

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effectiveness of Cognitive Behavioral Therapy (CBT) on sexual function and satisfaction of women with breast cancer after mastectomy

Protocol summary

Study aim

Determination of effectiveness of cognitive behavioral therapy on sexual function and satisfaction of women with breast cancer after mastectomy

Design

Clinical trial with two intervention and control groups, simple randomized, each group with 21 participants.

Settings and conduct

Women with breast cancer are selected according to inclusion and exclusion criteria from all women referred to the oncology ward of Golestan hospital in Ahvaz who have sexual dysfunction. the model of cognitive-behavioral therapy is explained and homework assignments are given. The feedback on the efficacy of the treatment, female sexual function index questionnaire and Larson questionnaire is completed by the intervention group after the end of the eight sessions. for control group, they will be given a training session

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with age 18-49; women with breast cancer after mastectomy; score less than 26.5 of female sexual function index questionnaire and less than 75 of Larson's sexual satisfaction questionnaire; married; to have sexual relation with husband; after complete chemotherapy Exclusion criteria: Menopause; pregnancy and lactation; psychotic disorder; hysterectomy; use drug or alcohol dependency; or psychotropic substances; treatment of another type of cancer or malignancy.

Intervention groups

Cognitive behavioral therapy is performed as 8 group sessions of 90-minute in three groups of 7 individuals and once a week by the researcher. The feedback on the efficacy of the treatment, female sexual function index questionnaire and Larson questionnaire is completed by the intervention group after the end of the eight sessions. after 2 month call to control group and female sexual function index and Larson questionnaires is completed and they will be given a training session.

Main outcome variables

1. sexual function 2.sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180616040113N1**

Registration date: **2019-02-15, 1397/11/26**

Registration timing: **retrospective**

Last update: **2019-02-15, 1397/11/26**

Update count: **0**

Registration date

2019-02-15, 1397/11/26

Registrant information

Name

Fatemeh Farhadi Cheshmeh Morvari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-06, 1397/04/15

Expected recruitment end date

2018-10-07, 1397/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Cognitive Behavioral Therapy (CBT) on sexual function and satisfaction of women with breast cancer after mastectomy

Public title

The effect of Cognitive Behavioral Therapy (CBT) on sexual function and satisfaction of women with breast cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with breast cancer after mastectomy Score less than 26.5 of female sexual function index questionnaire Married To have sexual relation with husband To have minimum one child After complete of chemotherapy course Diagnosis of breast cancer 6 month till 5 years before present in research Ability to attend in group therapy session Having at least elementary education Score less than 75 of Larson sexual satisfaction questionnaire Reproductive ages 18-49 years

Exclusion criteria:

Pregnancy and lactation Chronic diseases such as hypertension, diabetes and thyroid disease, and autoimmune diseases Menopause Taking antipsychotic drugs during the past 6 months Psychiatric disorders Use of Hormone Replacement Therapy (HRT) Drug addiction or alcohol dependence or psychoactive materials based on personal comments Treatment another type of cancer or malignancy Participate in concurrent therapy programs to reduce sexual problems and reduce other psychological problems The occurrence of a unpleasant event during the last 6 months Hysterectomy

AgeFrom **18 years** old to **49 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **42****Randomization (investigator's opinion)**

Randomized

Randomization description

In order to intervention, the women will be divided into two groups of 21 participants as control and intervention groups in randomized blocking , using four blocks and a one to one allocation ratio by use RAS software. Then,the intervention and control group's numbers will be held in envelops by block rows. The envelops will be closed and by Golestan Hospital's oncology secretary, they will be randomly assigned to eligible individuals in the study.

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**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

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Faculty of Nursing and Midwifery Ahvaz Jundishapur, Esfand Ave, Golestan Blvd, Ahvaz, Khuzestan

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Postal code

61357-15794

Approval date

2018-06-09, 1397/03/19

Ethics committee reference number

IR.AJUMS.REC.1397.189

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

Sexual function of women with breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Sexual function of women with breast cancer

Timepoint

Before the intervention- 8 weeks after intervention

Method of measurement

Female sexual function index questionnaire

2**Description**

Sexual satisfaction

Timepoint

Before the intervention- 8 weeks after intervention

Method of measurement

Larson sexual satisfaction questionnaire

Secondary outcomes

1

Description

Sexual desire

Timepoint

Before intervention- 8 weeks after intervention

Method of measurement

Female sexual function index questionnaire

2

Description

Sexual arousal

Timepoint

Before intervention- 8 weeks after intervention

Method of measurement

Female sexual function index questionnaire

3

Description

Vaginal Lubrication

Timepoint

Before intervention- 8 weeks after intervention

Method of measurement

Female sexual function index questionnaire

4

Description

Orgasm

Timepoint

Before intervention- 8 weeks after intervention

Method of measurement

Female sexual function index questionnaire

5

Description

Dyspareunia

Timepoint

Before intervention- 8 weeks after intervention

Method of measurement

Female sexual function index questionnaire

6

Description

Sexual pleasure

Timepoint

Before intervention- 8 weeks after intervention

Method of measurement

Female sexual function index questionnaire

Intervention groups

1

Description

Intervention group: Cognitive behavioral therapy result in more positive attitude toward sexual relation and

improved sexual function disorder of couples. Cognitive-behavioral therapy is organized in 8 group sessions. The research samples are divided into 3 groups of 7 people. The sessions are organized by a researcher once a week for 90 minutes. Educational content includes: Familiarity of members with each other and explaining the model of cognitive-behavioral therapy, Identifying their own thoughts and finding negative thoughts on sexual issues, types of beliefs and changing wrong beliefs, analysis of beneficial, body image and its changes during chemotherapy and mastectomy, relaxation training and imagination and confront negative excitements. Homework is given to the participants. After the end of eight sessions, the sexual function and sexual satisfaction questionnaires are completed by the intervention group.

Category

Treatment - Other

2

Description

Control group: Before starting treatment, sexual function Index and sexual satisfaction questionnaires are completed by the control group. Two months after starting treatment, the control group is contacted and sexual function Index and sexual satisfaction questionnaires are again completed, A training session is given to them. Educational content includes body image and its changes during chemotherapy and mastectomy, relaxation training and imagination and confront negative excitements. They are referred to consultant if they wish.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Dr Hojatollah Shahbazian

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Golestan Hospital, Farvardin Ave, Golestan Blvd, Ahvaz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Mohammad badvi

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vice chancellor of research of Ahvaz Jundishapur
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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

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**

Ahvaz University of Medical Sciences

Full name of responsible person

Parvaneh Mousavi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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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

there is no more information

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