Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of midwifery based counseling support program on body image and sexual satisfaction of breast

Protocol summary

Summary

The aim of this study is the effect of midwifery based on counseling support program On body image and sexual satisfaction of breast cancer survivor's women. This current study is a Controlled clinical trial. Study population are women with breast cancer. Sample size of study are 80 women with breast cancer Who determined in two intervention (n=40) and control (n=40) groups through random allocation. Study inclusion criteria are included: patients who suffer from breast cancer, married women, age group from 30 to 60 years, persons who are using hormone therapy. Exclusion criteria study are included: Attending in another psychotherapy process, other cancers, participation in educational and consulting sessions and have severe depression according to Beck depression inventory, to conduct complementary medicine interventions. The intervention is included of supportive program which consist of 6 weekly sessions for 90 minutes in intervention and Control group will receive only routine care of Breast cancer treatment. The questionnaire included: Demographic questionnaire, Beck Depression Inventory, questionnaire body image and sexual satisfaction. Study outcome is the effect of supportive program on body image and sexual satisfaction of patients with breast cancer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061928528N1**
Registration date: **2016-07-12, 1395/04/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-12, 1395/04/22

Registrant information

Name
Zeinab Hamzehgardeshi
Name of organization / entity
Mazandaran University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of midwifery based counseling support program on body image and sexual satisfaction of breast

Public title

Effect of counseling on body image and sexual satisfaction in women with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria of study are included: patients who

suffer from breast cancer, married women, age group from 30 to 60 years, persons who are using hormone therapy, primary and upper education and mastectomy. Exclusion criteria of study are included: attending in another psychotherapy process, other cancers, severe psychiatric disorders ((schizophrenia, bipolar disorder) (based on the individual's history in the patient's records and reports)), patients with using drugs, participation in educational and counselling sessions and having severe depression according to Beck depression inventory, conducting alternative interventions such as complementary, traditional and acupuncture medicine.

Age
From **30 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Due to educational and supportive nature of the intervention, there is no blinding. In this intervention first 80 people are included based on inclusion criteria and checklist, then 40 persons are assigned in case and 40 persons in control group according to table of random number.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences

Street address
Vice chancellor for research, Mazandaran University of Medical Sciences,Moalem street, Sari.

City
Sari

Postal code
48431-63181

Approval date
2016-06-21, 1395/04/01

Ethics committee reference number
IR.MAZUMS.REC.95.2230

Health conditions studied

1

Description of health condition studied
breast cancer

ICD-10 code
C50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Body image

Timepoint
Before and after the intervention

Method of measurement
Body image questionnaire scale

2

Description
Sexual satisfaction

Timepoint
Before and after the intervention

Method of measurement
Larson Sexual satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In the control group patients only will receive care and treatment related to breast cancer and receive no supportive program. For to control group educational benefits, after end of supportive sessions for intervention group and completion questionnaires by both groups, an educational program will be administered for patients in control group.

Category
Other

2

Description
Holding the supportive program consist of in 6 weekly sessions for 90 minutes in Meetings will be presented through lectures, discussions and homework at home. The first session is include of: 1) Talking about cancer and its effects, treatments and complications, 2) Dealing with stress, 3) Relaxation technique. Second session is include of: 1) Signs of stress and strategies for coping

with stress. The third session consisted of: 1) Information about breast, 2) Genital organs, 3) Relation to sex and body image. The fourth session is a bout : 1) Appropriate strategies a bout side effect cancer on sexuality, 2) Changes in appearance, 3) Strategy for effective communication. The fifth session is include of: 1) Sexual interaction, 2) Sexual response, 3) Strategies for being sexually healthy despite of breast cancer. The sixth session is include: strategies for sexual satisfaction in sexual relationship. It should be noted that in all of session we will consider time for host, discussions and assessing homework.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Cancer Center

Full name of responsible person

Dr. Zeinab Hamzehgardeshi

Street address

Nasibeh Nursing and Midwifery Faculty, Vesal street, sari, Mazandaran

City

sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Moalem street, Vice chancellor for research, Sari, Mazandaran University of Medical Sciences

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mazandaran 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

Mazandaran University Of Medical Sciences

Full name of responsible person

Dr. Zeinab Hamzehgardeshi

Position

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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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