

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Determination of therapeutic effect of tDCS in schizophrenic patients with predominant negative symptoms

Protocol summary

Study aim

Efficacy of transcranial direct stimulation in schizophrenia patients with dominant negative symptoms

Design

A clinical trial with real and sham stimulation groups, with parallel, double blind and randomized groups. Sample size was estimated using G power software with an effect size of 0.61 and alpha of 0.05 and 40 individuals. This number of samples is consistent with what has been stated in the research literature. A sample of 40 schizophrenic patients with predominant negative symptoms was randomly assigned to the 20 binary blocks of AB by the supervisor in two groups of 20 randomly assigned to the Web.

Settings and conduct

The study will be conducted at Zanjan University of Medical Sciences. Also In this study, participants and data analyzer will not be aware of the randomization process.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Ages 18 to 65 years People with DSM5 who have been diagnosed with schizophrenia and have predominantly negative symptoms. 3. Patients undergoing constant antipsychotic regimen for at least 4 weeks. Exclusion criteria: 1. Dependence on materials 2. Concurrent psychiatric disorder (including suicidal individuals) 3. Neurological diseases such as seizures, strokes, or cerebrovascular diseases 4. Physical illness such as malignancy, heart attack infection 5. Pregnancy 6. The existence of metal implants in the body 7. Skin disease involving scalp

Intervention groups

The first group received real tDCS intervention, the second group received placebo tDCS intervention.

Main outcome variables

Negative symptoms, positive symptoms, and degree of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200203046366N1**

Registration date: **2020-10-29, 1399/08/08**

Registration timing: **retrospective**

Last update: **2020-10-29, 1399/08/08**

Update count: **0**

Registration date

2020-10-29, 1399/08/08

Registrant information

Name

parya jalili khiavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3354 4002

Email address

dr.parya.jalili@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-20, 1398/03/30

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

2019-06-21, 1398/03/31

Actual recruitment end date

2019-08-22, 1398/05/31

Trial completion date

2019-11-21, 1398/08/30

Scientific title

Determination of therapeutic effect of tDCS in schizophrenic patients with predominant negative symptoms

Public title

Efficacy of transcranial direct current stimulation(tDCS) on schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People diagnosed with schizophrenia on the basis of DSM5 Patients receiving fixed antipsychotic treatment regimen for at least 4 weeks

Exclusion criteria:

1-substance dependency comorbid psychiatric disorder(including suicidal individuals) neurologic diseases such as epilepsy,CVA or cerebral vessels disease physical disease such as malignancy,infections and heart failure, pregnancy, the existence of a metal implant in the body and skin disease involving scalp

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyzer

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization, individual, layered, statistical software. A sample of 40 schizophrenic patients with dominant negative symptoms by random sampling available on the web at <https://www.sealedenvelope.com>, The number of 20 binary blocks AB is assigned by the supervisor in two groups of 20.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients do not know in which intervention group AB (real and sham intervention) are. 2- Data analysis is performed by the data analyzer. As they are not aware of the nature of the groups AB. All data will be encrypted.

Placebo

Used

Assignment

Parallel

Other design features

This clinical trial consists of two groups: real and sham intervention, double blind and randomized.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Azadi Square, Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

45136-15788

Approval date

2019-06-10, 1398/03/20

Ethics committee reference number

IR.ZUMS.REC.1398.102

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20-F29

ICD-10 code description

Schizophrenia, schizotypal and delusional disorders

Primary outcomes

1

Description

Positive and negative symptoms of schizophrenia

Timepoint

Pre-test, Post-test and follow up (one month after post-test)

Method of measurement

Positive and Negative Syndrome Scale

2

Description

Negative Symptoms

Timepoint

Pre-test, Post-test and follow up (one month after post-test)

Method of measurement

Scale for the Assessment of Negative Symptoms

3

Description

Depression

Timepoint

Pre-test, Post-test and follow up (one month after post-test)

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Actual excitation of 2 mA for 20 minutes and placement of the cathode electrode in the left DLPFC and anode in the patient's right Orbito Frontal. The intervention consists of 15 sessions per day.

Category

Rehabilitation

2

Description

Intervention group: The 2 mA stimulation is stopped after 60 seconds of the cathode electrode in the left DLPFC and the anode in the patient's right Orbito Frontal, the intervention consisting of 15 treatment sessions per day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Medical Center

Full name of responsible person

Priya Jalili Khiyavi

Street address

Ark Gate - Dr. Beheshti Hospital

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Web page address

http://zums.ac.ir/index.php?slc_lang=fa&sid=29

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shogli

Street address

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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

Parya Jalili Khiavi

Position

Resident of Psychiatry

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Parya Jalili Khiavi

Position

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Web page address

<http://zums.ac.ir/>

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

Not applicable

Title and more details about the data/document

All of information related to main outcome will be published.

When the data will become available and for how long

Start the access period from 2020

To whom data/document is available

Researchers and clinicians working in academic and scientific institutions

Under which criteria data/document could be used

Access to documents is possible to inform other researchers and clinicians. Access to documents is possible to work with the researcher.

From where data/document is obtainable

Zanjan Shahid Beheshti Hospital Psychiatry Department, Dr. Mina Shabani, Mobile: 0912744589 Zanjan Shahid Beheshti Hospital Psychiatry Department, Priya Jalili Khayavi, Mobile: 09144554389

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

Documents will be shared only when the reason for the request is announced by phone or e-mail. Response time is seven days.

Comments