Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of mindfulness-based cognitive therapy on resilience, quality of life, and tolerance of ambiguity in women with breast cancer

Protocol summary

Study aim
Investigating the effectiveness of mindfulness-based cognitive therapy in 8 sessions on quality of life, resilience, and tolerance of ambiguity in women with breast cancer

Design
A quasi-experimental study with a pretest-posttest design with a control group and a follow-up period with parallel groups, single-blind and randomized on 34 patients with breast cancer.

Settings and conduct
This study is being conducted at the Tabriz Pajhwok Association, in which 34 patients are randomly divided into two groups, and the experimental group receives 8 sessions of mindfulness therapy. The outcome assessors are blinded, and the therapists are not able to be blinded due to the nature of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Breast cancer Exclusion criteria: Having another medical condition or having severe psychiatric disorders and a history of receiving psychological interventions and taking psychiatric medications within the past 6 months

Intervention groups
In the present study, mindfulness-based cognitive therapy will consist of 8 intervention sessions in which participants will be taught the basics of mindfulness and explaining the problem from this perspective, mindfulness of breathing, mindfulness of daily activities including sexual activity, preventing mind wandering, identifying and accepting pleasant, unpleasant, and neutral feelings and thoughts, and mindfulness of thoughts.

Main outcome variables
on resilience, quality of life, and tolerance of ambiguity

General information

Reason for update

Acronym
MBCT

IRCT registration information
IRCT registration number: **IRCT20190924044866N5**
Registration date: **2025-09-30, 1404/07/08**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-30, 1404/07/08**
Update count: **0**

Registration date
2025-09-30, 1404/07/08

Registrant information

Name
Ali Asgharzade

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6649 2712

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-23, 1404/07/01

Expected recruitment end date
2025-10-07, 1404/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of mindfulness-based cognitive therapy on resilience, quality of life, and tolerance of

ambiguity in women with breast cancer

Public title
The effectiveness of mindfulness-based cognitive therapy on resilience, quality of life, and tolerance of ambiguity in women with breast cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having at least an eighth grade education. Over 18 years old Breast cancer (all stages of the disease) Willingness to participate in research (informed consent)
Exclusion criteria:
• Withdrawal from further cooperation • Absence of more than two meetings Having another medical condition or having severe psychiatric disorders (such as psychotic disorders, bipolar and major depressive disorders, neurocognitive disorders and substance abuse) diagnosed by a psychiatrist within the last year. • History of receiving psychological interventions and taking psychiatric medications within the past 6 months
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, to ensure both random and equitable allocation of participants, a rigorous scientific method known as concealed random allocation will be employed. The procedure will be conducted as follows: after determining eligible individuals and finalizing their enrollment, an independent colleague not involved in any other aspects of the trial will pre-determine the allocation sequence using a standard table of random numbers. To safeguard against manipulation or prediction, this predetermined random sequence will be immediately secured within sequentially numbered, opaque, sealed envelopes. Crucially, only after a participant is definitively enrolled in the study and all their baseline data has been completely collected will the corresponding envelope be opened to reveal their final group assignment—either to the intervention or control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will implement a single-blind design where participants and outcome assessors will be blinded to group allocation, while therapists will remain unblinded due to the psychological nature of the intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Tabriz Medical School Address: Tabriz , Golgasht Street , Next to Imam Reza Hospital , Medical School
City
Tabriz
Province
East Azarbaijan
Postal code
5159115705
Approval date
2025-07-01, 1404/04/10
Ethics committee reference number
IR.TBZMED.FMD.REC.1404.060

Health conditions studied

1

Description of health condition studied
Breast Cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Resilience
Timepoint
Before the intervention begins and after the intervention ends
Method of measurement
Connor and Davidson Resilience Questionnaire

2

Description
Quality of life
Timepoint
Before the intervention begins and after the intervention ends
Method of measurement

WHO-QOL-BREF Questionnaire

3

Description
Tolerance of ambiguity
Timepoint
Before the intervention begins and after the intervention ends
Method of measurement
Ambiguity Tolerance Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Women with breast cancer: 8 mindfulness sessions
Category
Treatment - Other

2

Description
Control group: Will continue standard medical care only, with identical assessments but no additional psychological intervention during the study period
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Pajhwok Association
Full name of responsible person
Elaheh khodadadi
Street address
Between Taleghani and Maghsoudieh intersection , Ark jadid
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Khosro Adibkia
Street address
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Ali Asgharzadeh
Position
Assisstant professor
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Person responsible for updating data

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psychology student

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

Data Dictionary
Not applicable