Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A comparative study of the effect of emotional schema therapy with cognitive behavioral therapy on quality of life, body image, resilience, and marital satisfaction in women with breast cancer who underwent mastectomy in 2015-2016

Protocol summary

Study aim
Evaluation of the effects of Emotional Schema Therapy on the Quality of Life in Women with Breast Cancer Post-Mastectomy

Design
This study is a randomized clinical trial targeting women diagnosed with breast cancer who have undergone mastectomy. The sample size is 36 participants, and individuals will be placed on a numbered list, then be randomly assigned to the experimental (will receive Emotional Schema Therapy intervention) and control groups (will receive Cognitive Behavioral Therapy) using sealed, opaque, and numbered envelopes, which each participant will select.

Settings and conduct
This study will be conducted at the "Didar Center for Counseling Mental Disorders and Problems" in Isfahan. Data will be collected and analyzed numerically. The instruments used will include standardized questionnaires and scales for measuring quality of life, body image, resilience, and marital satisfaction. Prior to the interventions, participants will be asked to complete the relevant questionnaires. After the therapeutic interventions for a specified duration (8 to 12 sessions), data will be collected again.

Participants/Inclusion and exclusion criteria
Inclusion criteria included women aged 18 to 65 years with a clinical diagnosis of breast cancer, a history of mastectomy, being married or in a marital relationship, and having psychological readiness. Exclusion criteria included the presence of a severe psychiatric disorder and receiving similar treatments.

Intervention groups
Control Group: Participants will undergo Cognitive Behavioral Therapy for a specified duration, spanning 8 to 12 sessions. Intervention Group: Participants will receive Emotional Schema Therapy for a specified duration, also spanning 8 to 12 sessions.

Main outcome variables
Changes in quality of life, body image scale, resilience, and marital satisfaction will be evaluated.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251121068065N5**
Registration date: **2026-06-12, 1405/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-12, 1405/03/22**
Update count: **0**

Registration date
2026-06-12, 1405/03/22

Registrant information

Name
kavoushgaran kavoushgaran

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 915 718 4680

Email address
atiye.hesary@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-10, 1405/03/20

Expected recruitment end date
2026-09-11, 1405/06/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effect of emotional schema therapy with cognitive behavioral therapy on quality of life, body image, resilience, and marital satisfaction in women with breast cancer who underwent mastectomy in 2015-2016

Public title
A comparative study of the effect of emotional schema therapy with cognitive behavioral therapy on quality of life, body image, resilience, and marital satisfaction in women with breast cancer who underwent mastectomy in 2015-2016
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Women diagnosed with breast cancer who have undergone mastectomy Participants aged between 18 and 65 years Married or in a marital relationship Psychologically prepared for individual and group therapy and willing to express their emotions and experiences
Exclusion criteria:
Participants must not have severe mental disorders (such as personality disorders, severe depression, or psychotic disorders) Participants must not be currently receiving similar treatments
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Following sample selection, participants will be randomly assigned to the experimental and control groups. In the first stage, after voluntary sample selection, all selected individuals are placed on a list (numbered 1 to 36). In the second stage, among these individuals, using a random method with sealed, opaque, numbered envelopes, participants are divided into experimental and control groups. Each individual randomly selects an envelope and is assigned to the relevant group.
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
Research Ethics Committee of Islamic Azad University-Najafabad Branch
Street address
Islamic Azad University Najafabad Branch, Daneshgah Blvd., Najafabad, Isfahan Province.
City
Najafabad
Province
Isfehan
Postal code
8514143131
Approval date
2025-12-11, 1404/09/20
Ethics committee reference number
IR.IAU.NAJAFABAD.REC.1404.265

Health conditions studied

1

Description of health condition studied
Women who have undergone mastectomy for breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

2

Description of health condition studied
Body image in women who have undergone mastectomy for breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

3

Description of health condition studied
Resilience in women who have undergone mastectomy for breast cancer
ICD-10 code
C50
ICD-10 code description

Malignant neoplasm of breast

4

Description of health condition studied
Marital satisfaction in women who have undergone mastectomy for breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
The participants' quality of life will be assessed using standardized questionnaires
Timepoint
Assessments will be conducted before the start of the intervention and after the completion of the treatment sessions (8 to 12 sessions).
Method of measurement
Quality of life before and after the treatment sessions will be measured using the World Health Organization Quality of Life questionnaire (WHOQOL) or the 36-Item Short Form Health Survey (SF-36).

2

Description
Body image will be assessed using questionnaires.
Timepoint
Assessments will be conducted before the start of the intervention and after the completion of the treatment sessions (8 to 12 sessions).
Method of measurement
Instruments such as the Body Image Scale (BIS) or a body image questionnaire for cancer patients will be used.

3

Description
The participants' level of resilience will be evaluated.
Timepoint
Assessments will be conducted before the start of the intervention and after the completion of the treatment sessions (8 to 12 sessions).
Method of measurement
The Connor-Davidson Resilience Scale (CD-RISC) will be used.

4

Description
Marital satisfaction will be examined.
Timepoint
Assessments will be conducted before the start of the intervention and after the completion of the treatment sessions (8 to 12 sessions).
Method of measurement
To evaluate marital satisfaction, the ENRICH Marital Satisfaction Questionnaire or the Dyadic Adjustment Scale (DAS) will be used.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Participants in this group will receive Cognitive Behavioral Therapy (CBT) over a specified period in 8 to 12 sessions.
Category
Behavior

2

Description
Intervention group: Participants in this group will receive Emotional Schema Therapy over a specified period in 8 to 12 sessions
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Didar Center for Counseling Mental Disorders and Problems
Full name of responsible person
Dr. Gholamreza Talebi
Street address
2nd Floor, Padna Building, No. 44, Amin Alley, Sheyri Bridge, opposite Seyed-al-Shohada Hospital, Isfahan
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rezatalebi@iau.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Iman Sadeghkhani
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Islamic Azad University Najafabad Branch, Daneshgah Blvd., Najafabad, Isfahan Province.

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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

Full name of responsible person
Gholamreza Talebi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

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Full name of responsible person
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Midwifery Educator

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Master

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Midwifery

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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