

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Aug 2026

Comparison of the Effectiveness of Combined Transcranial Direct Current Stimulation (tDCS) with Pharmacotherapy and Pharmacotherapy on Depression, Emotion Regulation, Response Inhibition, Problem Solving in Patients with Bipolar Disorders

Protocol summary

Study aim

Comparison of the Effectiveness of Combined Transcranial Direct Current Stimulation (tDCS) with Pharmacotherapy and Pharmacotherapy on Depression, Emotion Regulation, Response Inhibition, Problem Solving in Patients with Bipolar Disorders

Design

The present study is a clinical trial with pre-test, post-test and parallel group that will be randomized.

Settings and conduct

Samples are cited by a psychiatrist as per the admission criteria and, if not included in the exclusion criteria, enter the experimental groups. Then, after obtaining informed consent to participate in the research, the Hamilton Depression Rating Scale, the Gross Emotion Regulation Questionnaire, the GO no GO test and Tower of London are presented. The tDCS treatment program is then administered to the experimental group for 10 sessions of 20 minutes. The drug group will receive psychiatric drugs. It should be noted that the samples will not be admitted to the outpatient ward and referred to an outpatient psychiatrist's office, as well as the medications received by the psychiatrist from a medication category and in fact no significant differences in the medications as far as possible. Groups should be homogenous in this regard. After the intervention, the questionnaires and re-evaluation tests, as well as three months after the intervention, will be conducted to follow up the results. In order to prevent bias, the patient will be evaluated by someone other than the therapist.

Participants/Inclusion and exclusion criteria

Type 1 bipolar disorder with psychiatrist diagnosis

Intervention groups

Combination Transcranial Direct Current Stimulation (tDCS) with Pharmacotherapy Group. and Pharmacotherapy Group

Main outcome variables

Depression, Emotion Regulation, Response Inhibition, Problem Solving

General information

Reason for update

The present study was performed in a double-blind type and the researcher considered it necessary to update it.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191229045931N1**

Registration date: **2020-08-24, 1399/06/03**

Registration timing: **retrospective**

Last update: **2022-07-11, 1401/04/20**

Update count: **2**

Registration date

2020-08-24, 1399/06/03

Registrant information

Name

Elnaz Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Combined Transcranial Direct Current Stimulation (tDCS) with Pharmacotherapy and Pharmacotherapy on Depression, Emotion Regulation, Response Inhibition, Problem Solving in Patients with Bipolar Disorders

Public title

Effectiveness of Combined Transcranial Direct current Stimulation (tDCS) with Pharmacotherapy and Pharmacotherapy in Bipolar Disorders

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Type 1 bipolar disorder at the discretion of a psychiatrist
Willingness to participate in research
Age range minimum 18 and maximum 50 years
At least third grade education
No severe psychiatric disorders such as psychotic disorders and cognitive impairment
Lack of history of epileptic seizures and history of head injury
Failure to receive psychological and technological therapies at least one month before entering the study

Exclusion criteria:

Severe psychiatric disorders such as psychotic disorders and cognitive impairment
History of epileptic seizures and history of head injury
Consumption of drugs and alcohol
Existence of suicidal thoughts
Existence of rapid cycles of mania

AgeFrom **18 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

Random Number Generator v1.3 program will be used to assign sample members to two experimental groups. In this way, the number of sample people is given to this software and this program randomly places each number in a group according to its function.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the evaluator and the therapist are

separated and blinded, so that the therapist does not know how to evaluate and they are separated from each other.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of ZanzanUniversity of Medical Sciences

Street address

Ark Square, Shahid Beheshti Hospital, Department of Clinical Psychology, Zanzan, Iran

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1452488552

Approval date

2020-02-05, 1398/11/16

Ethics committee reference number

IR.ZUMS.REC.1398.452

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

It is a bipolar disorder

ICD-10 code

F31.4

ICD-10 code description

Bipolar disorder, current episode depressed, severe, without psychotic features

Primary outcomes**1****Description**

Depression

Timepoint

10 day and 3 month

Method of measurement

Hamilton Depression Scale

2**Description**

Emotion Regulation

Timepoint

10 day and 3 month

Method of measurement

Grass emotion regulation questionnaire

3

Description

Response Inhibition

Timepoint

10 day and 3 month

Method of measurement

GO no GO test

4

Description

Problem Solving

Timepoint

10 day and 3 month

Method of measurement

the tower of London

Secondary outcomes

1

Description

impulsivity

Timepoint

10 day and 3 month

Method of measurement

The Bart impulsivity scale

Intervention groups

1

Description

Intervention Group: Combination of tDCS and medication: The tDCS treatment program was performed for 10 sessions of 20 minutes (F3) and (F4) for the experimental group. The electric current by these electrodes, after passing through different areas (scalp, skull, etc.), reaches the surface of the cerebral cortex. The current that reaches this area charges the neurons. It is electrified and causes positive and negative poles, which leads to a change in the activity of that area.

Category

Treatment - Devices

2

Description

Intervention group: Medication: Mood stabilizing drugs will be prescribed by a psychiatrist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Seyedeh Elnaz Mousavi

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Ark Square, Shahid Beheshti Hospital, Department of Clinical Psychology, Zanjan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Research Zanjan University of Medical Sciences.

Full name of responsible person

Dr Alireza Shoghli

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Grant name

Grant code / Reference number

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

No

Title of funding source

No funding

Proportion provided by this source

1

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

Seyedeh Elnaz Mousavi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

"No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available