

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Oct 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

Inclusion 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)

Phone

+98 21 2243 9945

Email address

f.doostdari@sbmu.ac.ir

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
City
 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 993 051 8701

Email

doosalivand.h@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

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

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2243 9780

Email

info@sbmu.ac.ir

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

Full name of responsible person

Farnaz Doostdari

Position

Ph.D student in Clinical Psychology

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Unit 7, No. 29, Mosivand Alley, Qazvin Street

City

Tehran

Province

Tehran

Postal code

1333983181

Phone

+98 21 2243 9945

Fax**Email**

f.doostdari@sbmu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hoda Doos Alivand

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

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

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 23871

Fax**Email**

doosalivand.h@sbmu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farnaz Doostdari

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

No. 29, Mousavand Alley, Qazvin Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1333983181

Phone

+98 21 2243 9945

Email

farnazdoostdari@gmail.com

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