

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the Effectiveness of tDCS with conventional occupational Therapy in Improving cognitive functions in Patients with schizophrenia.

Protocol summary

Study aim

in the present study, we examine the effect of tDCS and conventional occupational therapy on the quantitative changes in brain waves of schizophrenic patients and their cognitive functions.

Design

A randomized, single blinded (patients), sham controlled clinical trial with a parallel group design of 30 patients.

Settings and conduct

This study was carried out at Razi Psychiatric Hospital and in the occupational therapy room. control group receives electrical stimulation only in the first 30 seconds of intervention, and then the current is disconnected. Individuals will not be aware of their group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The diagnosis of schizophrenia by a psychiatrist, the Mini-Mental State Examination (MMSE) score higher than 17 for women and over 18 for men.

Exclusion criteria: paranoid type of schizophrenia, changes in drug regimen over the past month or during the intervention, patients with ECT history, patients with skin problems, patients with chronic neurological diseases or musculoskeletal disorder in the upper limb.

Intervention groups

The intervention will be 6 sessions that takes 20 minutes. The anode electrode is placed on the F3 region, and the cathode electrode on the supraorbital area on the opposite side. An electrical stimulation with a 2 mA direct current will be applied to the F3 area. Patients in both groups will perform visual memory tasks during the intervention. The control group will receive only the first 30 seconds of electrical stimulation and they will do 3 visual memory tasks. The first task is to remember the order of the cards, then find the cards that their places have changed. The second task is to memorize the cards and then name the deleted cards, and the third task is to remember the cards and then name them all perfectly.

Main outcome variables

Activity of different parts of the brain; Cognitive

functions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180317039116N1**

Registration date: **2018-05-10, 1397/02/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-10, 1397/02/20**

Update count: **0**

Registration date

2018-05-10, 1397/02/20

Registrant information

Name

Elahe Fathi Azar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3386 1366

Email address

el.fathiazar@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-17, 1397/01/28

Expected recruitment end date

2018-05-18, 1397/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of tDCS with conventional occupational Therapy in Improving cognitive functions in Patients with schizophrenia.

Public title

effects of tDCS on cognitive functions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of schizophrenia by a psychiatrist. At least one year of being hospitalized. Having MMSE score higher than 17 for ladies and 18 for men.

Exclusion criteria:

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

by using a coin.

Blinding (investigator's opinion)

Single blinded

Blinding description

To eliminate the difference in the sense of initiating electrical stimulation between the groups, the control group will only receive electrical stimulation in the first 30 seconds.

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

Department of Occupational Therapy, The University

of Social Welfare and Rehabilitation Sciences,
Kodakyar St, Daneshjo Blvd, Evin, Tehran, Iran

City

tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.USWR.REC.1396.404

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Cognitive Functions

Timepoint

Before and after intervention

Method of measurement

The Cambridge Neuropsychological Test Automated Battery (CANTAB)- The Loewenstein Occupational Therapy Cognitive Assessment (LOTCA)

Secondary outcomes

1

Description

brain activity

Timepoint

before and after intervention

Method of measurement

quantitative electroencephalography

Intervention groups

1

Description

Intervention group: In this study, tDCS device will be used to stimulate cortex. The intervention will consist of 6 sessions, each lasting for 20 minutes. The anode electrode will be placed on F3 region, the left DLPFC, based on an international system of 10-20 EEGs, and the cathode electrode will be placed on the supraorbital area on the opposite side. An electrical stimulation of 2 mA through the surface of anodic electrode impregnated

with a physiologic serum solution, will be applied on F3 cortex. The stimulation was delivered every other day, and all patients perform visual memory tasks during the stimulation. At each session, all participants spend 20 minutes on 3 Tasks of visual memory while receiving brain stimulation. The first task is to remember the order of the cards, then find the cards that their places has changed. The second task is to memorize the cards and then name the deleted cards, and the third task is to remember the cards and then name them all perfectly.

Category

Treatment - Devices

2**Description**

Control group: In this study, tDCS device will be used to stimulate cortex. The intervention will consist of 6 sessions, each lasting for 20 minutes. The anode electrode will be placed on F3 region, the left DLPFC, based on an international system of 10-20 EEGs, and the cathode electrode will be placed on the supraorbital area on the opposite side. At the beginning of the sessions, an electrical stimulation with 2 mAh current would be applied to the F3 cortex for 30 seconds. Patients will not be informed about the interruption of the stimulation. The stimulation was delivered every other day. At each session, all participants spend 20 minutes on 3 Tasks of visual memory while receiving sham stimulation. The first task is to remember the order of the cards, then find the cards that their places have changed. The second task is to memorize the cards and then name the deleted cards, and the third task is to remember the cards and then name them all perfectly.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Razi Psychiatric Hospital

Full name of responsible person

Elahe fathi azar

Street address

shahid rastegar blv, taghi abad conjunction, shahre
rey, tehran

City

shahre rey

Province

Tehran

Postal code

18664

Phone

+98 21 3340 1226

Email

razi@uswr.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

hojat allah haghgoo

Street address

Department of Occupational Therapy, The University
of Social Welfare and Rehabilitation Sciences,
Kodakyar St, Daneshjo Blvd, Evin, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Phone

+98 21 2218 0083

Email

h.haghgoo@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

Full name of responsible person

Elahe Fathi Azar

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

Street address

no.51, Molavi Alley, Abo moslem Ave, masoudiyeh,
Afsariye junction,tehran

City

Tehran

Province

Tehran

Postal code
17889-17341
Phone
+98 21 3386 1366
Email
Elahe_fathi91@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Elahe Fathi Azar
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Occupational Therapy
Street address
no7. Molavi alley, abo moslem Ave, masoudiyeh,
Afsariye junction, tehran.
City
تهران
Province
Tehran
Postal code
1788917341
Phone
+98 21 3386 1366
Email
Elahe_fathi91@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Elahe Fathi Azar
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Occupational Therapy
Street address
no7. Molavi alley, abo moslem Ave, masoudiyeh,
Afsariye junction, tehran.
City
تهران
Province
Tehran
Postal code
1788917341
Phone
+98 21 3386 1366
Fax
Email
Elahe_fathi91@yahoo.com

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 more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available