Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of sexual counseling and sexual education based on self-efficacy theory on sexual function and marital satisfaction of women with breast cancer

Protocol summary

Study aim
Determining the effect of sexual education and counseling based on self-efficacy theory on sexual function and marital satisfaction of women with breast cancer

Design
This intervention is a randomized controlled clinical trial with parallel groups. Samples (50 Patient) will be randomly assigned into 2 groups by block method (25 in control group and 25 in intervention group).

Settings and conduct
Participants will be selected from breast cancer patients referred to the hematology department of a hospital in Bushehr city and hematology clinic, who have medical records and meet the study criteria. The purpose of the study will be explained to them through interviews. Written consent forms will be obtained from individuals who are willing to participate. Then, the sexual function questionnaire will be completed by each woman diagnosed with breast cancer. If these patients have at least one area of sexual dysfunction and their sexual function score in each area is below 3.9, it will be considered a disorder, and they will be included in the study. After that, the marital satisfaction questionnaire will be completed by women with breast cancer.This study was not blinded.

Participants/Inclusion and exclusion criteria
Inclusion: Have breast cancer and at least have lobectomy, Women of childbearing age, Being married, Has done radiation therapy or chemotherapy at least 3 months ago, Have problems in at least one field of sexual function. Exit criteria:Severity of illness, Pregnancy, use of psychiatric medications and sexual function enhancing drugs,Have disorders that disrupt sexual function

Intervention groups
In the intervention group, two training sessions and three counseling sessions based on self-efficacy theory will be held, and the control group will be given a booklet in the end.

Main outcome variables
Sexual function and marital satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231102059930N1**
Registration date: **2023-12-04, 1402/09/13**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-04, 1402/09/13**
Update count: **0**

Registration date
2023-12-04, 1402/09/13

Registrant information

Name
Azadeh Jamshidi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 917 272 5235

Email address
azadejam17@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-01, 1402/09/10

Expected recruitment end date
2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sexual counseling and sexual education based on self-efficacy theory on sexual function and marital satisfaction of women with breast cancer

Public title

The effect of sexual counseling and sexual education on sexual function and marital satisfaction of women with breast cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Women who have breast cancer and at least have lobectomy. Women of childbearing age. Being married. Have enough physical ability to attend meetings. Has done radiation therapy or chemotherapy at least 3 months ago. Have willingness to participate in the research. Have problems in at least one field of sexual function.

Exclusion criteria:

Pregnant patients. Patients using psychiatric medications. Have a history of using drugs to improve sexual function. Have disorders that disrupt sexual function(ovarian removal in women, mental problems, Alzheimer's and mental retardation and multiple sclerosis). Have received sexual education and sexual counseling at least 6 months before the research.

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into intervention and control groups by block randomization method. 5 blocks of 10 numbers will be used for blocking.At first, blocks of ten numbers are named with the labels A (intervention group) and B (control group), which will have 252 different states.Then 5 blocks are randomly selected from among the blocks. By choosing each block of ten numbers based on the order of letters, patients are placed in one of two groups, that is, with each block, 5 chances are given to each group.

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 Bushehr University of Medical Sciences

Street address

school of nursing and midwifery,Bushehr university of medical sciences,Rishehr avenue, Sabzabad avenue, Bushehr

City

Bushehr

Province

Boushehr

Postal code

7518759577

Approval date

2023-07-05, 1402/04/14

Ethics committee reference number

IR.BPUMS.REC.1402.071

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

sexual function

Timepoint

Before the intervention begins, after the intervention, as well as one month after the intervention

Method of measurement

Women's Sexual Function Questionnaire 19 questions

Secondary outcomes

1

Description

Marital Satisfaction

Timepoint

Before the intervention begins, after the intervention, as well as one month after the intervention

Method of measurement

Enrich Marital Satisfaction Questionnaire 23 questions

Intervention groups

1

Description

Intervention group: Holding 2 training sessions and three counseling sessions based on self-efficacy theory for one month and weekly follow-up by phone to answer questions one month after the end of the intervention.

Category

N/A

2

Description

Control group: There is no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Hematology shohadaye khalij Hospital

Full name of responsible person

Azadeh Jamshidi, senior consultant in midwifery

Street address

shohadaye khalij Hospital, Bushehr, Bushehr Province

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+98 77 3345 5381

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Dr. Akram Farhadi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Bushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Tayebeh Gharibi

Position

Trainer of Bushehr midwifery school

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Tayebeh Gharibi

Position
Trainer of Bushehr midwifery school
Latest degree
Master
Other areas of specialty/work
Midwifery
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Person responsible for updating data

Contact
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Full name of responsible person
Azadeh Jamshidi
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Master's student in counseling in midwifery
Latest degree
Bachelor
Other areas of specialty/work
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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 not a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available