Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Mindfulness-Based Cognitive Therapy (MBCT) on Alexithymia, Self-Critical Rumination, and Psychological Flexibility in Individuals with Somatic Symptom Disorder

Protocol summary

Study aim

Determining the effectiveness of mindfulness-based cognitive therapy (MBCT) on alexithymia, self-critical rumination, and psychological flexibility in people with somatic symptom disorder

Design

This clinical trial study is a controlled, parallel-group, unblinded, and randomized (sealed envelope) study. It is conducted on 38 individuals with somatic symptom disorder referred to psychotherapy centers located in Isfahan. The sealed envelope method was used for randomization.

Settings and conduct

38 eligible individuals were randomly assigned to two experimental and control groups (19 each). Both groups completed the pre-test questionnaires of emotional alexithymia, self-critical rumination, and psychological flexibility. The experimental group participated in 8 sessions of 90 minutes of mindfulness-based cognitive therapy at the analytical psychotherapy center. The control group did not receive any treatment. Finally, both groups completed the post-test.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having somatic symptom disorder; Age range between 20 and 50 years; Sufficient physical ability to attend the sessions; Informed consent and willingness to participate in the research process; Minimum literacy level (reading and writing skills) Exclusion Criteria: Receiving any psychological treatment in the control group ; Presence of acute psychological disorders such as depression or anxiety, according to psychiatric history; History of physical illnesses requiring medication or special dietary regimen

Intervention groups

19 eligible individuals who complete research questionnaires as a pre-test but do not receive any treatment. Intervention group: 19 eligible individuals who participated in mindfulness-based cognitive therapy sessions after the pre-test.

Main outcome variables

Alexithymia, self-critical rumination, psychological flexibility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250507065634N7**
Registration date: **2025-10-22, 1404/07/30**
Registration timing: **prospective**

Last update: **2025-10-22, 1404/07/30**
Update count: **0**

Registration date

2025-10-22, 1404/07/30

Registrant information

Name

mahnaz shafaei fallah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 930 0704

Email address

articlelab.com@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-25, 1404/08/03

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of Mindfulness-Based Cognitive Therapy (MBCT) on Alexithymia, Self-Critical Rumination, and Psychological Flexibility in Individuals with Somatic Symptom Disorder

Public title
The effectiveness of mindfulness-based cognitive therapy in Individuals with Somatic Symptom Disorder
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having somatic symptom disorder Age range between 20 and 50 years Sufficient physical ability to attend the sessions Informed consent and willingness to participate in the research process Minimum literacy level (reading and writing skills)
Exclusion criteria:
Receiving any psychological treatment in the control group Presence of acute psychological disorders such as depression or anxiety, according to psychiatric history History of physical illnesses requiring medication or special dietary regimen
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
Experimental and control groups: After selecting the sample, the next step involves dividing people into experimental and control groups using a random method. How to perform randomization: First step: After selecting the voluntary sample, all selected people are placed on a list (numbers from one to 38 are assigned to people). Second step: From these people, using a random method with sealed and opaque (numbered) envelopes, individuals are divided into experimental and control groups. Each person randomly selects an envelope and is divided into the corresponding group.
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 Committees of Islamic Azad University- Najafaba Branch
Street address
Islamic Azad University, Najafabad Branch, Daneshgah Boulevard, Najafabad, Isfahan, Iran
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Approval date
2025-07-24, 1404/05/02
Ethics committee reference number
IR.IAU.NAJAFABAD.REC.1404.149

Health conditions studied

1

Description of health condition studied
Somatic Symptom Disorder
ICD-10 code
F48.9
ICD-10 code description
Nonpsychotic mental disorder, unspecified

Primary outcomes

1

Description
Alexithymia
Timepoint
Before intervention and after intervention
Method of measurement
Toronto Emotional Alexithymia Questionnaire

2

Description
Self-Critical Rumination
Timepoint
Before intervention and after intervention
Method of measurement
The Self-Critical Rumination Questionnaire, Smart et al.

3

Description

Psychological Flexibility

Timepoint

Before intervention and after intervention

Method of measurement

Dennis and Vander-Waal Psychological Flexibility Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 19 participants who meet the inclusion criteria will be randomly assigned to the control group. They will complete the Alexithymia, Self-Critical Rumination, and Psychological Flexibility questionnaires, but no treatment will be given to this group.

Category

Behavior

2

Description

Intervention group: 19 people with somatic symptom disorder who refer to psychotherapy centers in Isfahan and meet the inclusion criteria will be randomly assigned to the study as the intervention group. They will complete the alexithymia, self-critical rumination, and psychological flexibility questionnaires as a pre-test. They will then undergo 8 mindfulness-based cognitive therapy sessions based on the Crane 2017 protocol, each session lasting 90 minutes, at the Isfahan Analytical Psychotherapy Center. After completing the sessions, they will complete the alexithymia, self-critical rumination, and psychological flexibility questionnaires as a post-test.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tahlili Psychotherapy Center

Full name of responsible person

Sajedeh Nourbehesht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

Zahra Soltani Tehrani

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
Demographic data and the main outcome results of the research can be shared after de-identification and preserving the privacy of individuals.

When the data will become available and for how long
Data can be made available 4 months after the results are published and after personally identifiable information is removed.

To whom data/document is available
The study data and documentation will be available to researchers and scholars working at reputable academic and scientific institutions.

Under which criteria data/document could be used
Research data and documentation may be used for scientific and research purposes. Users must undertake to keep non-identifiable data confidential.

From where data/document is obtainable
If you need data, please contact zahrasoltani.tehrani2000@gmail.com

What processes are involved for a request to access data/document
After receiving and reviewing the request from the researcher, the request will be responded to as soon as possible.

Comments