Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Optimization of transcranial stimulation protocol with direct flow on executive functions and reduction of symptoms in people with major depression

Protocol summary

Study aim

Comparison of the effectiveness of traditional and multichannel direct cranial stimulation (tDCS) and Sham tDCS on depressive symptoms, working memory in patients with cognitive flexibility, response inhibition, domain decision making, QEEG asymmetry regulation in patients with major depressive disorder

Design

A randomized, double-blind, randomized controlled clinical trial of 60 patients

Settings and conduct

This study will be performed in Beheshti Hospital clinic with transcranial stimulation method for 20 sessions.

Participants/Inclusion and exclusion criteria

 Having unipolar MDD diagnostic criteria based on (DSM-5) based on psychiatrist diagnosis and with psychological interview Do not take antidepressants now or have a regular medication regimen for the past 4 weeks. Number 17 on the Hamilton Depression Inventory .Exclusion criteria:Diagnosis of bipolar disorder Diagnosis of substance use or alcohol Detection of dementia Diagnosis of personality disorder.Diagnosis of brain injury, stroke or brain tumor.Existence or history of psychosis.Diagnosis of epilepsy or history of loss of consciousness

Intervention groups

Traditional transcranial stimulation: The anode is in the left dorsal prefrontal cortex (DLPFC) region (F3) and the cathode is in the right DLPFC region (F4) for 30 minutes and 20 days. Multichannel transcranial stimulation: It occurs in several networks of the brain for 30 minutes and 20 days. Control group: One of the significant points in clinical trials is the need for methods in which the degree of bias is minimized. In the protocols of the control group, the traditional transcranial stimulation method is used for this purpose.

Main outcome variables

Clinical signs of major depression; Executive function of people with major depression; Amplitude and coherence and asymmetry in the forehead cortex of people with major depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210517051330N1**
Registration date: **2021-06-20, 1400/03/30**
Registration timing: **prospective**

Last update: **2021-06-20, 1400/03/30**
Update count: **0**

Registration date

2021-06-20, 1400/03/30

Registrant information

Name

marzieh abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3354 4001

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Optimization of transcranial stimulation protocol with direct flow on executive functions and reduction of symptoms in people with major depression

Public title

Comparison of the effectiveness of traditional transcranial stimulation with multichannel extracranial stimulation on improving the clinical symptoms of people with major depression and improving their executive function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having diagnostic criteria for unipolar MDD based on psychiatrist diagnosis and clinical interview Age range between 75-18 years Failure to treat with at least one antidepressant Do not take antidepressants now or have a consistent medication regimen for the past 4 weeks Score 17 on the Hamilton Depression Inventory Willingness to participate in research Conscious consent to participate in research Have the opportunity to participate in evaluation and treatment sessions (daily) (in terms of distance, cost, etc.)

Exclusion criteria:

Diagnosis of bipolar disorder Diagnosis of substance use or alcohol Detection of dementia Diagnosis of personality disorder Diagnosis of brain injury, stroke or brain tumor Existence or history of psychosis Diagnosis of epilepsy or history of loss of consciousness Pregnancy Contraindications to the use of tDCS (cranial plates), such as those using a pacemaker. Currently or in the last 4 weeks the person has received another treatment for MDD (medication or other psychological treatments) Having diseases related to the scalp Having a history of head trauma and the presence of a device or tools in the head

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization Randomization unit: individual Randomization tool: Random number table How to make: First, the list of names of all members is obtained, then a score or number is assigned to each of them, and the required number is selected using a table of random numbers. Hiding: Using sealed envelopes in random order.

Blinding (investigator's opinion)

Double blinded

Blinding description

The subjects do not know the type of intervention. The patient receives the intervention in separate coded treatment rooms. No mirrors are installed on the patient's entrance and exit. Coding is done by one of the design partners. Patients do not see each other during the intervention. People who analyze the results do not know the nature of the study groups. The evaluation is done by someone other than the researcher.

Placebo

Used

Assignment

Parallel

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

Azadegan Square

City

Zanjan

Province

Zanjan

Postal code

45136-15788

Approval date

2021-05-25, 1400/03/04

Ethics committee reference number

IR.ZUMS.REC.1400.059

Health conditions studied

1

Description of health condition studied

Major Depression

ICD-10 code

F32.9

ICD-10 code description

Major depressive disorder, single episode, unspecified

Primary outcomes

1

Description
Percentage of people whose Beck questionnaire score is above 20
Timepoint
Measurement of depression before the intervention, in the tenth session of the intervention, after the intervention, one-month follow-up and three months after the intervention
Method of measurement
Beck Questionnaire

2

Description
Percentage of people whose Hamilton questionnaire score is above 17
Timepoint
Measurement before intervention, after the intervention, one-month follow-up and three months after the intervention
Method of measurement
Hamilton Depression Test

3

Description
Depression Score on the Montgomery–Åsberg Depression Rating Scale
Timepoint
Measurements before the intervention, after the intervention.one-month follow-up and three months after the intervention
Method of measurement
Montgomery–Åsberg Depression Rating Scale

4

Description
Cognitive test score in cantab test
Timepoint
Measurements before the intervention, after the intervention.one-month follow-up and three months after the intervention
Method of measurement
cantab test

5

Description
Analyze the electroencephalography results
Timepoint
Measurements before the intervention, after the intervention
Method of measurement
Electroencephalography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Traditional transcranial stimulation, in the treatment of direct current stimulation from the skull, two electrodes, one positive pole and the other negative pole, are placed on the head through a sponge pad soaked in conductive solution. Electric current by these electrodes reaches the surface of the cerebral cortex after passing through different areas (scalp, skull). The current that reaches this area charges the neurons with electricity and causes a positive and a negative pole, which leads to a change in the activity of that area.
Category
Treatment - Devices

2

Description
Intervention group: Intervention group: Group 2: Multichannel transcranial stimulation: Similar to the traditional method, except that smaller electrodes are used to stimulate networks and not just brain areas. Star Stim device is a combined electrical stimulation device with tape It is a brain that has 8 channels. This device has a cap that has designed 39 positions based on the 10-10 system to place the electrodes on the head. The electrodes include dry and wet gel carriers for electroencephalography, electrodes in different sizes for stimulation and combined electrodes, as well as reference electrodes. The software is related to this NIC device, which allows us to do so. Let us have an anodal study and also be able to include the sham group or the double-blind method in our studies.In this study, the stimulation is for 20 sessions of 30 minutes.
Category
Treatment - Devices

3

Description
Control group: Control group: A method to reduce bias in clinical trials that use brain stimulation therapies such as the traditional transcranial stimulation method. It is based on imitation of the same main treatment. Its duration is 30 minutes in the form of 30 seconds of ramp-up, 30 seconds of stimulation, 30 seconds of ramp down.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital Clinic
Full name of responsible person
Marzieh Abdi

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Ark Square. Shahid Beheshti Therapeutic and Psychiatric Education Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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
Marzieh Abdi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Outcomes and results are published in the form of statistics

When the data will become available and for how long

After publishing the article

To whom data/document is available

The data will be available to researchers

Under which criteria data/document could be used

Can be used for secondary studies

From where data/document is obtainable

marziehabdi@zums.ac.ir 09224863706

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

Will be sent after receiving the email

Comments

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