Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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-Iβ, 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

Phone

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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
Postal code
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
Sumaira Mehreen
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Soekarno Rd, Pipal Mandi, Peshawar,
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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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coordinator.ctu@kmu.edu.pk
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
Dr Sumaira Mehreen
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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 scientific inquiries

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Person responsible for updating data

Contact

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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