

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effectiveness of Mindful Interoceptive Exposure on improvement of symptoms of patients with Obsessive Compulsive Disorder

Protocol summary

Study aim

Evaluating the effectiveness of exposure techniques in the treatment of obsessive-compulsive disorder and their application in working with patients diagnosed with OCD

Design

The study is a parallel-group clinical trial conducted on 30 patients diagnosed with obsessive-compulsive disorder (OCD).

Settings and conduct

The study will be conducted in Kurdistan Province (Sanandaj city) at the Psychology Clinic of Ghods Hospital. After screening and random allocation without knowledge of their assigned group, participants will enter the study. The statistical assessor will also be blinded to the group assignments. Additionally, participants will not incur any costs for the services provided

Participants/Inclusion and exclusion criteria

inclusion criteria: • Willingness to participate in the study • Ability to read and write at a middle school level • Diagnosis of obsessive-compulsive disorder (OCD) based on a psychiatric evaluation • Not currently undergoing any psychotherapy • No changes in medication during the psychotherapy period Not inclusion criteria: • Presence of a psychotic disorder or lack of insight in OCD • Having intellectual or cognitive impairments such as intellectual disability, dementia, or delirium • Concurrent substance use disorders

Intervention groups

The study includes two groups: one group receives a structured and direct intervention of mindfulness-based exposure and response prevention (ERP), while the other group does not receive any specific intervention concurrently. The intervention program is based on a protocol that integrates cognitive-behavioral therapy with mindfulness.

Main outcome variables

Yale-Brown Obsessive Compulsive Scale (Y-BOCS)
Depression Anxiety and Stress Scale Anxiety sensitivity index 3 Multidimensional Assessment of Interoceptive

Awareness-2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220113053705N2**

Registration date: **2025-07-06, 1404/04/15**

Registration timing: **registered_while_recruiting**

Last update: **2025-07-06, 1404/04/15**

Update count: **0**

Registration date

2025-07-06, 1404/04/15

Registrant information

Name

Fateh Sohrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3371 8025

Email address

f.sohrabi20@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-02, 1404/04/11

Expected recruitment end date

2025-12-02, 1404/09/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The effectiveness of Minfdul Interoceptive Exposure on improvement of symptoms of patients with Obsessive Compulsive Disorder
Public title	The effectiveness of Minfdul Interoceptive Exposure on improvement of OCD symptoms
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	• Willingness to participate in the study • Ability to read and write at a middle school level • Diagnosis of obsessive-compulsive disorder (OCD) based on a psychiatric evaluation • Not currently undergoing any psychotherapy • No changes in medication during the psychotherapy period
Exclusion criteria:	• Presence of a psychotic disorder or lack of insight in OCD • Having intellectual or cognitive impairments such as intellectual disability, dementia, or delirium • Concurrent substance use disorders
Age	From 18 years old
Gender	Both
Phase	3
Groups that have been masked	• Data analyser
Sample size	Target sample size: 30
Randomization (investigator's opinion)	Randomized
Randomization description	After identifying and selecting eligible participants, they will be randomly assigned to the study groups through a lottery method. Specifically, the participants' names will be written on identical cards, which will then be randomly drawn from a designated container to divide the individuals into intervention and control groups. This approach is used to eliminate any potential bias in the allocation process and to enhance the internal validity of the study.
Blinding (investigator's opinion)	Single blinded
Blinding description	During the data analysis phase, the clinical evaluator or researcher reviewing the data is kept unaware of the participants' group assignments and their characteristics. The data are coded or anonymized in a way that prevents the evaluator from identifying which data belongs to which group. This procedure helps prevent evaluator bias in interpreting and assessing the data, thereby enhancing the validity of the study results.
Placebo	Not used
Assignment	

Parallel	
Other design features	
Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	research ethics committees of Kurdistan university of medical sciences
Street address	Faculty of Medicine, Kurdistan University of Medical Sciences, Pasdaran Ave.
City	Sanandaj
Province	Kurdistan
Postal code	۱۵۱۷۵-۶۶۱۷۷
Approval date	2025-06-10, 1404/03/20
Ethics committee reference number	IR.MUK.REC.1404.089
Health conditions studied	
1	
Description of health condition studied	Obsessive-Compulsive Disorder
ICD-10 code	F42
ICD-10 code description	Obsessive-compulsive disorder
Primary outcomes	
1	
Description	Yale-Brown Obsessive Compulsive Scale (Y-BOCS)
Timepoint	Before the intervention starts – after completing the treatment sessions – and three months after the last session
Method of measurement	Yale-Brown Obsessive Compulsive Scale (Y-BOCS)
2	
Description	Anxiety Sensitivity Index-3
Timepoint	Before the intervention starts – after completing the treatment sessions – and three months after the last session
Method of measurement	

3**Description**

Multidimensional Assessment of Interoceptive Awareness-2

Timepoint

Before the intervention starts – after completing the treatment sessions – and three months after the last session

Method of measurement

Multidimensional Assessment of Interoceptive Awareness-2

4**Description**

Depression, Anxiety and Stress scale

Timepoint

Before the intervention starts – after completing the treatment sessions – and three months after the last session

Method of measurement

Depression, Anxiety and Stress scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention group receives mindfulness-based exposure therapy as the treatment, which consists of four therapy sessions with specific goals and strategies. Details of the weekly sessions are provided in Table 1. This therapy is a third-wave cognitive-behavioral treatment and is one of the transdiagnostic approaches that utilize mindfulness skill training along with cognitive-behavioral techniques. All sessions (Sessions 1-8) are outlined according to the relevant protocol (Sohrabi et al., 2024; Kiyon, 2011; Kiyon, Francis & Shirz, 2018). The primary goal of the therapy, following the therapeutic contract and client preparation, is to facilitate the process of change, which continues with several main objectives pursued across multiple sessions. The first phase is introversion, which focuses on developing attention skills, attention restoration, and attention regulation within the context of emotion regulation, using mindfulness techniques. Next, in the extroversion phase, the learned skills provide a basis for confronting intrapersonal problems, employing mindful exposure techniques to address harmful personal contexts. Then, as skills expand, the interpersonal and extrapersonal phases broaden this confrontation to wider interpersonal contexts. Finally, these stages are integrated into a comprehensive therapeutic package.

Category

Treatment - Other

2**Description**

Control group: After being assigned to the control group, participants do not receive any specific psychotherapeutic intervention concurrently and continue to receive only their usual medication treatment.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Psychological Clinic of Ghods Hospital

Full name of responsible person

Dr Fateh Sohrabi

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Ghods Hospital. Pasdaran Ave. Shohadayy nirooy entezami Blv.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

kurdistan 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
Sanandaj University of Medical Sciences
Full name of responsible person
Fateh Sohrabi
Position
Assistant Professor
Latest degree
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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data related to the study will be provided in response to legitimate requests from the relevant organizations.

When the data will become available and for how long

After publication of the data

To whom data/document is available

Academic researchers can access the data upon submitting a formal and justified request.

Under which criteria data/document could be used

The individual must have a verified identity and submit the request through an official or academic organization. They must accept responsibility for maintaining confidentiality and not disclosing the data without permission, in accordance with ethical principles.

From where data/document is obtainable

They can correspond via the following email to make a

request: F.sohrabi20@gmail.com

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

After receiving the email and reviewing it through official channels, the request will be responded to as soon as possible.

Comments