Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the effectiveness of cognitive behavioral therapy based on mindfulness on the fear of disease progression and post-traumatic growth of women with breast cancer

Protocol summary

Study aim
Determining the effectiveness of cognitive behavioral therapy based on mindfulness on the fear of disease progression and post-traumatic growth among women with breast cancer

Design
The clinical trial has an experimental and control group with parallel groups, a blind strain, on 30 women with breast cancer, randomized, and the randomization method is used.

Settings and conduct
Place of study: medical oncology and hematology department of Imam Khomeini hospital in Sari city; Study population: 30 women with breast cancer; Type of blinding: single blind; How to blind: In this research, the participants are not aware of the details of the type of treatment and all attend the treatment sessions with the same environment and conditions. Therapists who are aware of the type of intervention (MBCT) implement a specific treatment method without change for everyone. Detailed information about the intervention will not be given to the participants until the end of the study to avoid bias.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women with breast cancer age range from 30 to 65 years old, suffering from breast cancer and willing to participate in treatment sessions. Exclusion criteria: suffering from other serious psychiatric diseases, serious physical diseases at the same time.

Intervention groups
The experimental group includes women with breast cancer who participate in eight 90-minute group sessions of mindfulness-based cognitive behavioral therapy (MBCT). These sessions include mindfulness exercises, meditation and paying attention to present experiences. The control group receive no intervention and only are followed up on usual and standard care.

Main outcome variables
Fear of disease progression; post-traumatic growth

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240826062875N1**
Registration date: **2024-09-09, 1403/06/19**
Registration timing: **prospective**

Last update: **2024-09-09, 1403/06/19**
Update count: **0**

Registration date
2024-09-09, 1403/06/19

Registrant information
Name
Ailin Abbasian
Name of organization / entity
Islamic Azad University, Semnan branch
Country
Iran (Islamic Republic of)
Phone
+98 11 3339 4700
Email address
ailinabbasian99@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-10-08, 1403/07/17
Expected recruitment end date
2024-11-07, 1403/08/17
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effectiveness of cognitive behavioral therapy based on mindfulness on the fear of disease progression and post-traumatic growth of women with breast cancer

Public title
The effectiveness of cognitive behavioral therapy based on mindfulness on the fear of disease progression and post-traumatic growth
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women who have been officially diagnosed with breast cancer. Women with breast cancer age range from 30 to 65 years. People who are not currently undergoing active treatment (such as chemotherapy or radiation therapy) and at least six months have passed since the end of treatment. People who have obtained a high score in the scales related to the fear of disease progression in the initial assessment. Women who are able to speak and understand Farsi language. Volunteers who are willing to participate in group sessions voluntarily and are able to do home exercises.
Exclusion criteria:
Women who have been diagnosed with severe mental disorders such as schizophrenia or bipolar disorder The existence of other serious physical diseases that limit the person's ability to participate in meetings People who are participating in other psychotherapy programs at the time of intervention
Age
From **30 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, simple randomization method is used to assign women with breast cancer to intervention and control groups. Each participant first receives a unique ID. These IDs are written on cards that are placed randomly in a large box. The cards are shuffled well and then taken out from the box one by one. In this way, each ID is randomly assigned to one of the intervention or control groups. The cards are divided into two piles and each pile is randomly assigned to one of the groups. This method ensures that the participants are assigned randomly and without bias in the groups and increases the validity of the research results.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this research, blinding is done unilaterally. Participants are unaware of the type of treatment they are receiving. All participants participate in therapy sessions that have similar environment and physical conditions. Therapists, aware of the type of intervention (MBCT), apply a consistent procedure to all groups and there are no apparent differences between sessions. To maintain blinding, participants are not provided with detailed information about the type of treatment and are only informed that they are participating in a study related to the effectiveness of mindfulness-based cognitive therapy. Exact details of the interventions will not be provided to participants until the end of the study to minimize bias effects. This method helps to evaluate the obtained results more accurately and without bias.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan Azad University
Street address
Islamic Azad University, Daneshgahi town, Semnan
City
Semnan
Province
Semnan
Postal code
3513137111
Approval date
2024-06-24, 1403/04/04
Ethics committee reference number
IR.IAU.SEMNAN.REC.1403.050

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
Fear of cancer progression
Timepoint
Before starting the intervention (pre-test), after completing 8 intervention sessions (post-test)
Method of measurement
Hershbach et al.'s fear of cancer progression questionnaire (2005)

2

Description
Post-traumatic growth
Timepoint
Before starting the intervention (pre-test), after completing 8 intervention sessions (post-test)
Method of measurement
Post-traumatic growth Tedeschi and Calhoun (1996)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention is based on Williams et al.'s treatment program (1952) in eight group sessions, each one for one and a half hours and during one month. In these sessions, which focus on mindfulness exercises, various mindfulness techniques are taught and participants are encouraged to practice these techniques during and between sessions. The main goal of this intervention is to reduce the fear of disease progression and increase post-traumatic growth in women with breast cancer. To reinforce the effect of the treatment, home exercises are provided between sessions and the participants' questions are answered so that the changes become more stable.
Category
Treatment - Other

2

Description
Control group: The control group does not receive any specific intervention and serves only as a comparison group. This group received only usual and standard care and did not participate in mindfulness-based cognitive-behavioral therapy (MBCT).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Educational and Medical Hospital, Sari
Full name of responsible person
Leila Shojaei
Street address
Medical Oncology and Hematology Department, Imam Khomeini Hospital, Amir Mazandaran Boulevard, Sari
City
Sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3335 0670
Email
emamsari.hospital@gmail.com
Web page address
https://imamhospital.mazums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University, Semnan branch
Full name of responsible person
Shahab Moradi
Street address
Islamic Azad University, Daneshgahi town, Semnan
City
Semnan
Province
Semnan
Postal code
3513137111
Phone
+98 23 3365 4040
Email
shahabmoradi66@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University, Semnan branch
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
Ailin Abbasian

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

Street address
Unit 1, Royal Apartment, Darya 6th St., Khazar Blvd., Sari

City
Sari

Province
Mazandaran

Postal code
4816813163

Phone
+98 11 3339 4700

Email
ailinabbasian99@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University, Semnan branch

Full name of responsible person
Ali Mohammadbagher

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Islamic Azad University, University Town, Semnan

City
Semnan

Province
Semnan

Postal code
3513137111

Phone
+98 23 3365 4040

Email
ambpsych@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University, Semnan branch

Full name of responsible person
Ailin Abbasian

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

Street address
Unit 1, Royal Apartment, Darya 6th St., Khazar Blvd., Sari

City
Sari

Province
Mazandaran

Postal code
4816813163

Phone
+98 11 3339 4700

Email
ailinabbasian99@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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
It is possible to share demographic data and the results of the main outcome of the research after de-identifying and preserving the privacy of individuals.

When the data will become available and for how long
Data can be made available one month after results are printed and after removing personally identifiable information.

To whom data/document is available
Research data and documentation will be available to researchers and researchers who are working in academic and scientific institutions. These people can access the data by submitting a request and after reviewing and approving the request.

Under which criteria data/document could be used
Research data and documents can be used for scientific and research purposes. Requests must be submitted in writing and include a full description of the purpose, methods, and type of analysis. After review and approval, users should share the results with the principal investigator to confirm the validity and accuracy of the analyses.

From where data/document is obtainable
If you need data, contact ailinabbasian99@gmail.com.

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

After receiving the request and checking it by the main researcher, the data will be sent to the requester within	7 days.
Comments	