Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Efficacy of Mindfulness-Based Cognitive Therapy (MBCT) on Rumination and Emotion Regulation in Patients with Anxiety and Depression

Protocol summary

Study aim
The Efficacy of Mindfulness-Based Cognitive Therapy on Rumination and Emotion Regulation in Patients with Anxiety and Depression

Design
A controlled clinical trial with parallel groups, without blinding, randomized, on 40 patients. The rand function of Excel software will be used for randomization.

Settings and conduct
The statistical population of the study will be all employed women referring to Rayan counseling centers in Ahvaz during the period of June 2026. In the sample selection stage, convenience sampling method will be used. After selecting the samples to a volume of 40 people, based on the research entry and exit criteria, the participants will be randomly assigned to two groups: "Mindfulness-Based Cognitive Behavioral Therapy" (intervention group) and "Waiting List" (control group).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged between 30 and 40 years, diagnosed with anxiety, depression, or anxiety-depression comorbidity based on a clinical interview or validated questionnaire, experiencing frequent rumination (according to questionnaire score or self-report) Exclusion criteria: Unwillingness to participate in the study, concurrent participation in other active psychological treatments

Intervention groups
Intervention group: All individuals who will receive mindfulness-based cognitive-behavioral therapy. Control group: All individuals who will not receive any intervention.

Main outcome variables
Rumination, Emotion Regulation, Anxiety, Depression

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260513069394N1**
Registration date: **2026-05-17, 1405/02/27**
Registration timing: **prospective**

Last update: **2026-05-17, 1405/02/27**
Update count: **0**
Registration date
2026-05-17, 1405/02/27

Registrant information
Name
Fatemeh Halajzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 3333 3333
Email address
fatemehhallajzadeh7@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-06-05, 1405/03/15
Expected recruitment end date
2026-06-21, 1405/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Efficacy of Mindfulness-Based Cognitive Therapy (MBCT) on Rumination and Emotion Regulation in Patients with Anxiety and Depression

Public title
Investigating the effect of mindfulness training on improving mental health in people with anxiety and depression

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Women in their 30s and 40s Diagnosis of anxiety, depression, or anxiety-depression comorbidity based on a clinical interview or validated questionnaire Score above the cutoff on standard depression or anxiety questionnaires Experience of frequent rumination as measured by questionnaire score or self-report

Exclusion criteria:
Unwillingness to participate in research Concurrent participation in other active psychological therapies

Age
From **30 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The statistical population of the study will comprise all employed women attending counseling center during the period of June 2026. In this type of effectiveness study, a two-stage approach is typically used: in the sampling stage, convenience sampling is employed. After selecting a sample of 40 participants, based on the study's inclusion and exclusion criteria, participants will be randomly assigned to two groups: "Mindfulness-Based Cognitive Behavioral Therapy" (intervention group) and "Waiting List" (control group). Randomization will be performed using permuted random blocks with variable sizes (4 and 6 participants) by an independent statistician who is not involved in the implementation process. The random allocation list will be generated using the RAND function in Excel software and then placed in opaque, sealed, and sequentially numbered envelopes to ensure the researcher and participants remain unaware of the allocation sequence (allocation concealment). The envelope will be opened, and the assigned group will be revealed only at the time each participant enters the study. To ensure baseline equivalence of variables (such as anxiety level and age), their distribution between the two groups will be examined during the statistical analysis phase.

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
Ethics Committee of Islamic Azad University of Ahvaz Branch

Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway

City
Ahvaz

Province
Khouzestan

Postal code
6134937333

Approval date
2026-04-30, 1405/02/10

Ethics committee reference number
IR.IAU.AHVAZ.REC.1405.104

Health conditions studied

1

Description of health condition studied
Anxiety and Depression

ICD-10 code
F41.3

ICD-10 code description
Other mixed anxiety disorders

Primary outcomes

1

Description
Rumination

Timepoint
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention

Method of measurement
The variable will be measured using the Nolen-Hoeksma and Maru (1991) rumination questionnaire.

2

Description
Emotion Regulation

Timepoint

1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention

Method of measurement

The variable will be measured using the Gross and John (2003) emotion regulation questionnaire.

3

Description

Anxiety

Timepoint

1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention

Method of measurement

The variable will be measured using the Beck et al. (1988) anxiety scale.

4

Description

Depression

Timepoint

1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention

Method of measurement

The variable will be measured using the Beck et al. (1996) Depression Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mindfulness-Based Cognitive Behavioral Therapy. Duration of each session: 90 minutes; Total number of sessions: 8 sessions, Session sequence: Twice a week; Key therapeutic tools: This intervention focuses on mindfulness, acceptance, emotional regulation, and coping with rumination. Main therapeutic tools include: Mindfulness exercises, training attention to the present moment, non-judgmental observation of thoughts and emotions. Session content: Session 1: Introduction to the therapy, explaining objectives, and pre-test administration. Session 2: Teaching the basics of mindfulness and attention to present moment experience. Session 3: Identifying automatic thoughts and dysfunctional thought patterns. Session 4: Practicing non-judgmental observation and acceptance of thoughts and emotions. Session 5: Teaching body awareness and practicing breathing and relaxation. Session 6: Working on emotional regulation and coping with rumination. Session 7: Practical mindfulness exercises in everyday situations. Session 8: Session summary, reviewing exercises, post-test administration, and determining follow-up.

Category

Treatment - Other

2

Description

Control group: The control group will not receive any intervention during the research, but will receive the treatment intervention after data collection to prevent factors that threaten the internal validity of the research, such as compensatory competition from the control group or demoralization.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rayan Counseling Center of Ahvaz

Full name of responsible person

Fatemeh Hallajzadeh

Street address

Between 4th and 5th Eastern Streets, Kianpars

City

Ahvaz

Province

Khouzestan

Postal code

6133921294

Phone

+98 61 3392 1294

Email

rjoharifard@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Aslan Egdarnezhad

Street address

Opposite Keshavarz Street, Farhang Shahr, Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

6134937333

Phone

+98 61 3334 8421

Email

a_eigder@ymail.com

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
Fatemeh Hallajzadeh

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

Street address
No. 23, Karkheh Street, Corner of Karkheh 3, East 13th Street, Kianpars

City
Ahvaz

Province
Khouzestan

Postal code
6155976185

Phone
+98 61 3333 3333

Email
fatemehhallajzadeh7@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
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Position
Master's student

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+98 61 3333 3333

Email
fatemehhallajzadeh7@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Fatemeh Hallajzadeh

Position
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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
Not applicable

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

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable