Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of mindfulness-integrated cognitive behavioral therapy on fear of cancer recurrence, body image, and post-traumatic growth among breast cancer survivors

Protocol summary

Study aim
To evaluate the effectiveness of mindfulness integrated cognitive behavioral therapy on fear of cancer recurrence, body image, and post traumatic growth in cancer survivors

Design
Randomized controlled trial with parallel group design. Total sample size 30 participants. Individual random allocation with allocation concealment.

Settings and conduct
The intervention will be delivered as eight sessions of MiCBT for the intervention group at Motahari Clinic, Shiraz. Data will be collected at baseline and post intervention using standardized questionnaires.

Participants/Inclusion and exclusion criteria
Female cancer survivors; age 18 to 50 years; at least 6 months post treatment; literacy in Persian; no severe psychiatric disorders; no concurrent psychological treatment

Intervention groups
MiCBT intervention group and a no intervention control group

Main outcome variables
Fear of cancer recurrence; body image; post-traumatic growth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260522069490N1**
Registration date: **2026-06-13, 1405/03/23**
Registration timing: **prospective**

Last update: **2026-06-13, 1405/03/23**
Update count: **0**

Registration date
2026-06-13, 1405/03/23

Registrant information

Name
Negin Sabetkish
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3623 0505
Email address
negin.sabetkishhh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-22, 1405/04/01

Expected recruitment end date
2026-08-16, 1405/05/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of mindfulness-integrated cognitive behavioral therapy on fear of cancer recurrence, body image, and post-traumatic growth among breast cancer survivors

Public title
The effect of mindfulness and cognitive behavioral therapy on anxiety, body image, and psychological growth in cancer survivors

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Female breast cancer survivors Age 18–50 years At least 6 months after completion of primary cancer treatment (surgery, chemotherapy, or radiotherapy) Ability to read and write Persian No current participation in structured psychological interventions No severe psychiatric disorders (based on clinical interview or medical history) Willingness to participate and signed informed consent

Exclusion criteria:

Diagnosis of severe psychiatric disorders (e.g., psychotic disorders or bipolar I disorder) Severe cognitive impairment or neurological disorders affecting participation Current substance or alcohol dependence Unstable or acute medical conditions during study period Inability to attend intervention sessions regularly (e.g., more than 2 missed sessions) Withdrawal of consent at any stage of the study

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization (simple) Participants will be randomly assigned to either the MiCBT intervention group or the control group using a simple randomization method (e.g., computer-generated random numbers or drawing lots). Each participant will be allocated to a group without any systematic order. To prevent prediction of group assignment, the allocation sequence will not be disclosed to the researcher in advance.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study is a randomized controlled trial with two parallel arms. After enrollment, participants will be randomly assigned to either the MICBT intervention group or the control group. Outcomes including fear of cancer recurrence, body image, and post-traumatic growth will be assessed at baseline and after the intervention. The intervention will be delivered through structured psychotherapy sessions, while the control group will not receive the specific intervention. Data will be collected using standardized self-report questionnaires.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, Islamic Azad University, Marvdasht Branch

Street address

Islamic Azad University, Marvdasht Branch, Kilometer 3, Takht-e Jamshid Boulevard, Marvdasht, Fars Province, Iran

City

Marvdasht

Province

Fars

Postal code

7371113119

Approval date

2026-06-08, 1405/03/18

Ethics committee reference number

IR.IAU.M.REC.1405.180

Health conditions studied

1

Description of health condition studied

Breast Cancer Survivors

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fear of cancer recurrence

Timepoint

Baseline and post intervention following eight sessions

Method of measurement

Fear Of Cancer Recurrence Inventory (FCRI), Depression Anxiety Stress Scale(DASS-21)

Secondary outcomes

1

Description

Body image

Timepoint

Baseline and post intervention following eight sessions

Method of measurement

Body Image Concern Inventory (BICI);

2

Description

Post traumatic growth in cancer survivors

Timepoint

Baseline and post intervention following eight sessions

Method of measurement

Posttraumatic Growth Inventory

Intervention groups

1

Description

Intervention group: Participants in this group will receive Mindfulness Integrated Cognitive Behavioral Therapy (MiCBT). The intervention consists of eight structured group sessions. The sessions include mindfulness training, identification and modification of dysfunctional thoughts, emotion regulation exercises, and related homework assignments. Sessions will be conducted weekly in an outpatient clinical setting.

Category

Behavior

2

Description

Control group: Participants in this group will not receive any structured psychological intervention and will only be assessed at baseline and post intervention. Usual care will be allowed if required.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Clinic

Full name of responsible person

Mohsen Arefian

Street address

Motahari Clinic, Karim Khan Zand Boulevard, Shiraz, Fars Province, Islamic Republic of Iran

City

Shiraz

Province

Fars

Postal code

۷۱۳۴۸۷۱۴۷۳۷

Phone

+98 71 3612 1000

Email

motahari@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Azad University Of Marvdasht

Full name of responsible person

Ahmadreza Oji Nezhad

Street address

Islamic Azad University, Marvdasht Branch, Marvdasht, Fars Province, Iran

City

Marvdasht

Province

Fars

Postal code

7371113119

Phone

+98 917 918 2372

Email

aoji62@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Azad University Of Marvdasht

Proportion provided by this source

50

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

Jahrom University

Full name of responsible person

Dr. Mohsen Arefian

Position

Assistant Professor, Jahrom University

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Jahrom University, Jahrom, Fars province, Iran

City

Jahrom

Province

Fars

Postal code

7414785318

Phone

+98 71 5437 2000

Email

M.arefian92@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Jahrom University

Full name of responsible person
Dr. Mohsen Arefian

Position
Assistant Professor, Jahrom University

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Jahrom University, Fars province, Iran

City
Jahrom

Province
Fars

Postal code
7414785318

Phone
+98 71 5437 2000

Email
M.arefian92@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Negin Sabetkish

Position
M.Sc. Student in Clinical Psychology

Latest degree
Bachelor

Other areas of specialty/work
Psychology

Street address
No. 335, 6/9 Alley, Farmandari, Sanaye St.

City
Shiraz

Province
Fars

Postal code
7196744699

Phone
+98 71 3623 0505

Email
negin.sabetkishhh@gmail.com

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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
Study data include participants' demographic characteristics, scores from from the Fear of Cancer Recurrence Inventory (FCRI), Body Image Concern Inventory (BICI), Posttraumatic Growth Inventory, and the DASS-21 questionnaire, and pre and post intervention evaluation data. The anonymized dataset will be available for research purposes after removal of identifiable information.

When the data will become available and for how long
Data will be made available one year after completion of final analysis and publication of results and will remain accessible for 5 years.

To whom data/document is available
Access will be restricted to researchers affiliated with recognized academic or research institutions with clear scientific objectives. Non academic or commercial requests will not be considered.

Under which criteria data/document could be used
Data will be used exclusively for non commercial secondary analyses within approved scientific purposes. Any further dissemination will require prior written approval.

From where data/document is obtainable
Requests should be submitted via the principal investigator's email. Following scientific and ethical review, approved applicants will receive encrypted de-identified datasets.

What processes are involved for a request to access data/document
Requests will be evaluated by the research team. Upon approval, data will be shared within 45 working days. A data access agreement may be required.

Comments
All data will be fully de-identified and no sensitive personal information will be disclosed.