2022-04-20, 1401/01/31
Ethics committee reference number
IR.ZUMS.REC.1401.029

Health conditions studied

1

Description of health condition studied
SOCIAL ANXIETY DISORDER
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Social anxiety
Timepoint
Before intervention and immediately after intervention and three months after intervention
Method of measurement
Liebowitz Social Anxiety Scale

Secondary outcomes

1

Description
Depression
Timepoint
Before intervention and immediately after intervention and three months after intervention
Method of measurement
Beck Depression Inventory-II

2

Description
Emotion regulation
Timepoint
Before intervention and immediately after intervention and three months after intervention
Method of measurement
Difficulties in Emotion Regulation Scale

3

Description
Quality of life
Timepoint
Before intervention and immediately after intervention and three months after intervention
Method of measurement
WHOQUL questionnaire

4

Description
Attentional bias
Timepoint
Before intervention and immediately after intervention and three months after intervention
Method of measurement
Attentional bias task

5

Description
Worry
Timepoint
Before intervention and immediately after intervention and three months after intervention
Method of measurement
Penn State Worry Questionnaire

6

Description
Asymmetry of brain waves
Timepoint
Before intervention and immediately after intervention and three months after intervention
Method of measurement
Electroencephalography

7

Description
Coherence of brain waves
Timepoint
Before intervention and immediately after intervention and three months after intervention
Method of measurement
QEEG

8

Description
Amplitude of brain waves
Timepoint
Before intervention and immediately after intervention and three months after intervention
Method of measurement
QEEG

Intervention groups

1

Description
Intervention group 1: Transcranial electrical stimulation for five days. Two sessions every day. Each session is twenty minutes and cognitive-behavioral therapy for fifteen to twenty sessions
Category
Treatment - Other

2

Description
Intervention group 2: Transcranial electrical stimulation for five days. Two sessions every day. Each session is twenty minutes
Category
Treatment - Other

3

Description
Control group: Sham cranial electrical stimulation and cognitive-behavioral therapy for fifteen to twenty sessions.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital in Zanjan
Full name of responsible person
parinaz sadat amiri
Street address
Dr. Beheshti Hospital, Ark square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Ehsan Sabouri
Street address
Zanjan University of Medical Sciences,East 12th, ZanjanStreet,
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4513956111
Phone
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info@zums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Zanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
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
Zanjan University of Medical Sciences
Full name of responsible person
Prinaz Sadat Amiri
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
By observing the data encoding, the whole data can be shared for the unidentifiable people.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
All researchers
Under which criteria data/document could be used
Allowed for research applications
From where data/document is obtainable
Prinaz Sadat Amiri Email: ami. parinaz 399@gmail.com
What processes are involved for a request to access data/document
One Month
Comments