

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Oct 2026

The effectiveness of mindfulness-integrated cognitive behavioral therapy (MiCBT) on episodic and semantic memory among breast cancer survivors

Protocol summary

Study aim

To evaluate the effectiveness of mindfulness integrated cognitive behavioral therapy on episodic and semantic memory in breast cancer survivors

Design

Two arm randomized controlled trial with parallel design. Individual random allocation. Total sample size 30 participants. Simple randomization 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 breast cancer survivors; age 18 to 50 years; at least 6 months post treatment; literacy in Persian; no severe psychiatric disorders; no concurrent structured psychological treatment

Intervention groups

MiCBT intervention group and a no intervention control group

Main outcome variables

Episodic memory; semantic memory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260522069488N1**

Registration date: **2026-06-24, 1405/04/03**

Registration timing: **registered_while_recruiting**

Last update: **2026-06-24, 1405/04/03**

Update count: **0**

Registration date

2026-06-24, 1405/04/03

Registrant information

Name

Marjan Rasekhi pour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3225 8554

Email address

marjan.rasekhipour@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 (MiCBT) on episodic and semantic memory among breast cancer survivors

Public title

The effect of mindfulness-based cognitive behavioral therapy on memory in breast cancer survivors

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Female breast cancer survivors Age between 18 and 50 years At least 6 months since completion of primary cancer treatment (surgery, chemotherapy, or radiotherapy) Ability to read and write in Persian No

current severe psychiatric disorders (e.g., psychosis or severe bipolar disorder) Not receiving concurrent structured psychological treatment Willingness to participate and provide 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	Research Ethics Committees of 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
Age From 18 years old to 50 years old Gender Female	Approval date 2026-06-08, 1405/03/18 Ethics committee reference number IR.IAU.M.REC.1405.178
Phase N/A Groups that have been masked No information Sample size Target sample size: 30 Randomization (investigator's opinion) Randomized Randomization description 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.	Health conditions studied <u>1</u> Description of health condition studied Breast Cancer Survivors ICD-10 code ICD-10 code description
Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel Other design features This study is a two-arm randomized controlled trial with a parallel design. Participants will be randomly allocated to either the MiCBT intervention group or the control group. Outcome assessments will be conducted at baseline (pre-test) and after the intervention (post-test). The intervention will be delivered through structured psychotherapy sessions, while the control group will not receive the specific intervention. Outcomes will be measured using standardized self-report questionnaires.	Primary outcomes <u>1</u> Description Episodic Memory Score in Breast Cancer Survivors Timepoint Assessment at Baseline (Before the Intervention) and After Completion of the Intervention Sessions Method of measurement Episodic memory will be assessed using the California Verbal Learning Test Second Edition, the Logical Memory Subtest of the Wechsler Memory Scale Fourth Edition, and the Autobiographical Recollection Test. <u>2</u> Description Semantic Memory Score in Breast Cancer Survivors Timepoint Assessment at Baseline (Before the Intervention) and After Completion of the Intervention Sessions Method of measurement Semantic memory will be assessed using the Semantic Verbal Fluency Test.
Secondary Ids empty	Secondary outcomes empty
Ethics committees <u>1</u> Ethics committee Name of ethics committee	Intervention groups <u>1</u> Description Intervention group: Participants in this group will receive

Mindfulness Integrated Cognitive Behavioral Therapy (MICBT). The intervention consists of eight structured group sessions. Each session includes mindfulness training, cognitive restructuring, attentional 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 specific psychological intervention and will only complete the baseline and post intervention assessments. They may continue to receive their usual care if needed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Clinic

Full name of responsible person

Dr. Mohsen Arefian

Street address

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

City

Shiraz

Province

Fars

Postal code

-

Phone

+98 71 3612 1000

Email

motahari@sums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Azad University Of Marvdasht

Full name of responsible person

Dr. Ahmadreza Oji Nezhad

Street address

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

Other

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 2252

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, jahrom, Fars province, Iran

City

jahrom

Province

Fars

Postal code

-

Phone

+98 917 392 0656

Fax**Email**

M.arefian92@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Azad University Of Marvdasht

Full name of responsible person

Marjan Rasekhi pour

Position

M.Sc. Student in Clinical Psychology

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

No. 5, 4th Floor, Eastern Saheli St., Alley 4, between
Imam Ali Bridge and Karandish

City

Shiraz

Province

Fars

Postal code

7145735678

Phone

+98 938 597 4307

Email

marjan.rasekhipour@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

Individual participant data include demographic characteristics, scores of fear of cancer recurrence, body image, post-traumatic growth questionnaires, and psychological test scores at baseline and post intervention. Data will be shared after removal of all personal identifiers (de-identified dataset).

When the data will become available and for how long

Data will be available 6 months after publication of the study results and will remain accessible for 5 years.

To whom data/document is available

Access to data will be granted to researchers affiliated with academic or research institutions with legitimate scientific objectives. Requests from non-academic or commercial entities will not be considered.

Under which criteria data/document could be used

Data will be used only for non-commercial research purposes. Any analysis must comply with ethical research standards, and secondary analyses must align with approved scientific objectives. Redistribution of data is not permitted.

From where data/document is obtainable

Requests should be submitted via the principal investigator's email. After scientific review and approval, de-identified data will be shared in digital format with the requester.

What processes are involved for a request to access data/document

Requests will be reviewed by the research team. If approved, data will be provided within 30 working days. A Data Use Agreement may be required prior to data sharing.

Comments

All datasets will be fully de-identified and no personal identifiers will be shared.