Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of Mindfulness-Integrated Cognitive Behavioral Therapy (MiCBT) and Exposure and Response Prevention (ERP) in Individuals with Obsessive-Compulsive Disorder with a History of Childhood Maltreatment

Protocol summary

Study aim
Comparison of the Effectiveness of Mindfulness-Integrated Cognitive Behavioral Therapy (MiCBT) and Exposure and Response Prevention (ERP) in Individuals with Obsessive Compulsive Disorder with a History of Childhood Maltreatment.

Design
The clinical trial has two intervention groups (in parallel), double-blind, with a total of 62 people randomized using the rand function of Excel software.

Settings and conduct
This study will be conducted at the psychiatric and psychological outpatient clinics of Shahid Beheshti University of Medical Sciences. Patients who obtain at least a moderate score on one of the CTQ subscales will be assessed using the SCID-5-CV to confirm the presence of depressive and anxiety disorders. Participants will be evaluated at three time points: pre-test, post-test, and follow-up. In this study, both participants and the statistical analyst will be blinded to the type of intervention

Participants/Inclusion and exclusion criteria
IInclusion criteria: Age 18–65 years, DSM-5-TR diagnosis of OCD confirmed by SCID-5-CV, a history of childhood maltreatment (moderate to severe score on at least one CTQ subscale), stable psychiatric medication for at least 4 weeks prior to treatment with no medication changes during the study, and provision of written informed consent. Exclusion criteria: Concurrent psychotherapy, severe cognitive or neurological disorders, substance or alcohol use disorders, psychotic disorders, suicidal ideation or suicide attempt during treatment, and absence from more than two treatment sessions.

Intervention groups
ERP group: 12 individual 60-90 minute sessions over 12 weeks. MiCBT group: 10 individual 60-90 minute sessions over 10 weeks.

Main outcome variables
Severity of obsessive-compulsive symptoms, Internalized shame, Obsessive beliefs, Emotion regulation and experiential avoidance

General information

Reason for update

Acronym
MiCBT, ERP

IRCT registration information
IRCT registration number: **IRCT20260421069122N1**
Registration date: **2026-07-06, 1405/04/15**
Registration timing: **prospective**

Last update: **2026-07-06, 1405/04/15**
Update count: **0**

Registration date
2026-07-06, 1405/04/15

Registrant information

Name
Farnaz Doostdari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date

2026-08-22, 1405/05/31

Expected recruitment end date

2027-05-22, 1406/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Mindfulness-Integrated Cognitive Behavioral Therapy (MiCBT) and Exposure and Response Prevention (ERP) in Individuals with Obsessive-Compulsive Disorder with a History of Childhood Maltreatment

Public title

Comparison of the Effectiveness of MiCBT and ERP in Individuals with Obsessive-Compulsive Disorder with a History of Childhood Maltreatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 18 to 65 years Providing written informed consent to participate in the study A diagnosis of Obsessive-Compulsive Disorder (OCD) according to DSM-5-TR criteria, established using the Structured Clinical Interview for DSM-5, Clinician Version (SCID-5-CV) A history of childhood maltreatment, defined as obtaining a score in the moderate-to-severe range on at least one subscale of the Childhood Trauma Questionnaire (CTQ) For participants receiving pharmacotherapy, maintaining a stable medication regimen for at least four weeks before the intervention and throughout the study period, with no changes in medication type or dosage

Exclusion criteria:

Inability to read and write Receiving concurrent psychotherapy (individual or group therapy) during the study period Severe cognitive or neurological disorders (e.g., intellectual disability, dementia, or organic brain disorders) that preclude meaningful participation in the intervention. Diagnosis of severe psychiatric disorders (e.g., psychotic disorders or bipolar disorder) based on the Structured Clinical Interview for DSM-5, Clinician Version (SCID-5-CV). Emergence of suicidal ideation or a suicide attempt during the course of treatment. Substance and alcohol abuse or dependence.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was employed. Randomization was performed using a random number table. For each participant, a random number between 0 and 1 was generated. Participants with random values greater than or equal to 0.5 were assigned to the Mindfulness-Integrated Cognitive Behavioral Therapy (MiCBT) group, whereas those with random values less than 0.5 were assigned to the Exposure and Response Prevention (ERP) group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and the statistical analyst will be blinded to the intervention conditions. Participants will not be informed about the specific type of intervention they receive, and the analyst responsible for data analysis will have no knowledge of group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Arabi Street, Daneshjoo Boulevard, Velenjak, Tehran, Iran

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Tehran

Province

Tehran

Postal code

1983969411

Approval date

2025-11-05, 1404/08/14

Ethics committee reference number

IR.SBMU.MSP.REC.1404.483

Health conditions studied

1

Description of health condition studied

Obsessive-compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-Compulsive Disorder (OCD)

Primary outcomes

1

Description
Severity of obsessive-compulsive symptom
Timepoint
Assessments were conducted before the intervention, immediately after the intervention, and three months following the completion of the intervention.
Method of measurement
Yale-Brown Obsessive Compulsive Scale (Y-BOCS)

Secondary outcomes

1

Description
Emotion dysregulation
Timepoint
Assessments were conducted before the intervention, immediately after the intervention, and three months following the completion of the intervention.
Method of measurement
Difficulties in Emotion Regulation Scale–Short Form (DERS-SF)

2

Description
Obsessive beliefs
Timepoint
Assessments were conducted before the intervention, immediately after the intervention, and three months following the completion of the intervention.
Method of measurement
Short Form of Obsessive Beliefs Questionnaire (OBQ-20)

3

Description
experiential Avoidance
Timepoint
Assessments were conducted before the intervention, immediately after the intervention, and three months following the completion of the intervention.
Method of measurement
Acceptance and Action Questionnaire-II (AAQ-II)

4

Description
Internalized Shame
Timepoint
Assessments were conducted before the intervention, immediately after the intervention, and three months following the completion of the intervention.
Method of measurement
Internalized Shame Scale (ISS)

Intervention groups

1

Description
Intervention group: Mindfulness integrated of cognitive behavioral therapy. Participants will participate in ten structured 60- to 90-minute MICBT sessions, conducted according to the standard Bruno Cayon protocol. It emphasizes components such as improving emotion regulation, enhancing cognitive flexibility and mindfulness, and reducing avoidance of situations that trigger obsessive thoughts and compulsive behaviors
Category
Treatment - Other

2

Description
Intervention group: Exposure and Response Prevention (ERP) therapy will be administered in twelve 60-90 minute sessions based on the standard Edna Foa protocol.. This intervention focuses on gradual exposure to obsession-triggering stimuli and prevention of compulsive responses to reduce anxiety and obsessive-compulsive symptoms.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatric and psychological outpatient clinics affiliated with Shahid Beheshti University of Medic
Full name of responsible person
Hoda Doosalivand
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Afshin Zarghi

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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Farnaz Doostdari
Position
Ph.D student in 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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data can be shared after de-identifying individuals, including the following: 1. Demographic data; 2. Data related to independent and dependent variables at pre-test, post-test, and follow-up.

When the data will become available and for how long

Start of access period before results are printed

To whom data/document is available

No restrictions

Under which criteria data/document could be used

Writing and publishing articles based on the data from this study is not permitted.

From where data/document is obtainable

Send your request to farnazdoostdari@gmail.com. 2. Visit the OSF.io website.

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

The data is available online at the mentioned site.

Comments