

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Country

Iran (Islamic Republic of)

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+98 24 23345

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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.		Secondary Ids	
		empty	
Public title		Ethics committees	
Treatment of patients with type 1 bipolar disorder: clinical trial a double-blind study		1	
Purpose		Ethics committee	
Treatment		Name of ethics committee	
Inclusion/Exclusion criteria		Ethics Committee of Zanjan University of Medical Sciences	
Inclusion criteria:		Street address	
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		Shahid Beheshti Hospital, Ark Gate, Saadi Crossroads, Zanjan Province	
Exclusion criteria:		City	
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		zanjan	
Age		Province	
From 18 years old to 65 years old		Zanjan	
Gender		Postal code	
Both		8431575143	
Phase		Approval date	
N/A		2022-05-02, 1401/02/12	
Groups that have been masked		Ethics committee reference number	
- Participant - Investigator		IR.ZUMS.REC.1401.049	
Sample size		Health conditions studied	
Target sample size: 60		1	
Randomization (investigator's opinion)		Description of health condition studied	
Randomized		Bipolar disorder type 1	
Randomization description		ICD-10 code	
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.		اختلال دو	
Blinding (investigator's opinion)		ICD-10 code description	
Double blinded		F39	
Blinding description		2	
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.		Description of health condition studied	
Placebo		Bipolar disorder type 1, mania, manic depression, bipolar depression	
Not used		ICD-10 code	
Assignment		ICD-10 code description	
Parallel		Primary outcomes	
Other design features		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 Zanzan

Full name of responsible person

Dear Dr. Ramin Maleki

Street address

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanzan University of Medical Sciences

Full name of responsible person

Dr. Parviz Ghezelbash

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Web page address

https://zums.ac.ir/cv/2524/%d9%be%d8%b1%d9%88%db%8c%d8%b2-%d9%82%d8%b2%d9%84%d8%a8%d8%a7%d8%b4

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanzan 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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Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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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

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