Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Title: The Effectiveness of tDCS over the DLPFC on reducing clinical symptomsimproving working memory and aberrant EEG functional connectivity in resting state schizophrenia patients: double-blind randomized controlled trial

Protocol summary

Study aim
Determining the rate of reduction of clinical symptoms, improvement of cognitive abilities and defective connections by stimulating direct current on the skull tDCS (anode in L-DLPFC, cathode in (L-TPC) and Sham_ tDCS in patients with schizophrenia.

Design
The present study is a clinical trial with pre-test, post-test and follow-up. The statistical population of this study is 30 people and they will be randomly assigned to two groups of 15. Random allocation is done by dividing the participants into target groups

Settings and conduct
Location of Beheshti Hospital - non-uniform examiner and therapist - pre-test, post-test and one and three month follow-up

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having a diagnosis of schizophrenia according to the criteria of the diagnostic and statistical guidelines of mental disorders version 5 - all patients experience positive symptoms despite a month of stabilization in the drug dose - the same dose and drug - being a man - being right - age 65-18 years. Exclusion criteria: having a history of suicide and abuse of alcohol and drugs _ having a history of neurological diseases, trauma to the head and the presence of a device or tools in the head.

Intervention groups
Direct cranial stimulation (tDCS) treatment program with electrodes 35 cm in size and 2 mA intensity for 10 sessions of 20 minutes in 5 working days with two sessions a day 2 hours apart for both groups, the first group of tDCS (anode In L-DLPFC, the cathode in (L-TPC, the same protocol in the second group (Sham-tDCS) will be run for forty seconds and after the sessions all the instruments will run again in the post-test and after three months The same tools will be run on the subjects again

Main outcome variables
Improving working memory; Improving defective brain waves; Improve positive symptoms; Improve negative symptoms, improve quality of life score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210608051514N1**
Registration date: **2021-06-20, 1400/03/30**
Registration timing: **prospective**

Last update: **2021-06-20, 1400/03/30**
Update count: **0**

Registration date
2021-06-20, 1400/03/30

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
2021-07-23, 1400/05/01

Expected recruitment end date
2021-10-23, 1400/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Title: The Effectiveness of tDCS over the DLPFC on reducing clinical symptomsimproving working memory and aberrant EEG functional connectivity in resting state schizophrenia patients: double-blind randomized controlled trial

Public title
treatment schizophrenia patients: double-blind randomized controlled trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a diagnosis of schizophrenia Having the ability to write informed consent Experience positive symptoms despite a month of stabilization in medication dose The same dose and medicine Being a man Being right-handed Age 65_18 years The dose of antipsychotic medication used by the person is constant at the beginning and during the research Stabilization in drug treatment for at least 6 weeks
Exclusion criteria:
Have a history of suicide and abuse of alcohol and substances other than caffeine and tobacco in the past month Have a history of neurological diseases such as Parkinson's, epilepsy, seizures, stroke and cardiovascular problems Having diseases related to the scalp Having a history of head trauma and the presence of a device or tool in the head Withdrawal from the study after absence in two consecutive sessions of treatment.
Age
From **18 years** old to **65 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**
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
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Postal code
8431575143
Approval date
2021-05-25, 1400/03/04
Ethics committee reference number
IR.ZUMS.REC.1400.058

Health conditions studied

1

Description of health condition studied
schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Negative symptoms:Theoretical definition: It is one of the clinical symptoms in schizophrenia that includes superficial emotion, poor speech, lack of motivation,

unhappiness and social transgression.Operational definition: The score that a person gets from the positive and negative symptoms of schizophrenia.Positive symptoms: Theoretical definition includes delusions, delusions, disturbed speech, and disturbed behavior that persist throughout a one-month period.Operational definition: The score that a person gets from the positive and negative symptoms of schizophrenia.

Timepoint

Pre-test-post-test-one-month follow-up-quarterly follow-up

Method of measurement

The score that a person gets from the questionnaire for measuring positive and negative symptoms in schizophrenia.

Secondary outcomes

1

Description

Working memory:Theoretical definition: means the ability to store and manipulate information in memory, which is an essential prerequisite for complex cognitive tasks such as learning, reasoning and comprehension.

Timepoint

Pre-test-post-test-one-month follow-up-quarterly follow-up

Method of measurement

The score a person gets from the n back test.

Intervention groups

1

Description

Intervention group: Treatment with stimulation of extracranial direct current with a current of 2 mA for 20 minutes on the lateral dorsal forehead cortex will receive ten sessions for five days and two sessions a day.

Category

Treatment - Other

2

Description

Control group: Treatment with stimulation of extracranial direct current with a current intensity of two milliamperes for 40 seconds on the lateral dorsal forehead cortex will receive ten sessions for five days and two sessions daily.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Men's emergency department of Shahidاستان زنجان

Full name of responsible person

Dear Dr. Ramin Maleki

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Sponsors / Funding sources

1

Sponsor

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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

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
Zanjan University of Medical Sciences

Full name of responsible person
Dr. Mohsen Dadashi

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)
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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is 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: Department of Clinical Psychology and Psychiatry, 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