

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Psychotherapy plus: augmentation of metacognitive therapy with prefrontal transcranial direct current stimulation (tDCS) on depressive symptoms, rumination, and brain waves pattern based on quantitative analysis of the electroencephalogram (QEEG) in individuals with major depressive disorder- sham-controlled randomized double-blind study.

Protocol summary

Study aim

Investigating the effect of transcranial direct current stimulation along with the strengthening of psychotherapy (metacognitive therapy) on depressive symptoms and rumination in people with major depression.

Design

Control group with non-random selection, with 3 experimental groups, double-blind, 60 patients.

Settings and conduct

Patients are examined and interviewed by a psychiatrist. It was performed in Mehr Razavi Clinic in Mashhad

Participants/Inclusion and exclusion criteria

Male and female outpatients with the age range of 20 to 60 years with a diagnosis of depression are used for the study. Entry criteria Not having a history of participating in a metacognitive psychotherapy program; not having a history of epilepsy or convulsions; not having a history of shock therapy (ECT); having a score above 20 in the Beck depression questionnaire; not having acute suicide to participate in treatment sessions; Positive safety screening to perform tDCS. Exit criteria Third, substance abuse or dependence in the past 6 months (excluding nicotine, with current or past nicotine use); Psychotic disorders (lifelong) including schizoaffective disorders or depressive episodes with psychotic symptoms (lifelong); bipolar disorders (types I and II); Neurological disorders, such as stroke in the last 2 years, epileptic attacks (for life), epilepsy, dementia, Parkinson's, Huntington's, multiple sclerosis, as well as any other neurological disease that leads to increased intracranial pressure or increased risk of epileptic seizures; Not having a current risk of suicide, based on the researcher's personal assessment

Intervention groups

Enriched psychotherapy without TDCS, a psychotherapy group enriched with active TDCS, and a psychotherapy group enriched with inactive TDCS and a control group

Main outcome variables

Investigating the effectiveness of treating depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190812044515N1**

Registration date: **2023-08-28, 1402/06/06**

Registration timing: **retrospective**

Last update: **2023-08-28, 1402/06/06**

Update count: **0**

Registration date

2023-08-28, 1402/06/06

Registrant information

Name

Vahid Farahmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3891 9096

Email address

v_farahmand_psy@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2022-12-11, 1401/09/20

Actual recruitment start date

2022-12-01, 1401/09/10

Actual recruitment end date

2022-12-16, 1401/09/25

Trial completion date

empty

Scientific title

Psychotherapy plus: augmentation of metacognitive therapy with prefrontal transcranial direct current stimulation (tDCS) on depressive symptoms, rumination, and brain waves pattern based on quantitative analysis of the electroencephalogram (QEEG) in individuals with major depressive disorder- sham-controlled randomized double-blind study.

Public title

Investigating the effect of Tdcs on metacognitive therapy in the treatment of major depressed people

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Not having a history of participating in a metacognitive psychotherapy program. Not having a history of epilepsy or convulsions. Not having a history of shock therapy (ECT). Having a score above 20 in the Beck depression questionnaire. Not having acute suicidality to participate in treatment sessions. Positive safety screening to perform tDCS.

Exclusion criteria:

Substance abuse or dependence in the last 6 months (excluding nicotine, with current or past nicotine use) Psychotic disorders (lifelong) including schizoaffective disorders or depressive episodes with psychotic symptoms (lifelong) Bipolar disorders (types I and II) Neurological disorders, such as stroke in the last 2 years, epileptic attacks (for life), epilepsy, dementia, Parkinson's, Huntington's, multiple sclerosis, as well as any other neurological disease that leads to increased intracranial pressure or increased risk of epileptic seizures Not having a current risk of suicide, based on the researcher's personal assessment

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Randomization to two groups of active tDCS or sham is done in the second step through the random assignment of identifiers by an independent clinical physician who is not involved in the study. To reduce bias during data collection and assessment of clinical endpoints, double-blind tDCS treatment is used. All study personnel, metacognitive therapists, and patients will have no knowledge of whether the active state or sham state will be activated by the tDCS device. Patients are asked not to discuss stimulation with other members of the group.

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Islamic Azad University - Shahrood branch

Street address

University blvd

City

Shahrood

Province

Semnan

Postal code

36199-43189

Approval date

2023-08-12, 1402/05/21

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1402.018

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

depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Depression score

Timepoint

Measurement of depression at the beginning of the study and 10 sessions after the intervention and 30 days after the last visit session

Method of measurement

Beck Depression Questionnaire and Nelen Hoeksma Rumination Questionnaire

Secondary outcomes

1

Description

Rumination

Timepoint

At the beginning of the study and the last visit and 30 days after the last visit

Method of measurement

Nelen Hoeksma Rumination Questionnaire

Intervention groups

1

Description

The first intervention group: metacognitive therapy + Active-tDCS, in the above intervention, after the session entered the main part, i.e. the challenge with beliefs, real tDCS with a current whose anode electrode in the posterior-lateral prefrontal cortex of the left DLPC is equivalent to the F3 point in the -20 system. 10EEG and the cathode electrode is on the top of the cingulate cortex on the opposite side, it is activated. And the brand used is ActivaDosII.

Category

Treatment - Devices

2

Description

Intervention group: second intervention group: metacognition therapy + sham-tDCS, in the above intervention, after the session enters the main part, i.e. the challenge with beliefs, tDCS is inactive, in such a way that the location of the electrodes is the same as the anodic stimulation electrodes, with this difference For the initial itching sensation, the current was applied only in the first 30 seconds and then stopped during the test. And the brand used is ActivaDosII.

Category

Treatment - Devices

3

Description

Intervention group: The third intervention group: metacognitive therapy, metacognitive therapy group based on the practical guide of metacognitive treatment of anxiety and depression was implemented for eight

sessions of 90-120 minutes among the subjects of the experimental group.

Category

Treatment - Other

4

Description

Control group: They did not receive any intervention during the treatment period, but they were assured that after the end of the research period, therapeutic intervention will be used to help them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr Razavi Clinic

Full name of responsible person

Azam Hosseini

Street address

Between Vakil Abad 13 and 15

City

Mashad

Province

Razavi Khorasan

Postal code

9188869547

Phone

+98 51 3603 9545

Email

v_farahmand_psy@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Research assistant

Street address

University street

City

Shahrood

Province

Semnan

Postal code

36199-43189

Phone

+98 23 3239 4530

Email

info@iau-shahrood.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Shahnaz Nouhi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

University blvd

City

Shahrood

Province

Semnan

Postal code

36199-43189

Phone

0092332394530

Email

psynut.sh@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Shahnaz Nouhi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

University blvd

City

shahrood

Province

Semnan

Postal code

36199-43189

Phone

+98 23 3239 4530

Email

psynut.sh@gmail.com

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

Islamic Azad University

Full name of responsible person

Shahnaz Nouhi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

University blvd

City

Shahrood

Province

Semnan

Postal code

36199-43189

Phone

002332394530

Email

psynut.sh@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

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Keeping ethical issues in mind, all analyzes are unimpeded

From where data/document is obtainable

To receive data, they can correspond with the following email: v_farahmand_psy@yahoo.com

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

After sending the request to the mentioned email, according to the volume of the request, the request will be answered between 1 and 7 days

Comments