Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Transcranial Alternating Current Stimulation (TACS) on the Symptoms of Patients with Obsessive-Compulsive Disorder (OCD): a double blind randomized clinical trial

Protocol summary

Study aim
Investigating the effect of Transcranial Alternating Current Stimulation on obsessive-Compulsive symptoms in patients with Obsessive-compulsive Disorder

Design
A double-blind randomized clinical trial, with two intervention and control groups, on 30 patients (15 people in each group), PLAN Software is used for block randomization.

Settings and conduct
The intervention is carried out in the research center of Hafez Hospital in Shiraz using electrical stimulation tool (TACS). The participants and the researcher do not know each person's group and the study is double-blind.

Participants/Inclusion and exclusion criteria
Entry criteria: Absence of other mental and neurological diseases. Exclusion criteria: Inability to receive TACS due to metallic implants, or history of seizures, or history of head injury, or history of neurosurgery, participants with anaphylaxis, pacemaker, mechanical heart valve, mechanical implant such as aneurysm clip, joint replacement thigh or any other piece of metal accidentally inserted into their body, a serious risk of suicide, a female subject who is pregnant or of childbearing age, sexually active, not using reliable contraception, or breastfeeding.

Intervention groups
Transcranial Alternating Current stimulation will be performed in 4 weeks, 2 days a week for 20 minutes with a frequency of 40 Hertz and a current of 2 milliamps. Electrodes are placed over the Dorsomedial Prefrontal Cortex (F3 and F4, according to the 10-20 system) to induce gamma activity. The control group will receive a sham stimulation for 30 seconds instead of the actual electric current.

Main outcome variables
Yale-Brown Practical Obsessive Compulsiveness Questionnaire score

General information

Reason for update

Acronym
TACS_ OCD

IRCT registration information
IRCT registration number: **IRCT20230603058374N1**
Registration date: **2023-06-07, 1402/03/17**
Registration timing: **prospective**

Last update: **2023-06-07, 1402/03/17**
Update count: **0**

Registration date
2023-06-07, 1402/03/17

Registrant information

Name
Elmira Zeinoddini meymand

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-15, 1402/03/25

Expected recruitment end date
2023-07-06, 1402/04/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Transcranial Alternating Current Stimulation (TACS) on the Symptoms of Patients with Obsessive-Compulsive Disorder (OCD): a double blind randomized clinical trial

Public title

The effect of electrical stimulation of the brain on the treatment of obsession

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

According to the DSM-5 diagnostic and statistical manual of obsessive-compulsive disorder Age between 18 and 60 years Obtaining a score of 16 (patients with severe and moderate disease conditions) on the Yale Brown scale Absence of other psychiatric and neurological diseases Ability to perform behavioral tests and answer questionnaires by the patient Signing a written consent form by the patient

Exclusion criteria:

Inconsistency with study inclusion criteria Patient's unwillingness to participate in the study Patient's inability to perform diagnostic tests Inability to receive tACS due to metal implants, or history of seizures, or history of trauma to the head, or history of neurosurgery Participants who have anasthenia gravis, a pacemaker, a mechanical heart valve, a mechanical implant such as an aneurysm clip, a hip replacement, or any other piece of metal accidentally inserted into their body Any current significant medical condition Serious risk of suicide A female subject who is pregnant or of childbearing potential, sexually active, not using reliable contraception, or breastfeeding

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

We use block randomization to generate sequences, which is a common technique in clinical trial design to reduce bias and achieve balance in assigning participants to treatment arms, especially when the sample size is small and the intervention and control groups are similar. The face is filled with participants almost simultaneously and completely randomly. For this purpose, 5 blocks of 6 (according to the sample size which is 30 people) have been considered. Blocking is done using plan software. The concealment stage is done by using sealed opaque envelopes in such a way that the created sequence is placed in the envelopes and given to the expert who is responsible for the electrical stimulation on the day of the experiment.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be double-blind, that is, the expert who performs the randomization process will place the patients in two intervention and control groups, and the researcher does not know which group each person is in. Also, Patients are also not given information about which group they are in. Other people, including the personnel of the hospital research center (place of intervention) and the patient's companions, do not know which group each person is in.

Placebo

Not used

Assignment

Parallel

Other design features

The study will be conducted as a double-blind randomized clinical trial, which will have two intervention and control arms. The entered people will be randomly assigned to one of the groups, and the number of members of the groups will be 15 people in each group, one group will actively receive electrical stimulation, and the other group will not receive this stimulation, and for Removing the psychological effect on the control patients, on the same day, the electrical device is placed on the head, but no stimulation takes place (Sham tACS)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Karimkhan Zand Blvd

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2023-05-21, 1402/02/31

Ethics committee reference number

IR.SUMS.REC.1402.094

Health conditions studied

1

Description of health condition studied
Obsessive Compulsive Disorder
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Obsessive-compulsive symptom score in the Yale Brown Questionnaire
Timepoint
Examining the amount of obsession compulsive symptoms before starting the study and at the end of the first, second and third weeks and Also, at the end of the intervention (end of the fourth week)
Method of measurement
Yale Brown Questionnaire:It was created by "Wayne K. Goodman" and his colleagues in 1989 in the United States. Yale Brown Obsessive Compulsive Psychology Test (YBOCS) is the most reliable theoretical test for diagnosing obsessive compulsive disorder in adults, which is used in counseling and psychology centers. This test is a self-report tool to measure obsessive thoughts and obsessive/compulsive behaviors. This questionnaire has 10 statements with a Likert scoring system (from 0 none to 4 very severe), of which 5 options are intended to evaluate obsessive thoughts and 5 other options are considered to evaluate practical obsessions. The two subscales in this questionnaire are: (a) "Obsessive thoughts": including aggressive obsessions, consuming obsessions, sexual obsessions, hoarding or collecting obsessions, religious obsessions, symmetry and order obsessions, miscellaneous obsessions, and physical obsessions, and (b) "Compulsions": including washing and cleaning, checking, repetition rituals, obsessive behaviors related to counting, order and order, hoarding , and various obsessive behaviors. This test can be performed individually or in groups for people 14 years old and above. On average, this test takes about 10 minutes to complete.

Secondary outcomes

1

Description
Beck depression questionnaire score
Timepoint
Checking the level of depression before the study and at the end of the first, second, third and fourth weeks (the end of the study)
Method of measurement
Beck Depression Questionnaire:The Beck Depression Questionnaire was first compiled by Beck et al. in 1961. It was revised in 1971 and published in 1978.In general, the content of this questionnaire is the semiotics of depression, but it emphasizes more on the cognitive content. This questionnaire is a type of self-assessment test and can be completed in five to ten minutes. The test items consist of a total of 21 items that are related to different symptoms. The subjects must answer it on a four-point scale from zero to three. Areas such as sadness, pessimism, feelings of helplessness and failure, feelings of guilt, sleep disturbance, loss of appetite, self-loathing, etc. constitute substances. In this way, 2 items are related to affection, 11 items are related to cognition, 2 items are related to obvious behaviors. 5 items are related to physical symptoms and 1 item is related to interpersonal semiotics. Accordingly, this scale determines different degrees of depression from mild to very severe, and its scores range from a minimum of 0 to a maximum of 63.

Intervention groups

1

Description
Intervention group: Transcranial Alternating Current Stimulation will be performed in 4 weeks, 2 days a week for 20 minutes with a frequency of 40 Hertz and a current of 2 milliamps. Electric current will be applied through conductive rubber electrodes. These electrodes are placed in sponge pads (5 x 7 cm2) soaked with 9% sodium chloride solution to increase the conductivity of the electric current and prevent the increase in temperature. Transcranial alternating current is simultaneously applied bilaterally. Electrodes are placed over the DMPFC (Dorsomedial Prefrontal Cortex) area (F3 and F4, according to the 10-20 system) to induce gamma activity.
Category
Treatment - Other

2

Description
Control group: It will receive a sham stimulation for 30 seconds instead of a real electric current.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez Medical Education Center
Full name of responsible person
Dr.Babak Hoseini
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2

Recruitment center
Name of recruitment center
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Next to Sizdeh Aban Bostan, Hafez St, Shiraz
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Web page address

Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Phone
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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
Shiraz University of Medical 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
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available