Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the Effectiveness of Computer-Based Cognitive Rehabilitation and Transcranial Direct Current Stimulation (tDCS) on Improving Cognitive Functions in Patients with Chronic Schizophrenia

Protocol summary

Study aim

The aim of this study is to compare the effectiveness of computer-based cognitive rehabilitation and transcranial direct current stimulation (tDCS) in improving cognitive functions, including attention, working memory, response inhibition, and impulse control, in patients with schizophrenia.

Design

This study is a randomized, single-blind, three-arm clinical trial (cognitive rehabilitation, tDCS, and control) with a parallel design. Fifty-four patients will be randomly assigned using block randomization stratified by age and gender through SPSS version 26, with allocation concealed in sealed opaque envelopes.

Settings and conduct

The study will be conducted at a rehabilitation center for patients with chronic psychiatric disorders. After screening, participants will be randomly assigned to one of three groups: cognitive rehabilitation, tDCS, or control. Sessions will be conducted by a trained therapist in a quiet setting, and participants will be blinded to group allocation (single-blind design).

Participants/Inclusion and exclusion criteria

Participants were patients with schizophrenia spectrum disorder aged 20 to 60 years who were clinically stable and provided informed consent. Those with severe neurological or cognitive disorders, brain injury, epilepsy, or acute psychotic episodes were excluded.

Intervention groups

Participants were randomly assigned to three groups: the first received computer-based cognitive rehabilitation using the Captain's Log software, the second underwent transcranial direct current stimulation (tDCS), and the control group received only routine pharmacological treatment and standard care.

Main outcome variables

Improvement of cognitive functions including attention, working memory, response inhibition, cognitive flexibility, and impulse control; reduction of positive and negative symptoms of schizophrenia.

General information

Reason for update

Acronym

CCRT-tDCS Study

IRCT registration information

IRCT registration number: **IRCT20240521061854N2**
Registration date: **2025-11-19, 1404/08/28**
Registration timing: **prospective**

Last update: **2025-11-19, 1404/08/28**
Update count: **0**

Registration date

2025-11-19, 1404/08/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-12, 1404/09/21

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Computer-Based Cognitive Rehabilitation and Transcranial Direct Current Stimulation (tDCS) on Improving Cognitive Functions in Patients with Chronic Schizophrenia

Public title
Comparison of the effectiveness of computer-based cognitive rehabilitation and transcranial direct current stimulation on cognitive functions in patients with schizophrenia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 and 60 years basic literacy in reading and writing definite diagnosis of schizophrenia spectrum disorder based on DSM-5 criteria and confirmed by a psychiatrist at least one year since disease onset and hospitalization stable medication regimen and clinical stability during the past three months (no medication change and stable psychotic symptoms) no history of major neurological or cognitive disorders, epilepsy, brain injury, or intellectual disability ability to participate and cooperate in cognitive rehabilitation sessions and cognitive assessments providing informed consent by the patient or legal guardian and obtaining institutional approval for participation
Exclusion criteria:
Presence of major neurological or cognitive disorders such as epilepsy, brain injury, or intellectual disability Current or recent (within the past six months) substance abuse or alcohol dependence Clinical instability or recent changes in antipsychotic medication during the past three months Presence of severe or disabling physical illness that prevents participation in therapeutic sessions or study assessments Inability to read, write, or understand test instructions and cognitive rehabilitation tasks Dominant psychiatric comorbidities other than schizophrenia spectrum disorders that may interfere with diagnosis Lack of informed consent or refusal to participate by the patient or legal guardian Pregnancy or breastfeeding (if female participants are included)
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, randomization of participants was performed after assessing the inclusion criteria and obtaining informed consent. A block randomization method with a block size of six was used to ensure a balanced distribution of participants across the three study groups (computer-based cognitive rehabilitation, transcranial direct current stimulation, and control). The unit of randomization was the individual, and no cluster randomization was applied. To control for demographic variables such as age and gender, stratified randomization was implemented. The allocation sequence was generated by the study statistician using SPSS version 26 and a table of random numbers, and the final assignment was conducted through numbered, opaque, sealed envelopes to maintain allocation concealment and prevent potential bias in the assignment process.
Blinding (investigator's opinion)
Single blinded
Blinding description
A single-blind design was implemented in this study. Participants were unaware of their allocation to one of the three groups (transcranial direct current stimulation, computer-based cognitive rehabilitation, or control group) to minimize potential bias due to expectancy effects. The researchers, intervention administrators, outcome assessors, and data analysts were aware of the group assignments, as full blinding was not feasible given the nature of the interventions. However, all participants were treated under similar environmental conditions, session schedules, and researcher interactions to minimize subjective bias across groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
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Approval date
2025-09-24, 1404/07/02

Ethics committee reference number
IR.UMA.REC.1404.070

Health conditions studied

1

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

Primary outcomes

1

Description
The cognitive performance scores of patients with chronic schizophrenia, assessed using standard neuropsychological tests (including the N-Back, Simple Stroop, and Continuous Performance Test).
Timepoint
Outcome measures will be assessed at three time points: pre-test (before the intervention), post-test (immediately after the intervention), and two-month follow-up (two months after the intervention).
Method of measurement
Cognitive functions of participants will be assessed using standardized neuropsychological tests and their computerized versions. Response inhibition, selective attention, and cognitive flexibility will be measured by the Simple Stroop Test; working memory and processing speed by the N-Back Task; sustained attention and impulsivity control by the Continuous Performance Test; and social cognition by the Reading the Mind in the Eyes Test. All assessments will be administered by a trained evaluator in a controlled environment.

Secondary outcomes

1

Description
Cognitive Flexibility: Changes in cognitive flexibility after the intervention will be assessed.
Timepoint
In this study, the secondary outcome variables will be measured at three time points: before the intervention (pre-test), immediately after the completion of the intervention (post-test), and two months after the intervention (follow-up).
Method of measurement
Simple Stroop Test

2

Description
Selective Attention: The effect of the intervention on selective attention will be evaluated.
Timepoint
In this study, the secondary outcome variables will be measured at three time points: before the intervention (pre-test), immediately after the completion of the intervention (post-test), and two months after the intervention (follow-up).
Method of measurement
Simple Stroop Test

3

Description
Response Inhibition: The study examines changes in response inhibition following the intervention.
Timepoint
In this study, the secondary outcome variables will be measured at three time points: before the intervention (pre-test), immediately after the completion of the intervention (post-test), and two months after the intervention (follow-up).
Method of measurement
Simple Stroop Test

4

Description
Processing Speed: Processing speed will be measured as a secondary outcome.
Timepoint
In this study, the secondary outcome variables will be measured at three time points: before the intervention (pre-test), immediately after the completion of the intervention (post-test), and two months after the intervention (follow-up).
Method of measurement
Simple Stroop Test

5

Description
Sustained Attention: Improvements in sustained attention after the intervention will be assessed.
Timepoint
In this study, the secondary outcome variables will be measured at three time points: before the intervention (pre-test), immediately after the completion of the intervention (post-test), and two months after the intervention (follow-up).
Method of measurement
Continuous Performance Test

6

Description
Impulsivity Control: The effect of the intervention on impulsivity control will be evaluated.
Timepoint
In this study, the secondary outcome variables will be measured at three time points: before the intervention (pre-test), immediately after the completion of the intervention (post-test), and two months after the intervention (follow-up).
Method of measurement
Continuous Performance Test

7

Description
Working Memory: Changes in working memory after the intervention will be measured.

Timepoint
In this study, the secondary outcome variables will be measured at three time points: before the intervention (pre-test), immediately after the completion of the intervention (post-test), and two months after the intervention (follow-up).

Method of measurement
n-back Test

8

Description
Social Cognition: The impact of the intervention on social cognition will be assessed.

Timepoint
In this study, the secondary outcome variables will be measured at three time points: before the intervention (pre-test), immediately after the completion of the intervention (post-test), and two months after the intervention (follow-up).

Method of measurement
Reading the Mind in the Eyes Test

Intervention groups

1

Description
Intervention Group 1: Computer-based Cognitive Rehabilitation. Participants in this group will perform cognitive rehabilitation exercises using the Captain Log software to improve cognitive functions such as working memory, cognitive flexibility, and attention.

Category
Rehabilitation

2

Description
Intervention Group 2: Transcranial Direct Current Stimulation (tDCS)Participants will undergo transcranial direct current stimulation to enhance cognitive functions such as attention and impulse control.

Category
Treatment - Devices

3

Description
Control group: Participants in this group will receive only standard pharmacological treatment and routine care without any additional intervention.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Dar-Shefa Center for the Treatment and Rehabilitation of Patients with Chronic Psychiatric Disorders

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3

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Sponsors / Funding sources

1

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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
The University of Mohaghegh Ardabili
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

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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
Undecided - It is not yet known if there will be 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
Raw data from neuropsychological test scores (including N-Back, Simple Stroop, and Continuous Performance Test) will be available in Excel format after de-identification of participants. Shared data will include only outcome-related variables (primary and secondary) and will not contain any personal or identifiable information of patients.

When the data will become available and for how long
Access to the data will begin six months after publication of the study results in a scientific journal and will remain available for five years thereafter.

To whom data/document is available
The data will be available to researchers and academic staff from universities and research centers who submit a written request and specify a clear research purpose.

Under which criteria data/document could be used
The data may be used only for research and educational purposes. Any commercial use or redistribution without written permission from the study investigators is prohibited. Requests must include a research proposal, study objectives, and a confidentiality agreement.

From where data/document is obtainable
Requests for access to study data or related documents should be directed to the corresponding researcher via email.

What processes are involved for a request to access data/document
Data access requests will be reviewed by the principal investigator upon receipt via email. The research purpose and eligibility of the applicant will be evaluated. Upon approval and signing of a confidentiality and data use agreement, anonymized data will be shared within 4 weeks.

Comments