Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the impact of mindfulness-based cognitive therapy (MBCT) on the neurobehavioral system and life expectancy of women with breast cancer

Protocol summary

Study aim

1. To determine the effect of mindfulness on reducing physiological responses to stress in women with breast cancer. 2. To determine the effect of mindfulness on increasing life expectancy in women with breast cancer. 3. Study to determine the relationship between changes in the neurobehavioral system and life expectancy in women with breast cancer

Design

This research is a quantitative and quasi-experimental study that uses a pretest-posttest design with a control group. In this design, two experimental and control groups are assigned by simple randomization.

Settings and conduct

In this study, 60 women with breast cancer will be randomly selected and assigned to two experimental groups (30 people) and control groups (30 people).

Participants/Inclusion and exclusion criteria

1.Women between the ages of 30 and 45. 2- Diagnosed with breast cancer by a specialist. 3- Not participating in any cognitive therapy or similar intervention program. 4- Physically and mentally capable of participating in mindfulness sessions and completing questionnaires. 5- Informed consent to participate in the study. 6- Definite diagnosis of breast cancer by a specialist (stage I to III, without metastasis). 7- Physical and mental ability to participate in group sessions and complete questionnaires.

Intervention groups

The experimental group will receive a mindfulness-based cognitive therapy intervention. The intervention will consist of 8 two-hour sessions over 4 weeks. Each session will include training in mindfulness techniques, meditation, stress reduction techniques, and coping skills.

Main outcome variables

Behavioral nervous system, life expectancy, reduction of rumination, acceptance and commitment to values, self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250825066997N1**
Registration date: **2025-10-07, 1404/07/15**
Registration timing: **prospective**

Last update: **2025-10-07, 1404/07/15**
Update count: **0**

Registration date

2025-10-07, 1404/07/15

Registrant information

Name

Romina Baradaran Agh Ghaleh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6651 7467

Email address

br.romix@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-21, 1404/07/29

Expected recruitment end date

2025-11-20, 1404/08/29

Actual recruitment start date

2025-10-22, 1404/07/30

Actual recruitment end date

2025-11-20, 1404/08/29

Trial completion date

2025-11-20, 1404/08/29

Scientific title

Investigating the impact of mindfulness-based cognitive therapy (MBCT) on the neurobehavioral system and life expectancy of women with breast cancer

Public title

Investigating the impact of mindfulness-based cognitive therapy (MBCT) on the neurobehavioral system and life expectancy of women with breast cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Women between the ages of 30 and 45. Diagnosed with breast cancer by a specialist. Not participating in any cognitive therapy or similar intervention program. Physically and mentally capable of participating in mindfulness sessions and completing questionnaires. Informed consent to participate in the study. Definite diagnosis of breast cancer by a specialist (stage I to III, without metastasis). Physical and mental ability to participate in group sessions and complete questionnaires. Having minimal literacy. Not having a severe psychiatric disorder (such as schizophrenia, bipolar disorder, or substance dependence) based on medical records or self-report. Not taking psychotropic or strong sedative medications that directly affect the neurobehavioral system (except in stable conditions and under the supervision of a physician).

Exclusion criteria:

Age

From **30 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, participants will be randomly assigned to the intervention and control groups in a 1:1 ratio using a simple randomization method. The random allocation sequence will be generated by an independent statistician using a computer-based random number table (Excel or SPSS). To ensure allocation concealment, the randomization sequence will be kept in sequentially numbered, opaque, sealed envelopes (SNOSE). After verifying inclusion and exclusion criteria and obtaining informed consent, the corresponding envelope will be opened, and the participant will be assigned to the designated group. The outcome assessor will be blinded to group allocation.

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

Ethics Committee of Islamic Azad University, Semnan Branch

Street address

Damghan road، 5th kilometer of Semnan

City

Semnan

Province

Semnan

Postal code

37111-35131

Approval date

2025-09-10, 1404/06/19

Ethics committee reference number

IR.IAU.SEMNAN.REC.1404.065

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast of unspecified site

Primary outcomes

1

Description

Behavioral nervous system

Timepoint

Before the intervention and after the intervention

Method of measurement

BRI - Behavioral Regulation Inventory

2

Description

Disappointment

Timepoint

Before the intervention and after the intervention

Method of measurement

Beck's Hopelessness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: The control group received only standard medical care during the study period and did not receive any group or individual psychotherapy intervention.
Category
Behavior

2

Description
The experimental group underwent MBCT intervention for eight sessions. The research tools included the Life Expectancy Questionnaire (BHI), the Behavioral Regulation Questionnaire (BRI), and the data were analyzed using independent and paired t-tests and Pearson correlation coefficient. The findings showed that after the intervention, the experimental group had a significant improvement in all variables compared to the control group.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Firuzgar Educational and Therapeutic Center
Full name of responsible person
Romina Baradaran
Street address
Firoozgar Hospital, Beh Afarin St., Karim Khan Zand Blvd.,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr. Shahab Moradi
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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
Semnan 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
Islamic Azad University, Semnan Branch
Full name of responsible person
Romina Baradaran
Position
University Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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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
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable