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 reffered 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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+98 61 3373 8395

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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

Age
From **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

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

City
Ahvaz

Province
Khouzestan

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 Hojatolah Shahbazian
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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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vice chancellor of research of Ahvaz Jundishapur University of medical sciences, Golestan Ave, Ahvaz, Iran

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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
Midwifery

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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