

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Effectiveness of Adding QEEG-Guided Neurofeedback to SSRIs in Patients with Obsessive-Compulsive Disorder (OCD)

Protocol summary

Study aim

The Effectiveness of Adding QEEG-Guided Neurofeedback to Selective serotonin reuptake inhibitors (SSRIs) in Patients with Obsessive-Compulsive Disorder (OCD)

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, on 60 patients.

Randomize.com was used for randomization.

Settings and conduct

conducted at Ibn Sina Hospital, Mashhad. In this study, 60 patients with OCD are divided into two groups.

Participants/Inclusion and exclusion criteria

1- Age between 18 and 40 years. 2- Diagnosis of OCD based on DSM-5 criteria by a psychiatrist. 3-Yale-Brown Obsessive-Compulsive Scale Y-BOCS test score > 16. 5- Absence of other Axis 1 disorders, schizophrenia, bipolar disorder, depression, etc., mental retardation, substance abuse or psychiatric disorders due to medical problems that require treatment (considering the high association of obsessive-compulsive disorder with depression mild and moderate depression is allowed to enter the plan) 6- Absence of other treatment or use of cognitive therapy.

Intervention groups

In this study, 60 patients with OCD are divided into two groups, intervention and control, and by the (Y-BOCS), Beck Depression Test and Beck Anxiety Test at the beginning and end of the study, the tests Cognitive CANTAB related to obsessive-compulsive disorder and QEEG are evaluated at the beginning and end of the study and every two weeks during the study. According to the psychiatrist's diagnosis, fluoxetine 40-60 mg or the equivalent of another SSRI approved for the treatment of OCD is prescribed for the two test groups, and the intervention group receives neurofeedback based on the brain map pattern three times a week for two months.

Main outcome variables

Examining the level of obsession before and after the intervention by the Yale-Brown Obsessive-Compulsive

Scale (Y-BOCS) test. changes of brain waves

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231021059781N1**

Registration date: **2023-10-24, 1402/08/02**

Registration timing: **prospective**

Last update: **2023-10-24, 1402/08/02**

Update count: **0**

Registration date

2023-10-24, 1402/08/02

Registrant information

Name

mazyar fathi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The Effectiveness of Adding QEEG-Guided Neurofeedback to SSRIs in Patients with Obsessive-Compulsive Disorder (OCD)
Public title	The Effectiveness of QEEG-Guided Neurofeedback in Patients with (OCD)
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: 1- Age between 18 and 40 years.2- Diagnosis of OCD based on DSM-1V criteria by a psychiatrist.3- Y-BOCS test score > 16.4- Filling the informed consent form.5- Absence of other Axis 1 disorders, for example, schizophrenia, bipolar disorder, depression, etc., mental retardation, substance abuse or psychiatric disorders due to medical problems that require treatment (considering the high association of obsessive-compulsive disorder with depression mild and moderate depression is allowed to enter the plan)6- Absence of other treatment or use of cognitive therapy. Exclusion criteria:
Age	From 18 years old to 40 years old
Gender	Both
Phase	N/A
Groups that have been masked	Investigator
Sample size	Target sample size: 30
Randomization (investigator's opinion)	Randomized
Randomization description	Block randomization The block randomization method is designed to randomize subjects into groups that result in equal sample sizes. This method is used to ensure a balance in sample size across groups over time. Blocks are small and balanced with predetermined group assignments, which keeps the numbers of subjects in each group similar at all times.[1,2] The block size is determined by the researcher and should be a multiple of the number of groups (i.e., with two treatment groups, block size of either 4, 6, or 8). Blocks are best used in smaller increments as researchers can more easily control balance.
Blinding (investigator's opinion)	Single blinded
Blinding description	Researchers who perform data analysis and data recording are kept blind to the data of the groups.
Placebo	Not used
Assignment	Parallel
Other design features	

Secondary Ids	empty
Ethics committees	1 Ethics committee Name of ethics committee کارگروه منطقه ای اخلاق در پژوهش‌های زیست پزشکی دانشگاه علوم پزشکی مشهد Street address Research Technology, Qurashi Building, next to Hoize Cinema, Mashhad, University St, Khorasan, Razavi City Mashhad Province Razavi Khorasan Postal code 9138813944 Approval date 2023-09-11, 1402/06/20 Ethics committee reference number IR.MUMS.MEDICAL.REC.1402.180

Health conditions studied

1	Description of health condition studied A disorder characterized by the presence of persistent and recurrent irrational thoughts (obsessions), resulting in marked anxiety and repetitive excessive behaviors (compulsions) as a way to try to decrease that anxiety. ICD-10 code F42 ICD-10 code description Obsessive-compulsive disorder
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Primary outcomes

1	Description Examining the level of obsession before and after the intervention in order to evaluate the effectiveness of the intervention using the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS), examining the changes in brain waves related to the disease before and after the intervention using the Neuroguide software and every two weeks thereafter From the beginning of the intervention. Checking the improvement of cognitive functions such as maintaining attention, visual memory, working memory, attention shift and response inhibition by CANTAB software before and after the intervention and every two weeks after the intervention. Checking the level of anxiety and depression in two stages: Before and after the end of the intervention by Beck's anxiety and depression questionnaires. Timepoint Illness before and after the intervention by and every
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two weeks after the start of the intervention
Method of measurement
(Y-BOCS), NEUROGUID, CANTAB , BDI, BAI

2

Description
Yale Brown Obsessive-Compulsive Scale
Timepoint
the beginning and end of the study,
Method of measurement
Yale Brown Obsessive-Compulsive Scale (Y-BOCS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 patients with OCD who, in addition to SSRI drug treatment (fluoxetine 40-60 mg or its equivalent from another SSRI approved for OCD treatment), are treated with neurofeedback based on brain mapping.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
bn Sina Hospital, Mashhad
Full name of responsible person
mazyar fathi
Street address
Razavi Khorasan Province, Mashhad, Boulevard, 8HGM+6QV
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Khorasan, Razavi, Mashhad, University St., next to Hoize Cinema, Qurashi Building, Research and Technology.
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Ali Talaei
Position
Professor of Psychiatry 1. Head of Psychiatric and Behavioral Sciences Research Center of Mashhad Un
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Specialist
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

No - There is not 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

Yes - There is a plan to make this available

Title and more details about the data/document

The data is published in a general and summarized form, and personal information will not be published separately.

When the data will become available and for how long

The access period starts from 1403 for one year

To whom data/document is available

Researchers who participate in this study and participate in the data analysis process can have access to the data.

Under which criteria data/document could be used

Conduct a similar study

From where data/document is obtainable

Psychiatry and Behavioral Sciences Research Center,
Mashhad University of Medical Sciences

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

Having the proposal justified and approved by the ethics committee

Comments