Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effectiveness of Transcranial direct current stimulation on reducing positive symptoms of schizophrenic patients and improving their quality of life

Protocol summary

Study aim
Investigating the effectiveness of TDCS on reducing positive symptoms and improving the quality of life in people with schizophrenia and the durability of its effect in one month of not receiving electrical stimulation

Design
non-randomized, single-blinded, sham-controlled clinical trial, phase-II clinical trial with 40 patients

Settings and conduct
the patients were admitted to Razi Psychiatric Hospital in Tehran, Iran. 40 eligible participants will be included and divided into two experimental and control groups. The participants in the intervention group received 10 times stimulation for 20 minutes on five consecutive days in two sessions with a current of 2 mA and assembly of the anode in the F3 area and the cathode in the T3 area. No intervention was provided in the control group.

Participants/Inclusion and exclusion criteria
inclusion criteria include: Schizophrenia diagnosis based on DSM-5 criteria by a psychiatrist Having a history of multiple hospitalizations Two weeks have passed since the last hospitalization Being literate in reading and writing Exclusion criteria include: Psychoses caused by drug =use History of epilepsy, brain surgery, intracranial metal implantation, concussion History of ECT

Intervention groups
The participants in the intervention group received ten sessions of stimulation for 20 minutes on five consecutive days in two sessions in the morning and in the afternoon with a current of 2 mA and assembly of the anode in the F3 area and the cathode in the T3 area. Participants in the control group did not receive any intervention.

Main outcome variables
Schizophrenia's Positive Symptoms; The Patient's Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221227056947N1**
Registration date: **2023-09-05, 1402/06/14**
Registration timing: **prospective**

Last update: **2023-09-05, 1402/06/14**
Update count: **0**

Registration date
2023-09-05, 1402/06/14

Registrant information

Name
Milad Kadkhoda

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-03-20, 1403/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of Transcranial direct current stimulation on reducing positive symptoms of schizophrenic patients and improving their quality of life

Public title
Investigating the effectiveness of transcranial direct current stimulation in schizophrenic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Schizophrenia diagnosis by a psychiatrist based on DSM-5 criteria Having a history of multiple hospitalizations 2 weeks have passed since the last hospitalization literate in reading and writing
Exclusion criteria:
Psychoses caused by drug use History of epilepsy History of Brain Surgery Intracranial metal implantation Clinically significant concussion History of having ECT
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
This study was single-blinded and full explanations about the treatment process are given to the patients. However an explanation about which patients belong to the experimental or control group will not be given.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of University of Social Welfare and Rehabilitation Sciences
Street address
University of Rehabilitation Sciences and Social Health Tehran, Koodakyar Deadend, Daneshju Blvd, Evin.
City
Tehran
Province
Tehran
Postal code
1985713834
Approval date
2023-08-22, 1402/05/31
Ethics committee reference number
IR.USWR.REC.1402.092

Health conditions studied

1

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

Primary outcomes

1

Description
Positive symptoms of schizophrenia
Timepoint
The positive and negative syndrom Scale was completed by the subjects in 3 stages, at the beginning of the study, after the implementation of the treatment protocol and one month after the intervention in order to evaluate the effect of the intervention before and after the treatment protocole and check the effects of the treatment over time.
Method of measurement
Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

1

Description
The Quality of Life Score
Timepoint
The World Health Organization Quality of Life - Brief (WHOQoL-Bref) Scale was completed by the subjects in 3 stages, at the beginning of the study, after the implementation of the treatment protocol, and one month after the intervention in order to evaluate the effect of the intervention before and after the treatment protocol and check the effects of the treatment over time.
Method of measurement
World Health Organization Quality of Life - Brief (WHOQoL-Bref)

Intervention groups

1

Description
Intervention group: The participants in the intervention group received 10 sessions of stimulation for 20 minutes on five consecutive days in two sessions in the morning and in the afternoon with a current of 2 mA and assembly of the anode in the F3 area and the cathode on the T3 area.
Category
Treatment - Devices

2

Description
Control group: The participants in the control group, like the intervention group, consisted of treatment-resistant schizophrenic patients who Recieve sham intervention.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Psychiatric Hospital
Full name of responsible person
Fereshteh Mo'meni
Street address
Razi Psychiatry Training and Treatment Center, Shahid Rostgar Blvd, Taghi Abad Road, Shahreri, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Ali Nazeri
Street address
Shahid Chahardehi Building, Razi Psychiatry Training Center, Shahid Rostgar Blvd, Varamin Road, Shahrerei, Tehran
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Fax
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Email
psychosisrc@uswr.ac.ir
Web page address
https://psychosis.uswr.ac.ir/
Grant name
Grant code / Reference number
1865
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Psychosis research center
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
University of social welfare and rehabilitation sciences
Full name of responsible person
Fereshteh Mo'meni
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
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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
There is no further information.

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
No - There is not a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All data except the part directly related to the disorder itself, along with the duration of the disease, the number of hospitalizations, the severity of the disease, and the questionnaires given to the patient can be cited. Things such as age, gender, and the department in which they are admitted cannot be cited or shared.

When the data will become available and for how long
Once the sampling is complete, the data is usable for 6 months.

To whom data/document is available
1. Members of the practical board of Universities 2. People who work in research centers affiliated to the Ministry of Science or Health 3. Ph.D. students in the field of psychology or psychiatry interns

Under which criteria data/document could be used
If the purpose of using the data is for educational and research purposes, the data can be shared.

From where data/document is obtainable
Applicants can contact the responsible author, Dr. Fereshte Momeni, via e-mail to receive the data.

What processes are involved for a request to access data/document
In this process, the applicant sends an email to the responsible author and requests for the data to be sent. In the e-mail, they should provide a full introduction of themselves and organizational affiliations, alongside a CV (if it's possible), the purpose of the request, and the use of the data. if the responsible author agrees with the request, this issue will be discussed with the Psychosis Research Center, and if the research team approves and provides permission, this data will be sent.

Comments