Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the effectiveness of dorsolateral prefrontal cortex transcranial direct current stimulation and modification of frontal alpha asymmetry in the prefrontal region on patients with major depressive disorder

Protocol summary

Study aim
Comparison of the effectiveness of dorsolateral prefrontal cortex transcranial direct current stimulation and modification of frontal alpha asymmetry in the prefrontal on patients with major depressive disorder

Design
Clinical trial with repeated measures, parallel-group, open-label, randomized on 46 patients, random list generator app used for randomization

Settings and conduct
The present clinical trial is open-label by convenience sampling method. participants are invited to study by online invitation. then participants will be assessed for the presence of depressive disorder and inclusion criteria using a semi-structured interview for Diagnostic and Statistical Manual of Mental Disorders. then they will be randomly assigned to two groups of 26 people. Group 1 will receive neurofeedback. The protocol will include 15 sessions of 20 minutes in the form of increasing beta waves in the range of 15-18 Hz and decreasing alpha waves in the range of 8-12 Hz in the F3 region. Group 2 will receive brain stimulation. The protocol will include 15 sessions of 20 minutes up to a maximum of 2 mA; The anode electrode will be on the F3 region and the cathode electrode will be on the F4. Questionnaires will be administered on Assessment Day, Session 5, Session 10, Session 15, and three months after the last session.

Participants/Inclusion and exclusion criteria
Age over 18 years Do not have any neurological disorders Absence of psychotic disorders Has not been on any medication or psychological treatment for up to 1 month before the start of the sessions Be right-handed Having depressive disorder

Intervention groups
The first group will receive stimulation on the dorsolateral prefrontal cortex, and the second group will receive neurofeedback treatment with alpha wave correction in the prefrontal cortex.

Main outcome variables
The severity of depression; feeling exhausted; Negative emotions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220316054306N1**
Registration date: **2022-04-04, 1401/01/15**
Registration timing: **prospective**

Last update: **2022-04-04, 1401/01/15**
Update count: **0**

Registration date
2022-04-04, 1401/01/15

Registrant information

Name
Shahab Lotfinia

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 23871

Email address
lotfiniashahab@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-09, 1401/01/20

Expected recruitment end date
2022-09-21, 1401/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of dorsolateral prefrontal cortex transcranial direct current stimulation and modification of frontal alpha asymmetry in the prefrontal region on patients with major depressive disorder

Public title
Comparison of the effect of dorsolateral prefrontal cortex stimulation and correction of asymmetry in alpha waves in depressive disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 18 years Do not have any neurological disorders Absence of psychotic disorders Has not been on any medication or psychological treatment for up to 1 month before the start of the sessions Be right hand Having depressive disorder based on a semi-structured interview
Exclusion criteria:
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
A code will be assigned to the people entering the study, and then each code will be randomly assigned to a group using the random list generator tool.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Shahid Beheshti University of Medical Science
Street address
Bldg No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2022-03-12, 1400/12/21
Ethics committee reference number
IR.SBMU.MSP.REC.1400.829

Health conditions studied

1

Description of health condition studied
Major depressive disorder
ICD-10 code
F32
ICD-10 code description
Major depressive disorder, single episode

Primary outcomes

1

Description
Depression score in Beck Depression Inventory
Timepoint
Before the study, in sessions 5, 10, 15 and three months after the last session
Method of measurement
Using Beck Depression Inventory

2

Description
Negetive and positive affects based on scores on positive and negative affect schedule
Timepoint
Before the study, in sessions 5, 10, 15 and three months after the last session
Method of measurement
Positive and Negative Affect Schedule

3

Description
Fatigue based on multidimensional fatigue inventory
Timepoint

Before the study, in sessions 5, 10, 15 and three months after the last session

Method of measurement

Multidimensional Fatigue Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Neurofeedback protocol will include 15 sessions of 20 minutes (3 sessions per week) in the form of increasing beta waves in the range of 18-15 Hz and decreasing alpha waves in the range of 8-12 Hz in the F3 region.

Category

Treatment - Devices

2

Description

Intervention group 2: Stimulation protocol will include 15 sessions of 20 minutes (3 sessions per week) up to a maximum of 2 mA; The anode electrode will be on the F3 region and the cathode electrode will be on the F4.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

Shahab lotfinia

Street address

Ayatollah Taleghani Hospital, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2303 1111

Email

taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9770

Email

Intl_office@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahab

Position

دانشجو دکتری

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

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Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9770

Email

lotfiniashahab@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Shahab

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

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

Clinical Study Report
Undecided - It is not yet known if there will be 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