Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of transcranial direct current stimulation on neurocognition in patients with type 1 bipolar disorder.

Protocol summary

Study aim
Determining the extent of improvement of cognitive abilities and brain signals by stimulating extracranial direct current in patients with bipolar disorder and healthy individuals

Design
The present study is a clinical trial with pre-test, post-test and follow-up. The statistical sample of this study is 45 people and they will be randomly assigned to three groups of 15. Random allocation is done by dividing the participants into target groups

Settings and conduct
Location of Beheshti Hospital - non-identical examiner and therapist - pre-test, post-test and quarterly follow-up

Participants/Inclusion and exclusion criteria
Inclusion criteria are: 1_ having an age of at least 18 and a maximum of 65 years 2_ having a diagnosis of bipolar disorder type 1 3 - patients in the euthemic phase of their disorder 4 Drug use and dependence 2_ Having a history of neurological diseases 3_ Having a disease related to the scalp 4_ Having a history of head trauma 5_ Having a device or tool in the head

Intervention groups
Cranial direct current stimulation (tDCS) treatment program with electrodes 35 cm in size and 2 mA intensity for 10 sessions of 20 minutes in 3 consecutive weeks for two groups, the first group tDCS (anode in L-DLPFC, cathode in (L -TPC, the same protocol will be implemented in the second group (Sham-tDCS) for forty seconds. Also in the third group, which is healthy people, the same protocol will be performed in the experimental group. Run and after three months the same tools will be run again on the subjects

Main outcome variables
attention, improve spatial visual memory, executive function, delay recognition, brain signals, brain information processing fluid

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210608051514N3**
Registration date: **2022-05-15, 1401/02/25**
Registration timing: **prospective**

Last update: **2022-05-15, 1401/02/25**
Update count: **0**

Registration date
2022-05-15, 1401/02/25

Registrant information
Name
farahnaz yousefi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-06-11, 1401/03/21
Expected recruitment end date
2023-06-11, 1402/03/21
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effectiveness of transcranial direct current stimulation on neurocognition in patients with type 1 bipolar disorder.

Public title
Treatment of patients with type 1 bipolar disorder: clinical trial a double-blind study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a diagnosis of bipolar disorder type one Being in the euthanic phase based on assessment The same dose and medicine Stabilization in medical treatment for at least 4 weeks Stabilization of drug and medicine dose during research
Exclusion criteria:
Having drug use and dependence up to 6 months before treatment Having a history of neurological diseases Having diseases related to the scalp Having a history of head injuries The presence of a device or tool in the head Exclude from the study after absence in two consecutive sessions of treatment Being left-handed
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Subjects are selected from purposive sampling method and using simple randomization method, based on which the subjects are assigned to the two groups of control and experiment by tossing coins.This method is used for two-group clinical trials, according to which one group is called a lion, and the other is called a line, and thus the number of coin samples is tossed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the clinical evaluator and therapist will be blind to assigning subjects to control and experimental groups. In addition, we use the clinical evaluator separately for baseline assessments and follow-up, and the therapist separately for treatment.Subjects will also be assigned to control groups or blind experiments, so that subjects will not meet outside of the sessions and will visit at times when no other subjects will be present.
Placebo
Not 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
Shahid Beheshti Hospital, Ark Gate, Saadi Crossroads, Zanjan Province
City
zanjan
Province
Zanjan
Postal code
8431575143
Approval date
2022-05-02, 1401/02/12
Ethics committee reference number
IR.ZUMS.REC.1401.049

Health conditions studied

1

Description of health condition studied
Bipolar disorder type 1
ICD-10 code
اختلال دو
ICD-10 code description
F39

2

Description of health condition studied
Bipolar disorder type 1, mania, manic depression, bipolar depression
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Executive performance: Executive performance refers to the ability to integrate thought and action to achieve a goal
Timepoint
pre test_post test_3mounth follow up
Method of measurement
The score that a person gets from the second part of the sequence test

2

Description

Spatial visual memory: means the ability to store and manipulate information in consciousness for a short period of time

Timepoint

pre test_post test_3mounth follow up

Method of measurement

The score that a person gets from the test of complex images

3

Description

Delayed Recognition: The ability to retrieve specific information after a period of time or distraction

Timepoint

pre test_post test_3mounth follow up

Method of measurement

The score that a person gets from the test of complex images

Secondary outcomes

1

Description

Attention is a cognitive process in which the mind focuses on a specific stimulus or stimuli from the environment and other environmental stimuli are ignored.

Timepoint

pre test_post test_3mounth follow up

Method of measurement

The score that a person gets from the sequence test in the first part

Intervention groups

1

Description

Intervention group: Treatment with stimulation of transcranial direct current stimulation with a cintensity of 2 mA for 20 minutes on the lateral dorsal forehead cortex will receive 10 sessions of 20 minutes in 3 consecutive weeks.

Category

Treatment - Other

2

Description

Control group: Intervention group: Treatment with stimulation of transcranial direct current stimulation with a cintensity of 2 mA for 40 seconds on the lateral dorsal forehead cortex will receive 10 sessions of 20 minutes in 3 consecutive

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Educational and Medical Center in Zanjan

Full name of responsible person

Dear Dr. Ramin Maleki

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Shahid Beheshti Hospital, Ark Gate, Saadi Crossroads, Zanjan Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

40

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
Omidreza Heidari
Position
Teaching assistant
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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
No - There is not 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
All information of individuals except names and confidential information will be published at the end of the research. Publishable information including: therapeutic changes, results of questionnaires, statistical results of signal analysis, dose and medication used
When the data will become available and for how long
The results of this research will be published three months after the end of the research
To whom data/document is available
All researchers, researchers, colleagues, and others
Under which criteria data/document could be used
To carry out similar projects and if all the material and intellectual rights of researchers are observed.
From where data/document is obtainable
Contact the following email address to receive the documentation: Farahnaz Yousefi Master of Clinical Psychology farahnaz.yosefi76@gmail.com Address: Beheshti Hospital, Ark Gate, Chahar Ra Saadi, Zanjan Province

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

The data will be provided to the applicant after receiving the e-mail of the applicant and observing the material and intellectual rights of the researchers.

Comments