

# 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 Šalvat

##### 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

Ardabil University of Medical Sciences

**Full name of responsible person**

Dr. Farhad Pourfarzi

**Street address**

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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**

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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**Latest degree**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Habibeh Salvat Ghojehbeiglou

**Position**

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**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**