Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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. Randomaize.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

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Iran (Islamic Republic of)

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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

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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

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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

Dr.mohammad hossein Ebrahimzadeh

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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

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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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