Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effectiveness of Minfdul 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 sensetivity 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
۱۵۱۷۵-۴۴۱۷۷

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

Anxiety Sensitivity Index-3

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
Street address
Ghods Hospital. Pasdaran Ave. Shohadayy nirooy entezami Blv.
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f.sohrabi20@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Dr Fardin Maleki
Street address
kirdistan University of Medica sciences- Pasdaran Ave.
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Ṡanandaj
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Phone
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Email
Fardin8725@gmail.com
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
Ph.D.

Other areas of specialty/work
Psychology

Street address
Clinical Psychology Branch, Faculty of Medicine, Kurdistan University of Medical Sciences, Pasdaran Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Fateh Sohrabi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Fateh Sohrabi

Position
Assistant Professor

Latest degree
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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