Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

Comparing the effectiveness of cognitive behavioral therapy; Transcranial Direct Current Stimulation and cognitive behavioral therapy with Transcranial Direct Current Stimulation on cognitive abilities of patients with obsessive-compulsive disorder: A randomized controlled trial

Protocol summary

Study aim

The general purpose of this research is to compare the effectiveness of three protocols including cognitive behavioral therapy, direct transcranial electrical stimulation therapy and cognitive behavioral therapy combined with direct transcranial electrical stimulation on the cognitive abilities of patients with obsessive compulsive disorder.

Design

This clinical trial has three groups in the form of parallel interventions on 60 patients, this trial is randomized and single-blind, and a table of random numbers is used for randomization.

Settings and conduct

Sampling of the research is carried out in all faculties of Roudehen University, first, the faculties are randomly selected in clusters, and after identification, 60 people are randomly selected according to the entry and exit criteria using random numbers on the website www.randomizer.org are placed in 3 intervention groups. Placement is done using sealed envelopes that the participants themselves choose and the group code is specified in it, thus the study will remain one-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of obsessive-compulsive disorder and age 18 to 35 years old / Exclusion criteria: use of psychiatric drugs, use of another psychotherapy, absence of two consecutive sessions

Intervention groups

Intervention group 1 receives 12 sessions of cognitive behavioral therapy. Intervention group 2 receives transcranial direct electrical stimulation treatment for 8 sessions. Intervention group 3 will receive a simultaneous combination of cognitive behavioral therapy and transcranial direct electrical stimulation.

Main outcome variables

The improvement of cognitive abilities in the group receiving CBT and TDCS at the same time will be more than the improvement of this variable in the two treatments individually.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230504058067N1**
Registration date: **2023-05-13, 1402/02/23**
Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**
Update count: **0**

Registration date

2023-05-13, 1402/02/23

Registrant information

Name

Maryam Hosseini

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-08-20, 1402/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of cognitive behavioral therapy; Transcranial Direct Current Stimulation and cognitive behavioral therapy with Transcranial Direct Current Stimulation on cognitive abilities of patients with obsessive-compulsive disorder: A randomized controlled trial

Public title

Effectiveness of Transcranial Direct Current Stimulation on obsessive-compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a diagnosis of obsessive compulsive disorder based on the Maudsley questionnaire Being in the age range of 18 to 35 years

Exclusion criteria:

Absence in two consecutive sessions in each of the treatments Taking psychiatric drugs Use of other psychotherapy services

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This controlled clinical trial study is going to be performed in Azad University both male and female students. Initial screening will be performed to determine the baselines. After screening, 60 participants are contacted via simple random sampling and shuffling. Upon arrival at the clinic, each invited person receives a sealed envelope with A, B or C code written on each envelope. This sequence is determined by someone other than the researchers using the site www.randomizer.org. Code A means the group will receive cognitive behavioral therapy; code B means the group will receive Transcranial Direct Current Stimulation and C means the group will receive cognitive behavioral therapy with Transcranial Direct Current Stimulation. Fisher and chi-square tests are also used to homogenize the underlying features.

Blinding (investigator's opinion)

Single blinded

Blinding description

First of all, in order to blind the trial, a PhD student of psychology from the research group, encode participants information. In this project, blinding means more than just keeping the name of the participants are allocated in treatment or control group hidden. The patients will be blinded in the sense that they do not know they are receiving which kind of therapies. So, the participants are prevented from knowing certain information that may somehow influence them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Roudehen Branch

Street address

Academic complex of Islamic Azad University, Roudehen branch, Motahari Blvd., Roudehen Town

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Postal code

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Approval date

2023-05-08, 1402/02/18

Ethics committee reference number

IR.IAU.R.REC.1402.007

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

Cognitive abilities include 8 subscales that are measured by Nejati cognitive abilities questionnaire.

Timepoint

Session 1, Session 5, Final Session, two months after the

last session

Method of measurement

Nejati cognitive abilities questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The protocol used for transcranial direct electrical stimulation in this research, according to the background, will be such that the intervention includes 2 milliamps of the anode position at F3 point and the cathode position at F4 point. The intervention consists of 8 sessions, each session of brain stimulation takes 20 minutes (either real or fake) and only one brain stimulation session will take place on each day. Meetings will be held two days a week.

Category

Treatment - Other

2

Description

Intervention group 2: In this group, cognitive behavioral therapy (12 sessions) is used simultaneously with transcranial direct electrical stimulation (8 sessions), so that after receiving 2 milliamperes, the anode position at the F3 point and the cathode position at the point F4 participates in a 45-minute cognitive-behavioral psychotherapy session for 20 minutes. Cognitive behavioral therapy includes psychoeducation about obsessive compulsive disorder, cognitive exercises such as cognitive restructuring, and behavioral exercises such as immersion.

Category

Treatment - Other

3

Description

Control group: In this group, cognitive behavioral therapy, which has the golden standard, is used as a control group. This protocol consists of 12 treatment sessions two days a week, which include psychoeducation about obsessive compulsive disorder, cognitive exercises, and behavioral exercises.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Counseling Center of Islamic Azad University, Roudehen branch

Full name of responsible person

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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

Islamic Azad University

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
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data obtained from participants will be published unrecognizably in the primary information table in the article. The general data will be shared simultaneously with the publication of the main article.
When the data will become available and for how long
The data will be shared at the same time as the main article publication.
To whom data/document is available
Mainly, this data will be available to academic researchers and clinicians.
Under which criteria data/document could be used
Thereafter publication of the article, a way of requesting data is introduced. Also, researchers can analyze the data only if the researchers agree.
From where data/document is obtainable
Simultaneously with the publication of the article, a way of requesting data is introduced.
What processes are involved for a request to access data/document
Initially, the request is sent to the responsible author, after reviewing the group in order to prevent any kind of abuse, the information is sent in the form of a zip file.
Comments