

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 51 3711 2540

##### Email address

fathima@mums.ac.ir

##### 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

## 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

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

##### City

mashhad

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fathimazyar@yahoo.com

##### Web page address

<https://pbsrc.mums.ac.ir/index.php>

## Sponsors / Funding sources

## 1

#### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Dr.mohammad hossein Ebrahimzadeh

#### Street address

Khorasan, Razavi, Mashhad, University St., next to Hoize Cinema, Qurashi Building, Research and Technology.

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#### Web page address

<https://v-research.mums.ac.ir/>

#### 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

##### Latest degree

Specialist

##### Other areas of specialty/work

Psychiatrics

##### Street address

Ibn-e Sina Psychiatric Hospital, Hor Al Ameli Blvd., Bu-Ali Sq., Ferdowsi Sq., Mashhad, Iran

##### City

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Ali Talaei  
**Position**  
1. Head of Psychiatric and Behavioral Sciences  
Research Center of Mashhad University of Medical Scie  
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Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
mazyar fathi  
**Position**  
researcher  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**

Psychiatrics  
**Street address**  
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Ali Sq., Ferdowsi Sq., Mashhad, Iran  
**City**  
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Razavi Khorasan  
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919083134  
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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