Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of mindfulness-based cognitive therapy on reducing perceived stress, anxiety, and psychosomatic symptoms in female patients with obsessive-compulsive disorder.

Protocol summary

Study aim
Investigating the effectiveness of mindfulness-based cognitive therapy on reducing perceived stress, anxiety, and psychosomatic symptoms in female patients with obsessive-compulsive disorder

Design
a randomized, double-blind, parallel-group clinical trial

Settings and conduct
Women with obsessive-compulsive disorder who refer to the Ahvaz Psychological Counseling Center will be included in the study if they are eligible and will be randomized, two-group, and parallelly assigned to the intervention and control groups. This study will be conducted in an unblinded manner.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Age between 20 and 45 years; A diagnosis of obsessive-compulsive disorder (OCD) confirmed by a psychiatrist;Agreement to comply with the rules of participation in the study. Exclusion criteria:Currently receiving pharmacological treatment for any Axis I or Axis II psychiatric disorder; Concurrent participation in any other treatment program during the study period.

Intervention groups
Intervention group: Mindfulness skills training sessions include training in mindfulness techniques (such as body scanning, sitting meditation, and conscious stretching) and cognitive therapy skills to manage obsessive thoughts, reduce perceived stress, reduce anxiety, and modulate psychosomatic symptoms. They are held over 8 sessions, each session being held once a week for 120 minutes. The equipment used includes a quiet meeting room, guided meditation audio files, and homework booklets. Control group: No intervention will be performed.

Main outcome variables
Perceived stress, anxiety, and psychosomatic symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260701070039N1**
Registration date: **2026-08-22, 1405/05/31**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-22, 1405/05/31**
Update count: **0**

Registration date
2026-08-22, 1405/05/31

Registrant information

Name
Nahid Pourameri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3334 6898

Email address
nahid.pourameri@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-20, 1405/05/29

Expected recruitment end date
2026-10-21, 1405/07/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of mindfulness-based cognitive therapy on reducing perceived stress, anxiety, and psychosomatic symptoms in female patients with obsessive-compulsive disorder.

Public title
Investigating the effect of mindfulness in reducing psychological symptoms in women with obsessive-compulsive disorder.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in research Age range 20 to 45 years Acceptance of the rules of participation in the course Having obsessive-compulsive disorder as diagnosed by a psychiatrist Having at least a high school diploma or equivalent to answer the questionnaire questions

Exclusion criteria:
Currently receiving pharmacotherapy for any Axis I or Axis II psychiatric disorder. The presence of learning disabilities or cognitive deficits that impair understanding of mindfulness concepts Participating in other treatment programs while participating in research

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were allocated to two intervention groups (mindfulness-based cognitive therapy) and control groups in a 1:1 ratio. The method used is simple randomization, in which the randomization unit is the participant; cluster or stratified allocation methods were not used in this study. The random sequence was prepared using the random number generator of IBM SPSS Statistics software version 26 by a third party outside the main research team (independent of the implementation and evaluation process). For this purpose, an independent random number from a uniform distribution in the range [0,1] was generated for each of [N] participants using the RANDOM function and by fixing the initial number for sequence reproducibility; participants whose generated number was less than 0.5 were placed in the intervention group and the rest in the control group. In order to ensure allocation concealment and prevent group prediction, opaque, opaque, sealed, and numbered envelopes in sequential order (from 1 to [N]) were used. The name of the group (intervention or control) is written on cards and placed inside the envelopes according to the random sequence prepared. The identification code of each participant is written on the relevant envelope only after his/her entry into the study is confirmed and informed consent is obtained. The envelope is opened only by the main study administrator, in the presence of the participant and after the registration and baseline assessments are completed. In this way, the researcher and the participant remain unaware of the relevant group until the final moment of allocation.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee ،Islamic Ahvaz University

Street address
3rd Floor, Administrative Building, Islamic Azad University, Ahvaz Branch, Farhang Shahr, Golestan Highway, Ahvaz, Iran.

City
Ahvaz

Province
Khouzestan

Postal code
37333- 61349

Approval date
2026-05-26, 1405/03/05

Ethics committee reference number
IR.IAU.AHVAZ.REC.1405.145

Health conditions studied

1

Description of health condition studied
Obsessive-compulsive disorder

ICD-10 code
F42

ICD-10 code description
Obsessive-compulsive disorder

2

Description of health condition studied
Generalized anxiety disorder

ICD-10 code
F41.1

ICD-10 code description
Generalized anxiety disorder

3

Description of health condition studied
Somatization disorder
ICD-10 code
F45.0
ICD-10 code description
Somatization disorder

Primary outcomes

1

Description
The score that the subject obtains from the Cohen Perceived Stress Questionnaire.
Timepoint
Before the intervention begins (pre-test), after the intervention ends (post-test).
Method of measurement
Cohen's Perceived Stress Scale (PSS)

2

Description
The score that the subject obtains from the Spielberger Anxiety Inventory (STAI-Y).
Timepoint
Before the intervention begins (pre-test), after the intervention ends (post-test).
Method of measurement
Spielberger Anxiety Inventory (STAI-Y)

3

Description
The score that the subject obtains from the Lacourt Psychosomatic Symptoms Questionnaire.
Timepoint
Before the intervention begins (pre-test), after the intervention ends (post-test).
Method of measurement
Lacourt Psychosomatic Symptoms Questionnaire (2013)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1- Pre-test: Before the start of the first session, all participants in the intervention group will be given tests related to the research variables. 2- Implementation of the intervention: The sessions will be presented regularly and step by step according to the mentioned educational content. The intervention includes an educational-training course consisting of 8 sessions that will be held weekly. The total duration of the intervention is 2 months (8 weeks). The steps of implementing the intervention are as follows:. Practical homework-based exercises for use at home will be provided to the participants at the end of each session. 3- Post-test: Immediately after the end of the eighth session, a post-test will be taken from the group members to evaluate the changes achieved. Follow-up test: In order to measure the sustainability of the intervention effects, a follow-up stage will be conducted 60 days after the end of the last session by re-administering the tests. Session content: Session 1: Introduction and basics of mindfulness: explaining the goals of treatment, getting to know each other, defining the concept of mindfulness, and practicing "conscious eating" to understand presence in the moment. Session 2: Understanding the mind and thoughts: examining how the mind works, distinguishing between "being" and "doing," and practicing "observing thoughts as mental events" (not objective facts). Session 3: Focusing on the body: teaching the "body scan" exercise to identify physical tensions caused by obsessions and improving sensory awareness. Session 4: Facing difficulties: teaching an acceptance approach to obsessive thoughts and unpleasant feelings; replacing avoidance with active observation. Session 5: Acceptance and release: practicing the "three-minute breathing space" technique to manage impulses and obsessive thoughts in critical moments. Session 6: Unpleasant thoughts and emotions: examining the relationship between negative automatic thoughts and symptoms of obsessions; Practice "cognitive distancing" from thought content.Session 7: Self-care and adaptive skills: Identifying warning signs of relapse and developing an action plan for self-care in stressful situations.Session 8: Summary and relapse prevention: Reviewing key learnings, examining challenges in the treatment path, emphasizing continuity of practice in daily life, and discussing strategies for maintaining treatment gains.In these sessions, mindfulness skills and practical exercises are taught. In the final sessions, emphasis is placed on consolidating learning, practicing adaptive strategies, and preventing relapse.After completing the intervention sessions, participants will be given a post-test. Also, in order to assess the sustainability of the treatment effects, a follow-up test will be conducted for the intervention group 60 days after the end of the intervention.
Category
Treatment - Other

2

Description
Control group: No intervention will be performed
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Fanous Rah Specialized Counseling and Psychology Clinic

Full name of responsible person
Zahra Dasht-e-Bozorgy
Street address
Unit 10, 5th Floor, Hani Medical Complex, Corner of 14th St., Vahabi St., Kianpars, Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
6133613395
Phone
+98 916 305 9829
Email
dashtbozorgi.z@iau.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Aslan Oghdernejad
Street address
No. 162, Between Zahed and Manateq Sts., Komeil St., Zeytoon-e Karmandi, Ahvaz, Khuzestan, Iran.
City
Ahvaz
Province
Khouzestan
Postal code
۶۱۳۴۹-۳۷۳۳۳
Phone
+98 61 3334 8361
Fax
+98 61 3334 8336
Email
info@iauahvaz.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Nahid Pourameri
Position
Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
No. 162, Between Zahed and Manateq Sts., Komeil St., Zeytoon-e Karmandi, Ahvaz, Khuzestan, Iran.
City
Ahvaz
Province
Khouzestan
Postal code
6164635686
Phone
+98 61 3334 6898
Email
nahid.pourameri@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Samira Seyed Asiaban
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Third Floor, Faculty of Humanities, Islamic Azad University, Ahvaz Branch, Farhang-shahr, Golestan Highway, Ahvaz, Iran.
City
Ahvaz
Province
Khouzestan
Postal code
6134937333
Phone
+98 61 3334 8420
Fax
+98 61 3334 8336
Email
Seyedasiaban63@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Nahid Pourameri

Position
Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
No. 162, Between Zahed and Manateq Sts., Komeil St., Zeytoon-e Karmandi, Ahvaz, Khuzestan, Iran.
City
Ahvaz
Province
Khouzestan
Postal code
6164635686
Phone
+98 61 3334 6898
Email
nahid.pourameri@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available