Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of Cognitive-Behavioral Stress Management Training on Pain Self-Efficacy, Quality of Life, Psychological Well-being, and Fear of Body Image in Women with Breast Cancer

Protocol summary

Study aim
the Efficacy of Cognitive-Behavioral Stress Management Training on Pain Self-Efficacy, Quality of Life, Psychological Well-being, and Fear of Body Image in Women with Breast Cancer

Design
A semi-experimental design with pre-test-post-test and follow-up Purposive sampling, randomly assigned 30 individuals to experimental and control groups

Settings and conduct
From all women with early-stage breast cancer (stage 1-2) at Imam Khomeini Hospital and Tuba Clinic in Sari, 30 were selected in a targeted non-random way based on inclusion and exclusion criteria and were randomly assigned to experimental and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Receiving a diagnosis of non-metastatic stage (1-2) breast cancer Being between 30-50 years old Have undergone mastectomy surgery Not having taken psychiatric medication in the past three months Not suffering from severe physical illnesses such as cancer, MS, Alzheimer's, or similar conditions Not having a history of serious psychiatric disorders such as psychosis or similar conditions (based on the initial clinical interview) Having minimum education up to a high school diploma Having an informed consent agreement to participate in the research study Not undergoing any other treatments or psychological interventions during the research Exclusion criteria: Having more than 2 absences in treatment Taking psychiatric medication or substances in the past three months Suffering from mania or a psychotic disorder

Intervention groups
The experimental group received ten 2-hour cognitive-behavioral stress management sessions, while the control group received no intervention. Both groups completed the questionnaires in three stages.

Main outcome variables
The intervention has significantly increased pain self-efficacy, quality of life, psychological well-being, and reduced fear of body image in women with breast cancer.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240712062397N1**
Registration date: **2024-08-01, 1403/05/11**
Registration timing: **retrospective**

Last update: **2024-08-01, 1403/05/11**
Update count: **0**

Registration date
2024-08-01, 1403/05/11

Registrant information
Name
Fatemeh Toghani Hoolari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-06-22, 1402/04/01
Expected recruitment end date
2023-07-22, 1402/04/31

Actual recruitment start date
2023-06-22, 1402/04/01
Actual recruitment end date
2023-08-15, 1402/05/24
Trial completion date
2023-11-28, 1402/09/07

Scientific title
Efficacy of Cognitive-Behavioral Stress Management Training on Pain Self-Efficacy, Quality of Life, Psychological Well-being, and Fear of Body Image in Women with Breast Cancer

Public title
Investigating the Efficacy of Cognitive-Behavioral Stress Management Training in Breast Cancer Patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Female gender Being between 30-50 years old Non-invasive stage (1-2) of breast cancer Have undergone mastectomy surgery Having informed consent to participate in the study Not having a history of serious psychiatric disorders such as psychosis or similar conditions (based on the initial clinical interview). Not having any other severe physical diseases Not having taken psychiatric medication in the past three months Having minimum education up to a high school diploma
Exclusion criteria:
Having more than 2 absences in treatment Recurrence of the disease Suffering from a specific obvious physical disease during the intervention period Having mania or psychotic disorder
Age
From **30 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Actual sample size reached: **25**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
All the participants in the experimental and control groups are unaware of the implementation process and the expected results of the training and how to be assigned to the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research at Islamic Azad University, Sari Branch
Street address
Islamic Azad University, Sari Branch, Research Ethics Committee, 7th Kilometer Darya Road (Farah Abad), Khazar Square, Sari, Mazandaran, Iran
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Province
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Postal code
48184-194
Approval date
2023-04-17, 1402/01/28
Ethics committee reference number
IR.IAU.SARI.REC.1402.047

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
Pain self-efficacy score in pain self-efficacy questionnaire
Timepoint
In three stages: before the start of the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement
Pain Self-efficacy Questionnaire

2

Description
The quality of life score in the quality of life questionnaire (WHOQOL-BREF)
Timepoint
In three stages: before the start of the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement
World Health Organization quality of life questionnaire -

short form (WHOQOL-BREF)

3

Description
Psychological well-being score in Ryff questionnaire
Timepoint
In three stages: before the start of the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement
Ryff psychological well-being questionnaire (RSPWB-18)

4

Description
Body image fear score in Littleton's questionnaire
Timepoint
In three stages: before the start of the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement
Littleton's Fear of Body Image Questionnaire (BICI)

Secondary outcomes

1

Description
General health score
Timepoint
In three stages: before the start of the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement
Ryff's Psychological well-being and World Health Organization's quality of life questionnaire

Intervention groups

1

Description
Intervention Group: The experimental group underwent cognitive-behavioral stress management training based on Michael Anthony's protocol (translated by Safarzadeh and Karami, 2013) in ten 120-minute sessions. They completed questionnaires before, immediately after, and one month after the sessions.
Category
Other

2

Description
Control Group: The control group did not receive any intervention. They only completed the questionnaires at the same three stages as the experimental group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Fatemeh Toghani
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Imam Khomeini Medical Education Center (RA), Razi St., Sari, Mazandaran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
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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
Islamic Azad University
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

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Fatemeh Toghani

Position
Student

Latest degree
Master

Other areas of specialty/work
Psychology

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

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

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