

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing Transcranial direct current stimulation with and without drug therapy on symptoms of patient with obsessive compulsive disorder: a Clinical trial

Protocol summary

Summary

This study is aimed to compare the effectiveness of the Transcranial direct current stimulation (TDCS) of the brain and medication on symptoms of patients with obsessive compulsive disorder in a pre- and post- tests design. Sample size consists of 40 patients in two groups, 20 patients in each group, one with medication and the other one without medication. Patients will be selected by a psychiatrist based on structured clinical interview according to diagnostic criteria of Diagnostic and Statistical Manual of Mental Disorders (DSM -5), from Toloo clinic in Rasht. Yale-Brown questionnaire (YBOCS) will be used to assess the severity of obsessive compulsive symptoms. The minimum score of 16 is required entering the study. After signing the informed consent and considering inclusion and exclusion criteria, treatment resistant obsessive compulsive patients will enter the study. Exclusion criteria is defined as consuming anticonvulsant medication during in the past 6 months, pregnancy, or unwilling to continue the study. Interventions; Intervention in Group 1: Twenty medical treatment - resistant patients suffering from obsessive compulsive disorders will be entered in this group. They will receive brain electrical stimulation (Transcranial direct current stimulation) while getting no medication. Therapy will be carried out in four thirty-minute sessions with one-week interval between each two sessions and music will be played to calm the patients during electrical stimulation. Intervention Group 2: Twenty medical treatment - resistant patients suffering from obsessive compulsive disorders will be entered in this group. Treatment consists of sufficient dose of Serotonin reuptake inhibitors (SSRI), Fluoxetine 80 mg or Setraline 200 mg, daily in combination with brain electrical stimulation. In both group, therapy will be carried out in four thirty-minute sessions with one-week interval between each two sessions and a direct continuous

electrical stimulation will be sent to the cortex through electrical for a maximum duration of thirty minutes. Music will be played for patients in order to calm them during the sessions. YBOCS will be used to assess the efficacy of treatment one and three month later.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017031121965N6**
Registration date: **2017-04-21, 1396/02/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-21, 1396/02/01

Registrant information

Name

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Name of organization / entity

Guilan University of Medical Sciences, «Kavosh»
Cognitive Behaviour Sciences and Addiction Research

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2017-03-11, 1395/12/21

Expected recruitment end date

2017-06-11, 1396/03/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing Transcranial direct current stimulation with and without drug therapy on symptoms of patient with obsessive compulsive disorder: a Clinical trial

Public title

The effect of current stimulation and drug therapy on obsessive compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with obsessive compulsive disorder; minimum score of 16 form YBOCS; aged between 18-55 years. Exclusion criteria: Antiepileptic drug therapy in the previous 6 months; neurologic disease; pregnancy; low intelligence quotient; head injury; any metallic instrument in brain or skull.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Guilan University of Medical

Sciences

Street address

Vice chancellor for research of Guilan University of Medical Sciences, the upper floor of Iran Radiator Representation, in front of the Sepah bank, West Shahid Beheshti Blvd.

City

Rasht

Postal code

4193893345

Approval date

2016-10-30, 1395/08/09

Ethics committee reference number

IR.GUMS.REC.1395.271

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**

obsessive – compulsive disorder

Timepoint

Measured time intervals will be before the treatment and one and three months after the treatment.

Method of measurement

Yale-Brown test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group 1: Twenty medical treatment - resistant patients suffering from obsessive compulsive disorders will be entered in this group. They will receive brain electrical stimulation (Transcranial direct current stimulation) while getting no medication. Therapy will be carried out in four thirty-minute sessions with one-week interval between each two sessions and music will be played to calm the patients during electrical stimulation. Follow up visits will be one and three month later. Comparing to the other noninvasive stimulation, TDCS is a new and noninvasive brain electrical stimulation method that is safe, low cost and simply designed in order to use in outpatient settings.

Category

Treatment - Other

2

Description

Intervention Group 2: Twenty medical treatment - resistant patients suffering from obsessive compulsive disorders will be entered in this group. Treatment consists of sufficient dose of Serotonin reuptake inhibitors (SSRI), Fluoxetine 80 mg or Setraline 200 mg, daily in combination with brain electrical stimulation. Therapy will be carried out in four thirty-minute sessions with one-week interval between each two sessions and music will be played to calm the patients during electrical stimulation. Follow up visits will be one and three month later. Comparing to the other noninvasive stimulation, TDCS is a new and noninvasive brain electrical stimulation method that is safe, low cost and simply designed in order to use in outpatient settings

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tooloo Specialty and Subspecialty of Psychiatry Clinic of Rasht

Full name of responsible person

Dr Kiomars Najafi

Street address

Tooloo Specialty and Subspecialty of Psychiatry Clinic ,Shabnam alley, Golsar Crossroads, in front of the Municipality of Area (3), Rasht, Iran.

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Guilan University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

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Vice chancellor for research of Guilan University of Medical Sciences, the upper floor of Iran Radiator Representation, in front of the Sepah bank, Shahid Beheshti Blvd.

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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

Vice chancellor for research, Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University Of Medical Sciences

Full name of responsible person

Dr Kiomars Najafi

Position

Psychiatrist, Assistant Professor

Other areas of specialty/work

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Full name of responsible person

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Position

Master Of science in Psychology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty