Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of schema therapy and psychodrama therapy on body image, social isolation, self-esteem, and phantom pain in mastectomy patients in Tehran.

Protocol summary

Study aim

Determining the difference in the effectiveness of schema therapy and psychodramatic therapy on body image, social isolation, self-esteem, and phantom pain in mastectomy patients, Tehran.

Design

60 mastectomy patients were selected through purposive sampling and randomly assigned to three groups of 20. Pre-test, post-test, and follow-up were conducted for all three groups. In the qualitative part, data collection was done through library methods and data analysis was done through analysis of covariance. In the quantitative part, the first experimental group underwent (10 sessions, 90 minutes) emotional schema therapy protocol, and the second experimental group underwent 10 sessions, 90 minutes, psychodrama therapy protocol, and the control group did not receive the intervention and a post-test was administered after the intervention.

Settings and conduct

After random sampling and completion of questionnaires, schema therapy and psychodrama therapy sessions are conducted for the sample at Tehran's Super Specialty Hospital.

Participants/Inclusion and exclusion criteria

Going through a recovery period after mastectomy, no definitive diagnosis of a comorbid mental disorder, no physical illnesses other than breast cancer, informed consent to participate in the research, experiencing a definite diagnosis of a mental or physical illness during the research, occurrence of an incident that had a psychological impact on the subject, and the subject's desire to abandon treatment.

Intervention groups

Three groups: pre-test, post-test, and follow-up. The first experimental group received emotional schema therapy, and the second experimental group received psychodrama therapy, and no intervention was performed in the control group.

Main outcome variables

Schema therapy and psychodramatic therapy will be meaningful on body image, social isolation, self-esteem, and phantom pain of mastectomy patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251128068136N1**
Registration date: **2025-12-25, 1404/10/04**
Registration timing: **prospective**

Last update: **2025-12-25, 1404/10/04**
Update count: **0**

Registration date

2025-12-25, 1404/10/04

Registrant information

Name

Mona Shukri Shams

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3377 8070

Email address

shokri.kia@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-30, 1404/10/09

Expected recruitment end date

2026-03-29, 1405/01/09

Actual recruitment start date

2025-12-30, 1404/10/09

Actual recruitment end date

2026-05-20, 1405/02/30

Trial completion date

2026-08-20, 1405/05/29

Scientific title

Comparing the effectiveness of schema therapy and psychodrama therapy on body image, social isolation, self-esteem, and phantom pain in mastectomy patients in Tehran.

Public title

Comparing the effectiveness of schema therapy and psychodrama therapy on body image, social isolation, self-esteem, and phantom pain in mastectomy patients in Tehran.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Recovering from a mastectomy Lack of definitive diagnosis of comorbid mental disorder Not having any other physical illness or disease other than breast cancer. Informed consent to participate in research

Exclusion criteria:

Experiencing a definite diagnosed mental or physical illness during the research An incident or event that has a significant psychological impact on the subject Subject's willingness to abandon treatment

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

تعداد ۶۰ نفر بیماران ماستکتومی ، با استفاده از روش نمونه گیری هدفمند وبر اساس ملاک ها ورود انتخاب خواهند شدو به صورت تصادفی ساده از نوع قرعه کشی، به هر یک از اعضای جامعه آماری یک شماره اختصاص داده می‌شود. سپس، اعداد به صورت تصادفی انتخاب می‌شوند و اعضای متناظر با این اعداد، به عنوان نمونه انتخاب می‌شوندودر دو گروه آزمایش و یک گروه گواه گماردهخواهندشد.(۲۰ نفر در هرگروه)

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 ،Islamic Ahvaz University

Street address

Administrative Complex،First Floor،Islamic Azad University، Ahvaz Branch، Farhang Shahr،Golestan Highway،Ahvaz،Iran

City

Ahvaz

Province

Khouzestan

Postal code

6461821920

Approval date

2025-05-24, 1404/03/03

Ethics committee reference number

IR.IAU.AHVAZ.REC.1404.050

Health conditions studied

1

Description of health condition studied

Comparing the effectiveness of schema therapy and psychodramatic therapy on body image, social isolation, self-esteem, and phantom pain in mastectomy patients in Tehran.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The score that the subject will obtain from the Multidimensional Body-Self Relationships Questionnaire will be the body image variable.

Timepoint

Pre-test 7 days, post-test 7 days, intervention 60 days, follow-up 60 days after the post-test.

Method of measurement

Multidimensional Body-Self Relationships Questionnaire (MBSRQ)

2

Description

The score that the subject will obtain from the Chalabi and Amirkafi Social Isolation Questionnaire will be the social isolation variable.

Timepoint

Pre-test 7 days, post-test 7 days, intervention 60 days, follow-up 60 days after the post-test.

Method of measurement
Chalpi and Amirkafi Social Isolation QuestionnaireChalpi and Amirkafi Social Isolation Questionnaire

3

Description
The score that the subject will obtain from the Eysenck Self-Esteem Scale will be the self-esteem variable.
Timepoint
Pre-test 7 days, post-test 7 days, intervention 60 days, follow-up 60 days after the post-test.
Method of measurement
Eysenck Self-Esteem Scale (ESI)

4

Description
The score that the subject will obtain from the Wang Bakker pain scale will be the phantom pain variable.
Timepoint
Pre-test 7 days, post-test 7 days, intervention 60 days, follow-up 60 days after the post-test.
Method of measurement
Vankbacker pain scale

Secondary outcomes

empty

Intervention groups

1

Description
ntervention group: The first intervention group: 1- A pre-test will be given to the intervention group. 2- The second stage will be given to the first intervention group in 20 90-minute sessions. 3- A post-test will be given to the first intervention group. 4- The fourth stage will be a follow-up of the first intervention group after a month.
Category
Treatment - Other

2

Description
Intervention group: Second intervention group: Second intervention group - 1- Pre-test will be taken from the intervention group. 2- The second stage of the second intervention group will be given short-term solution-focused therapy in 8 2-hour sessions. 3- Post-test will be taken from the second intervention group. 4- The fourth stage of follow-up will be done from the two intervention groups after a month.
Category
Treatment - Other

3

Description
Control group: No intervention will be performed.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Laleh Superspecialty Hospital
Full name of responsible person
Dr. Karmaali Basari
Street address
Tehran, Shahrak-e Gharb, South Simaye Iran Street, Laleh Subspecialty Hospital.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mohammad Taghipour Birgani
Street address
First floor office complex،Islamic Azad University of Ahvaz Branch، Farhang Shahr،Golestan Highway،Ahvaz،Iran
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6134937333
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+98 61 3334 8336
Email
Parivaladmomen50@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
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

Mona Shukri Shams

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Student

Latest degree

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Other areas of specialty/work

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Email

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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

I will make a decision after completing the research and results.

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available