

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

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

#### Protocol summary

2016-07-12, 1395/04/22

#### 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.

#### Registrant information

##### Name

Zeinab Hamzehgardeshi

##### Name of organization / entity

Mazandaran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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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

#### 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

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 about: 1) Appropriate strategies about side effect cancer on sexuality, 2) Changes in appearance, 3) Strategy for effective communication. The fifth session includes: 1) Sexual interaction, 2) Sexual response, 3) Strategies for being sexually healthy despite of breast cancer. The sixth session includes: 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**

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**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

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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****Street address**

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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*