

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Evaluation of the effect of brain stimulation therapy by tDCS on the working memory of patients with schizophrenia with a recent onset

Protocol summary

Study aim

- 1) Determination of working memory's function of schizophrenic patients with recent onset
- 2) Determination of working memory's function of schizophrenic patients after tDCS and Sham treatments
- 3) Comparison of changes in working memory's function of schizophrenic patients after sham and tDCS treatments

Design

Double-blind randomized clinical trial with control group, with one intervention in each group, for 40 patients, with a two-week intervention and follow-up for one week

Settings and conduct

In this trial, 40 patients with schizophrenia will be randomly assigned to two groups of intervention and control group. Simple randomization will be performed by Randlist. Both patients and evaluaters will be blinded. Patients will receive the assigned intervention, 2 sessions per week, for two weeks, at the morning. Working memory task will be used prior and after each session of tDCS and control, and also one week after the end of study. At the end of each session patients will score fatigue with visual analogue scale (VAS). Differences between measurements as well as between groups will be analyzed with repeated measures ANOVA and if a significant difference is available the timing will be defined

Participants/Inclusion and exclusion criteria

inclusion criteria: 1. diagnosis of schizophrenia based on semi structured standard interview 2.onset<2 years 3.drug naive or receiving an stable dose on antipsychotic 5.no medication affecting central nervous system
exclusion criteria: 1.History of/present epilepsy 2.malfunctions of blood circulation 3.metabolic disorders 4. hormonal disorders 6.established cognitive disorders 7.untreated poor vision 8.handicapped hands 9.intellectual disability (IQ<75)

Intervention groups

An intervention was conducted on 40 schizophrenic

patients admitted to university clinics or with schizophrenia diagnosed at Razi Hospital. These patients will be randomly divided into intervention and control groups.

Main outcome variables

Working memory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160528028118N2**

Registration date: **2018-03-17, 1396/12/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-17, 1396/12/26**

Update count: **0**

Registration date

2018-03-17, 1396/12/26

Registrant information

Name

Sara Farhang

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 984133803353

Email address

farhangs@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research center for psychiatry and behavioral sciences, Tabriz University of Medical Sciences

Expected recruitment start date

2018-02-20, 1396/12/01
Expected recruitment end date
 2018-09-23, 1397/07/01
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Evaluation of the effect of brain stimulation therapy by tDCS on the working memory of patients with schizophrenia with a recent onset

Public title
 The effect of tDCS brain stimulation on memory improvement in schizophrenic patients

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 1. diagnosis of schizophrenia based on semi structured standard interview 2.onset<2 years 3.age>18 years old 4.drug naive or receiving an stable dose on antipsychotic 5.no medication affecting central nervous system
Exclusion criteria:
 1.History of/present epilepsy 2.malfunctions of blood circulation 3.metabolic disorders 4. hormonal disorders 5.established cognitive disorders 6.untreated poor vision 7.handicapped hands 8.intellectual disability (IQ<75)

Age
 From **18 years** old to **60 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **60**

Randomization (investigator's opinion)
 Randomized

Randomization description
 simple randomization, with "individuals" as units of randomization, by a randomized list generated by Randlist software

Blinding (investigator's opinion)
 Double blinded

Blinding description
 In this study, participants and research team of Outcome are unaware of the allocation of study groups.

Placebo
 Used

Assignment
 Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of tabriz university of medical science

Street address

Tabriz, Gulgasht street, tabriz university of medical science, The central building no.2, third floor

City

tabriz

Province

East Azarbaijan

Postal code

51999

Approval date

2017-01-23, 1395/11/04

Ethics committee reference number

IR.TBZMED.REC.1395.1142

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

working memory

Timepoint

before intervention, during sessions of intervention, after intervention, onemonth after intervention

Method of measurement

Working memroy task

Secondary outcomes

1

Description

fatigue

Timepoint

after each session of intervention

Method of measurement

visual analouge scale

Intervention groups

1

Description

Transcranial direct current stimulation, two session per week

Category

Treatment - Devices

2

Description

Control group: Sham Transcranial direct current device with no stimulation, two session per week

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Sara Farhang

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Razib hospital, Ael-Goli Blvd, Tabriz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Ali Fakhari

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Habibeh Barzegar

Position

Psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

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Latest degree

Specialist

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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 of anonymous data could be shared

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

researchers

Under which criteria data/document could be used

formal request from the supporting organization

From where data/document is obtainable

research center for psychiatry and behavioral sciences

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

submitting the request and reason as a proposal

Comments

Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Latest degree
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