

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effect of Transcranial Direct Current Stimulation along with Affective Expectations Manipulation on Affective Experience and Anhedonia among Anhedonic Patients Suffering from Major Depression Disorder

Protocol summary

Study aim

effect of transcranial direct current stimulation along with affective expectations manipulation on affective experience and anhedonia among anhedonic patients suffering from major depression disorder

Design

The clinical trial will be conducted on 45 patients with parallel groups, double-blind and simple randomization through lottery.

Settings and conduct

Anhedonic patients suffering from Major Depressive Disorder who refer to Hafez and Ebne Sina hospitals in Shiraz City throughout the performing phase of the study will be randomized to the experimental groups through the lottery method. For blinding, some subjects receive actual stimulation, while others receive sham stimulation. The effect of the intervention on anhedonia symptom will be investigated by Using objective and subjective tools.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Obtaining the initial diagnosis of major depressive disorder with anhedonia using a structured clinical interview and questionnaire, The patient should be able to perform the behavioral test and answer the questionnaires. Exclusion criteria: The presence of comorbid disorders such as substance abuse, psychotic disorders, bipolar disorder, anxiety disorders and psychotic symptoms, the presence of metal parts in the head.

Intervention groups

Intervention group 1: In this group, during one session the participants through the tDCS device first receive electrical stimulation of 2 milliamps for 20 minutes on the head, Then positive emotions are induced through positive explanations about a movie. Intervention group 2: During a session, the participants receive sham stimulation through the tDCS device and then induction

of positive emotions through positive explanations about a movie. Intervention group 3: transcranial electrical stimulation and then induction of neutral emotions.

Main outcome variables

Anhedonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230513058161N2**

Registration date: **2023-08-11, 1402/05/20**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-11, 1402/05/20**

Update count: **0**

Registration date

2023-08-11, 1402/05/20

Registrant information

Name

Somayeh Daneshvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 8351

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somayedaneshvar@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Transcranial Direct Current Stimulation along with Affective Expectations Manipulation on Affective Experience and Anhedonia among Anhedonic Patients Suffering from Major Depression Disorder

Public title

Effect of Stimulation along with Affective Expectations Manipulation on Anhedonia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Obtaining the initial diagnosis of major depressive disorder with anhedonia using a structured clinical interview and questionnaire. The patient should be able to perform the behavioral test and answer the questionnaires.

Exclusion criteria:

The presence of comorbid disorders such as substance abuse, psychotic disorders, bipolar disorder, anxiety disorders, and psychotic symptoms. The presence of metal parts in the head

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of people to desired groups by simple random method and by lottery. For this purpose, we prepare three sheets on which we write the experimental groups. Then, with each patient's visit, one of the sheets is randomly removed and the patient is assigned to the selected group.

Blinding (investigator's opinion)

Double blinded

Blinding description

All the participants will be explained how the device works, and all individuals who participate in the study think that they will receive the intervention, however, some do not. In this way, after placing the transcranial direct current stimulation device on the subjects' heads, some receive actual stimulation, while others receive fake or sham stimulation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

5th floor, Shiraz University Central Building, Islamic Republic Blv, Shiraz

City

Shiraz

Province

Fars

Postal code

7194684471

Approval date

2023-05-28, 1402/03/07

Ethics committee reference number

IR.SUMS.REC.1402.088

Health conditions studied**1****Description of health condition studied**

Major Depression Disorder

ICD-10 code

F32.2

ICD-10 code description

Severe depressive episode without psychotic symptoms

Primary outcomes**1****Description**

Anhedonia

Timepoint

Before and after the intervention

Method of measurement

Positive Valence Systems Scale-21 questionnaire

Secondary outcomes**1****Description**

Probabilistic reward

Timepoint

Before and after the intervention

Method of measurement

Probabilistic reward task

Intervention groups

1

Description

Intervention group 1: transcranial direct current stimulation and then induction of positive emotions. In this group, the participants first receive electrical stimulation through one session, at the rate of 2 milliamps for 20 minutes, on the dorsomedial prefrontal cortex via the tDCS device, and then positive emotions will be induced. In this way, the short pleasurable video clip will be shown to the subject at the end of the stimulation. Before playing the movie, the positive emotional information about the movie will be presented to the subjects in order to manipulate the emotional expectations of the individuals.

Category

Treatment - Other

2

Description

Intervention group 2: Sham transcranial electrical stimulation then induction of positive emotions. In this group, during a session the participants first receive sham stimulation on the dorsomedial prefrontal cortex through the tDCS device, and then positive emotions are induced. In this way, at the end of the stimulation, the person will be shown the desired short pleasurable movie, and before playing the movie, in order to manipulate the emotional expectations of the person, positive emotional information about the movie will be presented to the person.

Category

Treatment - Other

3

Description

Intervention group 3: In this group, during a session the participants first receive electrical stimulation at the rate of 2 milliamps for 20 minutes on the dorsomedial prefrontal cortex through the tDCS device, and then neutral emotions are induced. In this way, at the end of the stimulation, the person will be shown the desired short pleasurable movie, and before playing the movie, neutral emotional information about the movie will be presented to the person.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Babak Hosseini

Street address

Chamran Blvd, Shiraz

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2

Recruitment center

Name of recruitment center

Ebne sina Hospital

Full name of responsible person

Ebrahim Moghimi Sarani

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Eighth Ave, Hafez Ave, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempur

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7th floor, central building of Shiraz University of Medical Sciences, Zand Ave

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۷۱۳۳۶- ۷۱۳۴۸

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vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Somayeh Daneshvar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Other areas of specialty/work

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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

All data can be shared in spss file format

When the data will become available and for how long

One month after results publication

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data can be used for any statistical analysis, subject to permission from the researchers

From where data/document is obtainable

E-mail address of the corresponding author

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

After request, the responsible author will send the data

within a maximum period of one month.

Comments