

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the Effectiveness of EEG-Based Neurofeedback Therapy Versus Conventional Therapies (Medication and Mindfulness-Based Cognitive Behavioral Therapy) in Improving Symptoms of Obsessive-Compulsive Disorder Patients: A Randomized Controlled Trial

Protocol summary

Study aim

To investigate the effectiveness of EEG-based neurofeedback (NFB) treatment versus current treatments for the improvement in symptoms among OCD patient

Design

Randomised, parallel group, superiority trial with four arms. Sample size: 80 OCD patients. Randomisation: Centralised and computerised using random number generator software.

Settings and conduct

The trial will be conducted in the Psychiatry Unit at Lady Reading Hospital, Peshawar.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. OCD patients diagnosed according to DSM-V criteria. 2. Age range: 18–40 years. Exclusion Criteria: 1. Neurological conditions such as stroke, head injury, epilepsy, or dementia. 2. Severe medical conditions (e.g., hepatic or renal failure). 3. History of psycho-surgery or neurosurgical procedures. 4. Substance abuse or drug dependence. 5. Psychiatric comorbidities including schizophrenia, psychosis, or delusional disorders.

Intervention groups

There will be four intervention groups with equal participants (n=20 each), randomly assigned: Group A: Treatment as usual (psychopharmacological treatment only). Group B: Mindfulness-Based Cognitive Behavioral Therapy (MBCT) + psychopharmacological treatment. Group C: EEG-based Neurofeedback (NFB) + psychopharmacological treatment. Group D: Combined MBCT and NFB treatment. All participants, except Group A, will undergo 12 weekly sessions of therapy (MBCT: 50 mins; NFB: 30 mins + prep time).

Main outcome variables

Primary Outcome: 1. Reduction in OCD symptom

severity, assessed using the Yale Brown Obsessive Compulsive Scale (YBOCS). Secondary Outcomes: 1. Levels of depression, anxiety, and stress (DASS-21). 2. Insight and belief delusionality (Brown Assessment of Belief Scale). 3. Childhood trauma severity (MACE). 4. Biomarker levels (IL-6, IL-1 β , C-reactive protein).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250304064931N1**

Registration date: **2025-05-29, 1404/03/08**

Registration timing: **registered_while_recruiting**

Last update: **2025-05-29, 1404/03/08**

Update count: **0**

Registration date

2025-05-29, 1404/03/08

Registrant information

Name

Sumaira Mehreen

Name of organization / entity

Lady Reading Hospital Peshawar

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-28, 1404/02/08

Expected recruitment end date

2025-08-27, 1404/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of EEG-Based Neurofeedback Therapy Versus Conventional Therapies (Medication and Mindfulness-Based Cognitive Behavioral Therapy) in Improving Symptoms of Obsessive-Compulsive Disorder Patients: A Randomized Controlled Trial

Public title

Comparison of the Effectiveness of EEG-Based Neurofeedback Therapy Versus Conventional Therapies (Medication and Mindfulness-Based Cognitive Behavioral Therapy) in Improving Symptoms of Obsessive-Compulsive Disorder Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosed with Obsessive-Compulsive Disorder (OCD) according to DSM-5 criteria. Aged between 18 and 40 years. No neurological disorder (stroke, head injury, epilepsy, dementia). No severe medical conditions (e.g., hepatic failure, renal failure). No history of psycho-surgery or neurosurgical procedures.

Exclusion criteria:

Psychiatric comorbidity (schizophrenia, psychosis, delusional disorders). Substance abuse or drug dependence.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

To implement random allocation, we will use OpenEpi software to generate a list of random numbers corresponding to participant IDs. Each eligible participant will be assigned a unique identifier, and based on the random number sequence, they will be allocated to either the intervention or control group in a 1:1 ratio. Allocation will be performed using a simple randomization approach without stratification or blocking. The randomization list will be prepared in advance by an independent statistician not involved in

participant recruitment to maintain allocation concealment. The group assignments will be placed in sequentially numbered, opaque, sealed envelopes, which will be opened only after participant enrollment.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomized controlled trial (RCT) design

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Board- Lady Reading Hospital
Peshawar

Street address

Soekarno Rd, Pipal Mandi, Peshawar, 25000

City

Peshawar

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25000

Approval date

2024-01-14, 1402/10/24

Ethics committee reference number

283/LRH/MTI

Health conditions studied**1****Description of health condition studied**

Obsessive-Compulsive Disorder (OCD) is a chronic mental health condition characterized by persistent, intrusive thoughts (obsessions) and repetitive behaviors or mental acts (compulsions) that an individual feels compelled to perform. These symptoms can cause significant distress, interfere with daily functioning, and diminish quality of life. The study focused on understanding the clinical presentation, underlying mechanisms, and potential interventions for individuals affected by OCD. Emphasis was placed on early diagnosis, treatment outcomes, and the socio-cultural context influencing symptom expression and treatment adherence.

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Obsessive compulsive disorder

Timepoint

Before intervention (baseline), and on every follow up (monthly in group A for 3 months which is treatment as usual group, and weekly in treatment group B, C and D for 12weeks

Method of measurement

Yale brown obsessive compulsive scale (YBOCS)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Group A (treatment as usual)

Category

Treatment - Drugs

2

Description

Intervention group: Group B (mindfulness based cognitive therapy with medication)

Category

Treatment - Other

3

Description

Intervention group: roup C (electroencephalogram based neurofeedback with medication)

Category

Treatment - Other

4

Description

Intervention group: Group D (Mindfulness based cognitive therapy/Electroencephalogram based neurofeedback without medication)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Lady Reading Hospital, Medical Teaching Institute

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khyber Medical University Peshawar

Full name of responsible person

Dr. Syed Muhammad Shabbir Ali Naqvi

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Web page address

<https://kmu.edu.pk/>

Grant name

N/A

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

N/A

Proportion provided by this source

1

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

2

Sponsor

Name of organization / entity

Lady Reading Hospital Peshawar

Full name of responsible person

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Grant name
N.A

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
N/A

Proportion provided by this source
1

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
University of Peshawar

Full name of responsible person
Sumaira Mehreen

Position
PhD scholar

Latest degree
Master

Other areas of specialty/work
Clinical psychology

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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

I will provide study protocols, data analysis, and codes

When the data will become available and for how long

After the completion of my thesis, I will provide for a long time.

To whom data/document is available

To IRCT and other members

Under which criteria data/document could be used

For research and educational purposes

From where data/document is obtainable

from websites and journals

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

online

Comments

N/A