

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Efficacy of transcranial direct stimulation on amplification of neuropsychological function in patient with obsessive-compulsive disorder: A double-blind randomized clinical trial with the control group

Protocol summary

Study aim

Evaluation of direct and alternating electrical stimulation on amplification of neuropsychological function in people with obsessive-compulsive disorder.

Design

A double-blind, randomized clinical trial with a control group on 40 patients. Random allocation software will be used for randomization.

Settings and conduct

40 patients will be randomly assigned into two groups of 20. This clinical trial is double-blind and the patient and the outcome assessor are not aware of the type of intervention. The study site will be Fatemi Hospital in Ardabil.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of schizophrenia based on DSM V; age:18-50 years old; required written informed consent signed by patients' guardian. Exclusion criteria: pregnancy; existence of metal implants in the body; history of neurological diseases.

Intervention groups

40 patients will be randomly assigned to two groups: sham and tDCS. The first group (tDCS) will receive 1.5 mA electrical stimulation in 20 sessions of 20 minutes in 10 days (2 sessions per day with an interval of 20 minutes). Stimulation will be performed in the praorbital left cathodal-cortex frontal inferior right anodal. Sham stimulation is as same as active stimulation, except that there will be no current and the device will turn off after one minute.

Main outcome variables

Neuropsychological function; obsessive-compulsive symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044793N2**

Registration date: **2022-01-15, 1400/10/25**

Registration timing: **prospective**

Last update: **2022-01-15, 1400/10/25**

Update count: **0**

Registration date

2022-01-15, 1400/10/25

Registrant information

Name

Habibeh Salvat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3381 9647

Email address

habibehsalvat@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-09, 1400/11/20

Expected recruitment end date

2022-06-10, 1401/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of transcranial direct stimulation on amplification

of neuropsychological function in patient with obsessive-compulsive disorder: A double-blind randomized clinical trial with the control group

Public title

Direct electrical stimulation of the brain in obsessive-compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of obsessive-compulsive disorder based on DSM V Age: 18-50 years old Required written informed consent signed by patients' guardian

Exclusion criteria:

History of neurological diseases such as seizures, strokes, or cerebrovascular diseases The existence of metal implants in the body Pregnancy

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the Restricted Randomization method of block randomization and in each phase, we will have 4 blocks. Generation of random sequences via the blocking method will be done by Random Allocation software. To conceal, we use Allocation Concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Also, non-transparent envelopes sealed with random sequences will be used, that in this method each random sequence is recorded on a card and the cards are placed in the envelope in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration, according to the order of entry of the eligible participants, one of the envelopes will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The executive specialist of electrical brain stimulation will be aware of the research topic and will perform therapeutic interventions. He codes the patients and refers them to a psychologist to check the patient's mental state and record the relevant criteria based on

the same code. The patients will be tested in the same condition in the Neurotherapy room and the electrodes of the device will be connected to them, but they will not be aware of the type of stimulation. The experimenter who assesses outcome measures will be independent from the one who applied intervention and will be blind to stimulation condition. This method of double-blinding is based on previous works in the field of transcranial electrical stimulation (Gandinga et al., 2006).

Accordingly, this study will be a double-blind study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ardabil University of Medical Sciences

Street address

End of University Street, Ardabil University of Medical Sciences

City

Ardabil

Province

Ardabil

Postal code

56189-85991

Approval date

2021-05-17, 1400/02/27

Ethics committee reference number

IR.ARUMS.REC.1400.081

Health conditions studied

1

Description of health condition studied

Obsessive-compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Neuropsychological function

Timepoint

Before intervention (baseline 1, 2). after the intervention.14, 30 and 90 days after the intervention

Method of measurement

Cambridge Neuropsychological Test Automated Battery (CANTAB)

2

Description

Working memory

Timepoint

Before intervention (baseline 1, 2). after the intervention.14, 30 and 90 days after the intervention

Method of measurement

Cambridge Neuropsychological Test Automated Battery (CANTAB)

3

Description

Inhibition response

Timepoint

Before intervention (baseline 1, 2). after the intervention.14, 30 and 90 days after the intervention

Method of measurement

Cambridge Neuropsychological Test Automated Battery (CANTAB)

4

Description

Cognitive flexibility

Timepoint

Before intervention (baseline 1, 2). after the intervention.14, 30 and 90 days after the intervention

Method of measurement

Cambridge Neuropsychological Test Automated Battery (CANTAB)

5

Description

Executive functions

Timepoint

Before intervention (baseline 1, 2). after the intervention.14, 30 and 90 days after the intervention

Method of measurement

Test Wisconsin Cards

6

Description

Severity of obsessive-compulsive symptoms

Timepoint

Before intervention (baseline 1, 2). after the intervention.14, 30 and 90 days after the intervention

Method of measurement

Maudsley Obsessional-Compulsive Inventory

7

Description

Evaluation of anxiety symptoms

Timepoint

Before intervention (baseline 1, 2). after the

intervention.14, 30 and 90 days after the intervention

Method of measurement

Beck Anxiety Inventory (BDI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group, participants will receive supraorbital left cathodal-cortex and frontal inferior right anodal tDCS stimulation for 20 sessions of 20 minutes in 10 days (two sessions per day at 20-minute intervals) with an intensity of 1.5 mA .

Category

Treatment - Devices

2

Description

Control group: in this group, participants receive sham electrical stimulation with the same actual stimulation protocol for 20 sessions in 10 days, while the current generator increases the current to 1.5 mA in 30 seconds, and then gradually over a period of 30 seconds, the current reaches zero.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Psychiatry, Fatemi Hospital

Full name of responsible person

Dr. Anita Azarkolah

Street address

Department of Psychiatry, Fatemi Hospital, Sareyn Station, Ardabil

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Ardabil University of Medical Science

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

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Anita Azarkolah

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Full name of responsible person

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Psychology

Latest degree

Master

Other areas of specialty/work

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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

Due to the confidentiality of the participant's personal characteristics

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

No - There is not a plan to make this available

Title and more details about the data/document

All collected data for the primary outcome measures only after anonymizing.

When the data will become available and for how long

Starting 12 months after publication

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

En To raise the level of knowledge about the treatment of OCD

From where data/document is obtainable

Raw data and documents generated for this study are available from the corresponding authors and institution on reasonable request.

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

A formal request from person/institutions should be sent to the corresponding authors and corresponding institutions via email (for international users) and mail (for national users).

Comments