

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Investigating the effect of mindfulness - based cognitive counseling on sexual self-esteem of women with breast cancer after mastectomy.

Protocol summary

Study aim

Determining the effect of mindfulness based cognitive counseling on the sexual self-esteem of women with breast cancer after mastectomy.

Design

The clinical trial will have an intervention and a control group. Randomization: random blocks (6 blocks of 4 each) will be divided into two groups of 25 people - a total of 50 people in the intervention group and the control group together, including the possibility of dropping). This study is a blind strain.

Settings and conduct

The samples are selected from women who refer to Golestan Hospital with total mastectomy and will be placed randomly (6 blocks of 4) in two groups of 25 (the main sample size is 22) intervention and control. Demographic and sexual self-esteem questionnaires will be given to people of both groups before and after the intervention to fill. The researcher will be blind - the test will be conducted by someone other than the researcher.

Participants/Inclusion and exclusion criteria

Married women ; with breast cancer ; in reproductive age ; with total mastectomy surgery ; After completing the course of chemotherapy and obtaining a score lower than 87 from the sexual self-esteem questionnaire Non-entry criteria Having chronic diseases and other cancers Psychotic people addiction metastasis Participate in the same program

Intervention groups

intervention group : includes training in meditation, mindfulness and cognitive restructuring. Also, self-compassion and kindness towards oneself is also considered. The intervention will consist of 8 face-to-face 90-minute sessions, which will be taught to the people of the intervention group according to the protocol of this treatment. control group : if the treatment is effective, the people in the control group will receive the same treatment in the offline educational file after the research is completed.

Main outcome variables

Sexual self-esteem and its dimensions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231128060209N1**

Registration date: **2024-02-05, 1402/11/16**

Registration timing: **prospective**

Last update: **2024-02-05, 1402/11/16**

Update count: **0**

Registration date

2024-02-05, 1402/11/16

Registrant information

Name

Sareh Khosravikhorram

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-14, 1402/11/25

Expected recruitment end date

2024-02-29, 1402/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of mindfulness – based cognitive counseling on sexual self-esteem of women with breast cancer after mastectomy.

Public title

the effect of mindfulness – based cognitive counseling on women with breast cancer .

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

being married Having sex with her husband Having at least one child Women of reproductive age with breast cancer who have undergone total mastectomy surgery After completing chemotherapy Ability to participate in group therapy sessions possessing at least a middle school education Breast cancer diagnosis 6 months to 5 years before participating in the research Obtaining a score lower than 87 from the sexual self-esteem questionnaire Women aged 30 to 49

Exclusion criteria:

Suffering from chronic diseases such as blood pressure, diabetes and thyroid and autoimmune diseases Taking Antipsychotic drugs in the last 6 months Active psychotic disorders Use of hormone replacement drugs Drug addiction or dependence on alcohol or psychoactive substances based on the individual's own opinion Treatment of another type of cancer or malignancy The occurrence of an unfortunate event during the last 6 months Participation in concurrent treatment programs to reduce sexual problems and reduce other psychological problems hysterectomy metastasis

Age

From **30 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the total sample size is 52 participants (26 participants in each group, considering the potential for drop), selected in the form of 13 blocks of 4. The random allocation of research samples to Group A (control) and Group B (intervention) will be done by generating random sequences, and the formation of blocks will be done using the Random Allocation Software. Each of the generated random sequences is recorded on a registration card, and the cards are placed inside opaque envelopes (13 envelopes). Finally, the sealed envelopes are placed in a box in order. When the study participants who meet the criteria enter, one of the envelopes is

randomly opened by a third person, who is a secretary, and the assigned group becomes apparent. Each block consists of 4 patients, and the order of patients being assigned to Group A or B is determined based on the selected block sequence. The fifth patient is again randomly selected from one of the blocks (selected by the secretary), and the type of intervention is assigned to the fifth to eighth patients according to the order of the blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the fact that our intervention is a consultation method, it is not possible to blind the researcher, the consultant (specialist related to the treatment) and the participants, so we can only have the blinding of the analyst (statistician).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

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School of Nursing and Midwifery - Jundishapur University of Medical Sciences Ahvaz – - Esfand Street – Golestan - Ahvaz - Iran

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Postal code

33337- 61357

Approval date

2023-11-26, 1402/09/05

Ethics committee reference number

IR.AJUMS.REC.1402.449

Health conditions studied**1****Description of health condition studied**

Sexual self-esteem in women with breast cancer after mastectomy

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Sexual self-esteem of breast cancer patients after mastectomy

Timepoint

Comparison of the scores obtained from the short-form female sexual self-esteem questionnaire (SSEI-W-SF) before and after the intervention in both intervention and control groups.

Method of measurement

Women's Sexual Self-Esteem Questionnaire of Zeinabadi and Schwarz Short Form Persian Version .

Secondary outcomes

empty

Intervention groups

1

Description

The intervention will consist of 8 sessions of 90 minutes in one day, but in 2 separate hours and for 2 groups of 12 people. mindfulness based cognitive counseling will be done for the test group. The content of the counseling sessions is according to the protocol of mindfulness treatment and reference books and includes : meditation - breathing exercises - kindness to painful and damaged body parts - cognitive beliefs - home practice, etc. This process will be done in cooperation with Ahvaz University of Medical Sciences and Ahvaz Hospital.

Category

Rehabilitation

2

Description

Control group: If the intervention is effective, the control group will also receive the educational package of Mindfulness based cognitive counseling (including video, audio, PowerPoint, etc.) after completing the study in the form of a CD or file.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Educational and Medical Center of Ahvaz

Full name of responsible person

Parvaneh Mousavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Ahvaz University of Medical Sciences

Proportion provided by this source

40

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

Ahvaz University of Medical Sciences

Full name of responsible person

Sareh Khosravikhorram

Position

Master degree student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Web page address**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