Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of mindfulness-based cognitive therapy and compassion therapy on self-criticism, anxiety sensitivity, and task intolerance in women with generalized anxiety disorder

Protocol summary

Study aim

The aim of this study is to investigate and compare the effectiveness of mindfulness-based cognitive therapy and compassion therapy on reducing self-criticism, anxiety sensitivity, and intolerance of uncertainty in women with generalized anxiety disorder.

Design

A phase 2, randomized, parallel-group, controlled clinical trial on 45 patients. Participants were assigned to three groups (mindfulness-based cognitive therapy, compassion therapy, and control group). Randomization was performed in a simple manner using the rand function in SPSS software.

Settings and conduct

Location & Procedure:Conducted at Ahvaz psychology clinics, participants are screened by a psychiatrist before therapy. They receive mindfulness-based cognitive therapy or compassion therapy in controlled settings.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Having a diagnosis of generalized anxiety disorder according to psychiatric criteria. 2. Willingness to participate in the study and completing an informed consent form. Exclusion criteria 1. Having a severe psychiatric disorder such as bipolar disorder or schizophrenia that may affect the results of the study. 2. Receiving concurrent psychological or pharmacological treatments that could interfere with the effectiveness of the treatments being studied.

Intervention groups

Intervention groups: 1. Mindfulness-based cognitive therapy 2. Compassion therapy 3. Control group (no intervention)

Main outcome variables

In this study, the outcome variables include self-criticism, anxiety sensitivity, and intolerance of uncertainty, which are measured as a result of mindfulness-based cognitive therapy and compassion therapy interventions. These variables will be measured at the beginning and end of the study and their changes will be analyzed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250315065094N1**
Registration date: **2025-05-29, 1404/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-29, 1404/03/08**
Update count: **0**

Registration date

2025-05-29, 1404/03/08

Registrant information

Name

masomeh ostad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-21, 1404/01/01

Expected recruitment end date

2026-03-19, 1404/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of mindfulness-based cognitive therapy and compassion therapy on self-criticism, anxiety sensitivity, and task intolerance in women with generalized anxiety disorder

Public title

Comparing the effectiveness of mindfulness-based cognitive therapy and compassion therapy on psychological characteristics associated with generalized anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Receiving a diagnosis of generalized anxiety disorder based on the criteria of the Fifth Diagnostic and Statistical Manual of Mental Disorders (DSM-5) and based on the diagnosis of the psychiatrist of the counseling center 2. Cooperation and support during the intervention period; 3. No other mental disorders are present at the same time as the diagnosis of the psychiatrist of the counseling center 4. Subjects agree and sign a written consent form

Exclusion criteria:

Continuous use of medication that could interfere with the interventions under study; Failure to cooperate or attend 2 consecutive treatment sessions.

Age

From **20 years** old to **36 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method, individual unit, using sealed envelopes, in which a card is first prepared for each participant. These cards are usually numbered or marked to indicate the group to which they have been assigned. The cards are then placed in opaque, sealed envelopes. This is done to prevent researchers or participants from seeing the contents of the envelopes. Then, as each participant enters the study, an envelope is randomly selected. The contents of that card are removed and the group assigned to that individual is recorded.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University, Ahvaz Branch, Faculty of Humanities

Street address

Islamic Azad University, Ahvaz Branch, Faculty of Humanities

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AHVAZ

Province

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Postal code

61349-37333

Approval date

2025-01-27, 1403/11/08

Ethics committee reference number

IR.IAU.AHVAZ.REC.1403.434

Health conditions studied

1

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Participants' self-criticism score after treatment

Timepoint

Before the start of treatment (pre-test), at the end of the intervention period (post-test), at the follow-up 3 months after the end of treatment

Method of measurement

Using the Self-Criticism Questionnaire (NQR), which consists of 20 questions with a five-level response scale from 1 (never) to 5 (always), an overall score is calculated based on the sum of the scores of the questions. A higher score indicates a greater level of self-criticism.

Secondary outcomes

1

Description

Participants' anxiety sensitivity levels after treatment

Timepoint

At the end of treatment and also at follow-up 3 months after the end of the treatment intervention

Method of measurement

Using the Anxiety Sensitivity Questionnaire (ASQ), consisting of 15 questions with a five-level response scale from 1 (strongly disagree) to 5 (strongly agree), the total score is calculated based on the sum of the scores of the questions. A higher score indicates greater anxiety sensitivity.

2

Description

Average Intolerance of Uncertainty Score after Treatment

Timepoint

At the end of the 8-week intervention period and at follow-up 3 months after the end of treatment

Method of measurement

Using the Intolerance of Task Difficulty Scale (IRTQ), which consists of 10 questions with a five-level response, a total score is calculated by summing the scores of the questions. A higher score indicates greater intolerance of task difficulty.

Intervention groups

1

Description

Experimental group 1: Mindfulness-based cognitive therapy - Treatment method: This treatment includes training in present-moment awareness skills, acceptance of thoughts and feelings, and mindfulness meditation exercises. - Number of sessions: 8 therapy sessions - Duration of each session: 90 minutes - Duration of the course: 8 weeks - Session content: Includes training in mindfulness exercises, emotion regulation techniques, and strategies for reducing self-criticism and anxiety - Tools used: Exercise booklet, meditation audio files, and treatment guide

Category

Behavior

2

Description

Intervention group: Experimental group 2: Compassion therapy- Treatment method: This intervention includes training in techniques to increase self-compassion, reduce internal criticism, and exercises related to positive emotions and acceptance.- Number of sessions: 8 therapy sessions- Duration of each session: 90 minutes- Duration of the course: 8 weeks- Content of the sessions: Mental exercises to cultivate compassion, techniques to reduce anxiety related to self-criticism, and emotional acceptance training- Tools used: Exercise booklet, audio files of compassion guidance, and educational resources

Category

Behavior

3

Description

Control group: Control group: Control group: - Intervention: This group does not receive any therapeutic intervention and only routine research assessments are performed on them.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Ahvaz Branch

Full name of responsible person

Fariba Hafezi, Advisor and Associate Professor

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

It is entirely funded by the student.

Proportion provided by this source
1
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
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Fariba Hafezi and Masoumeh Ostad
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
In this study, individual patient data (IPD) will not be published. The reasons for non-publication include the following: 1. Maintaining confidentiality and privacy of participants: Due to the sensitive nature of the data, the personal and clinical information of the participants is protected and will not be published. 2. Legal and ethical requirements: According to ethical regulations and research guidelines, the publication of personal data requires specific consent and strict security controls. 3. Inability to completely anonymize data: Given the structure of the data, even after removing personal details, the data may remain identifiable, which increases the risk of revealing the identity of the participants. 4. Legal and organizational restrictions: Some institutions and organizations related to this study do not allow the publication of raw personal data, and public publication requires legal approval. 5. Research objectives and analysis method: The analyses used in this study are designed to present general results and there is no need to publish individual data.
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