

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Isfahan

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

City

Isfahan

Province

Isfahan

Postal code

8135866531

Phone

+98 31 3237 1841

Email

rezatalebi@iau.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Iman Sadeghkhani

Street address

Islamic Azad University Najafabad Branch, Daneshgah Blvd., Najafabad, Isfahan Province.

City

Najafabad

Province

Isfahan

Postal code

8514143131

Phone

+98 31 4229 3086

Email

sadeghkhani@pel.iaun.ac.ir

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

Street address

Islamic Azad University Najafabad Branch, Daneshgah Blvd., Najafabad, Isfahan Province.

City

Najafabad

Province

Isfahan

Postal code

9514143131

Phone

+98 913 317 0681

Email

rezatalebi@iau.ac.ir

Person responsible for scientific 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

Street address

Islamic Azad University Najafabad Branch, Daneshgah Blvd., Najafabad, Isfahan Province.

City

Najafabad

Province

Isfahan

Postal code

8514143131

Phone

+98 913 317 0681

Email

rezatalebi@iau.ac.ir

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

Islamic Azad University

Full name of responsible person

Nasim khademi

Position

Midwifery Educator

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Islamic Azad University Najafabad Branch, Daneshgah Blvd., Najafabad, Isfahan Province.

City

Najafabad

Province

Isfahan

Postal code

8514143131

Phone

+98 913 270 4522

Email

Khademi_nasim@yahoo.com

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