Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of repetitive Transcranial Magnetic Stimulation(rTMS) and Cognitive-Behavioral Therapy(CBT) on Symptoms of obsessive-compulsive disorder, Symptoms of Depression, Cognitive Flexibility, and Working Memory in People with Obsessive-Compulsive Disorder

Protocol summary

Study aim
Comparison of the effectiveness of Transcranial Magnetic Stimulation and Cognitive-Behavioral Therapy on symptoms of obsessive-compulsive disorder, Symptoms of Depression, Cognitive Flexibility, and Working Memory in People with Obsessive-Compulsive Disorder

Design
Randomized controlled trial with 2 interventional groups with parallel groups on 30 patients that will be randomly assigned into two groups. (15 members for each one)

Settings and conduct
30 patients will be selected from who refer to the psychiatric clinic of Beheshti hospital of Zanjan and they will be divided in 2 groups randomly. After obtaining informed consent to participate in the research, the Yale-Brown Obsessive, Compulsive Scale the Hamilton Depression Rating Scale, The cognitive flexibility inventory, the n-back task will be done. The questionnaires and re-evaluation tests, will be repeated after intervention as post test and one month follow up. The patient will be evaluated by someone other than the therapist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Full diagnostic criteria for obsessive–compulsive disorder based on DSM-5 ; No previous psychological treatment; No previous transcranial direct current stimulation and neurofeedback interventions. Exclusion criteria: Personality disorders; Psychotic disorders; Past history of seizures and epilepsy ; Electrical or Metal object in the body

Intervention groups
Intervention Group 1: Cognitive-Behavioral Therapy: Treatment sessions are performed in 18-20 sessions (each session approximately 45-90 minutes twice a week) ; Intervention group2: Each person receives repetitive transcranial magnetic stimulation with a frequency of 1 Hz, over the right dorsolateral prefrontal cortex five times a week for two weeks

Main outcome variables
Symptoms of obsessive-compulsive disorder, Symptoms of Depression, Cognitive Flexibility, Working Memory

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200805048316N1**
Registration date: **2020-11-05, 1399/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-05, 1399/08/15**
Update count: **0**

Registration date
2020-11-05, 1399/08/15

Registrant information

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arash fazeli

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
2020-11-04, 1399/08/14
Expected recruitment end date
2021-06-05, 1400/03/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of repetitive Transcranial Magnetic Stimulation(rTMS) and Cognitive-Behavioral Therapy(CBT) on Symptoms of obsessive-compulsive disorder, Symptoms of Depression, Cognitive Flexibility, and Working Memory in People with Obsessive-Compulsive Disorder

Public title
Comparison of the effectiveness of transcranial magnetic stimulation and cognitive-behavioral therapy in improving people with obsessive-compulsive disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Full diagnostic criteria for obsessive-compulsive disorder by diagnosis of a psychiatrist and psychologist based on DSM-5 Intermediate school Degree Signing a written consent No previous psychological treatment No previous Transcranial Direct-Current Stimulation (tdcs) and neurofeedback interventions
Exclusion criteria:
Risk of suicide Personality disorder Psychotic disorders Seizures and epilepsy records The presence of an electrical or metal object in the body Bipolar disorder
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
First of all each sample is given a specific code, then each code is written on a piece of paper and the papers are poured into a container. According to the sample size in each groups, a few papers will be randomly drawn.
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 committe of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences, Azadi Square, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
45156-13191
Approval date
2020-08-04, 1399/05/14
Ethics committee reference number
IR.ZUMS.REC.1399.180

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
Symptoms of obsessive-compulsive disorder
Timepoint
Before intervention, After the intervention, One month after the intervention
Method of measurement
Yale Brown Obsessive-Compulsive Scale questionnaire

Secondary outcomes

1

Description
Depression
Timepoint
Before intervention, After the intervention, One month after the intervention

Method of measurement
Hamilton Derepssion Rating Scale

2

Description
Working memory
Timepoint
Before intervention, After the intervention, One month after the intervention
Method of measurement
N-Back task

3

Description
Cognitive flexibility
Timepoint
Before intervention, After the intervention, One month after the intervention
Method of measurement
Cognitive flexibility questionnaire

Intervention groups

1

Description
Intervention Group 1: Cognitive-Behavioral Therapy: Treatment for 18-20 sessions (each session approximately 45-90 minutes twice a week) according to the protocol (Leahy,2012); Sessions 1–2: Assess presenting problem; Inquire regarding all symptoms; Assess presence of obsessions and compulsions; Assess avoidance behaviors; Assess feared consequences; Assess internal and external triggers of obsessional anxiety; Assess impairment in social, educational, and occupational functioning; Inform patient of diagnosis and provide education on Obsessive–compulsive disorder(OCD); Educate patient regarding treatment options, including medication; Sessions 3–4: Evaluate homework; Review all obsessions, compulsions, and avoided situations; Assess motivation for treatment; Build motivation; Describe cognitive-behavioral conceptualization of OCD and describe cognitive-behavioral treatment; Obtain patient's commitment to proceed with treatment; Introduce cognitive model; Identify automatic thoughts, obsessional anxiety, compulsions or urge to ritualize, and triggering situations; Evaluate automatic thoughts; Sessions 5–6: Evaluate homework; Re- administer self-report questionnaires to assess mood and track progress; Educate patient regarding intrusive thoughts as normal phenomena; Evaluate validity of automatic thoughts; Help patient devise behavioral experiments; Sessions 7–10: Continue modifying automatic thoughts, dysfunctional assumptions; Continue helping patient devise behavioral experiments; Help patient complete exposure hierarchies; Plan initial exposure sessions; Conduct exposure to initial items on hierarchies of obsessions and avoided situations; Teach postponing, slowing, and changing repetitions; Sessions 11–16: Examine and challenge any thoughts related to avoidance of exposure; Examine and challenge any thoughts related to lapses in rituals; Complete exposure to items higher up hierarchies of obsessions and avoided situations; Continue to help patient block rituals; Examine any lapses in response prevention; Sessions 17–20: Assess attainment of goals to determine whether treatment may be tapered; Track progress in identifying and modifying thoughts; Assess any life problems related to OCD or patient improvement; Ensure that exposure is being performed to items highest on the hierarchy; Monitor any lapses
Category
Treatment - Other

2

Description
Intervention group2: Each person receives repetitive transcranial magnetic stimulation (rTMS) with a frequency of 1 Hz, four attempts per session, and 500 pulses each time over the right dorsolateral prefrontal cortex(rDLPFC). And receive a total of 2000 pulses per session. The sessions will be performed five times a week for two weeks.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Mohsen Dadashi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person

Alireza Shogli

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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
Zanjan 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

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Mohsen Dadashi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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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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student

Latest degree
Bachelor

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Total data after unidentifiable people as SPSS can be shared.

When the data will become available and for how long

Six months later print the results.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

researchers in academic and scientific institutions

From where data/document is obtainable

DR. Beheshti Hospital, Zanjan, Department of Clinical Psychology, Dr Mohsen Dadashi, Mobile: 0098 9127433559. Dr. Beheshti Hospital, Zanjan, Department of Clinical Psychology,Arash Fazeli, Mobile: 0098 9178661215

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

Documents will be shared only when the reason for the request is announced by phone or e-mail

Comments