

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of group counseling on body image and sexual satisfaction in women with breast cancer.

Protocol summary

Summary

Aim of this study was conducted to evaluate the effect of group counseling on the body image and sexual satisfaction in women affected by breast cancer. Inclusion criteria: Iranian; living in Mashhad; The ability to read and write; Aged 18 to 50 years; lives with his wife; Mastectomy; At least 6 months from mastectomy; chemotherapy; radiotherapy and hormone therapy in the past. Exclusion criteria: university education in medicine and psychology; Medication for sexual dysfunction; disorders of sexual function before the disease; psychiatric drugs; mental illnesses the disease; psychological counseling during the last 6 months. This study clinical trial design with pretest and post-test in the 60 women (18-50 years) with breast cancer who admitted to Omid Hospital Cancer Clinic. Samples are available sampling and randomly assigned to two group intervention (n = 30) and a control group (n = 30). The data collection tool was (BIBCQ) Body Image After Breast Cancer Questionnaire and (ISS) Sexual Satisfaction Instrument completed by participants in the pretest and then in the follow-up post test (after 1 months). The intervention group received counseling of sexual satisfaction and body image, in 4 session (60-90) minute. While the control group routine guidance includes wound care and complications of chemotherapy have received. Data were analysed in SPSS-16 using the paired t-test and the independent t-test.

General information

Acronym

Counseling of Breast Cancer

IRCT registration information

IRCT registration number: **IRCT2016100130073N1**

Registration date: **2017-02-12, 1395/11/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-12, 1395/11/24

Registrant information

Name

Fatemeh Vakili

Name of organization / entity

Mashhad University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

vakilif931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-08-20, 1395/05/30

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group counseling on body image and sexual satisfaction in women with breast cancer.

Public title

The effect of counseling on body image and sexual satisfaction in women with breast cancer.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Iranian: living in Mashhad: The ability to read and write: Aged 18 to 50 years: lives with his wife: Mastectomy: At least 6 months from mastectomy: chemotherapy: radiotherapy and hormone therapy in the past. Exclusion criteria: university education in medicine and psychology: Medication for sexual dysfunction: disorders of sexual function before the disease: psychiatric drugs: mental illnesses before the disease: psychological counseling during the last 6 months.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Biomedical Research, Mashhad
University of Medical Sciences- IR.MUMS.REC

Street address

Building Qureshi, Daneshgah Avenue, mashhad,
Khorasan Razavi, Iran

City

Mashhad

Postal code

9138813944

Approval date

2016-06-11, 1395/03/22

Ethics committee reference number

IR.MUMS.REC.1395.154

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50.9

ICD-10 code description

Breast, unspecified

Primary outcomes

1

Description

Sexual Satisfaction

Timepoint

Before Intervention, 1 month after intervention

Method of measurement

Standard Questionnaire

2

Description

Body Image

Timepoint

Before Intervention, 1 month after intervention

Method of measurement

Standard Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group, 4 sessions of group counseling (60-90) minutes, twice a week, the number of people in each group 10, counseling in relation to body image and sexual satisfaction after breast cancer have received.

Category

Lifestyle

2

Description

The control group routine guidance includes wound care and complications of chemotherapy have received.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Fatemeh Vakili

Street address

Mashhad University of Medical Sciences

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Research Mashhad University

Street address

Building Qureshi, Daneshgah Avenue, Mashhad,
Khorasan Razavi, Iran, Islamic Republic Of

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Talat Khadivzadeh

Position

Reproductive Health PHD

Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Position

MSc of Counseling Midwifery

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty