Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 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 droge 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

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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
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target 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 ZanjanUniversity of Medical Sciences
Street address
Ark Square, Shahid Beheshti Hospital, Department of Clinical Psychology, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
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
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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