Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of group counseling based on problem solving on sexual quality of life in patients suffering from breast cancer

Protocol summary

Summary

Objectives: Aim of this study is to determine the effect of group counseling based on problem solving therapy on sexual quality of life in patients suffering from breast cancer. Design: This study is a clinical trial in two groups. Participants: The population will be 110 randomly selected women who suffering from breast cancer in Mahdieh MRI center in Hamadan city, Iran. A sample of 55 patients in the intervention group and 55 patients in the control group will be determined. Method: Before starting the study SQOL-F questionnaire will be completed by both groups and then they will divide into intervention and control groups. The intervention group will divide into groups of 25 to 30 persons that they will participate in 6 meeting. Each meeting will last 1 to 1.5 hours. At the end of women concealing meeting, a meeting will be perform for women's husbands to give them some information. Husbands will complete SQOL-M questionnaire before and after the meeting. After that, two groups will give two months to practice the skills that have learned. After two months two groups will complete the SQOL-F questionnaire again. During the study there is no intervention on control group. However, at the end of study whole of information will be given to the control group as well. A main outcome measure is sexual quality of life in breast cancer patients. Comparison of two groups will done before and two months after intervention in term of sexual quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100910426N15**
Registration date: **2016-10-28, 1395/08/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-28, 1395/08/07

Registrant information

Name
Parisa Parsa
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Hamadan University of Medical Sciences

Expected recruitment start date

2016-10-21, 1395/07/30

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group counseling based on problem solving on sexual quality of life in patients suffering from breast cancer

Public title

The effect of group counseling based on problem solving on sexual quality of life in patients suffering from breast cancer in MRI center of Hamadan city in 2016

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Aged between 25 to 50 years old; married; living with her husband; Diagnosis of breast cancer at least 6 moths ago; being in stage I and II breast cancer; lack of participating in any counseling programs and training on breast cancer in the past; lack of undergoing chemotherapy. Exclusion criteria: No participate in meeting more than two sessions; Severity of disease during the study; the incidence of other serious illnesses such as: heart disease, kidney, liver and mental illness during the study; existence of other factors that will effect on sexual life of patients such as: disaster and important change in the life and marital relationships such as violence and divorce during the study, using drugs that interfere with sexual activity, drug addiction and so on.
Age
From **25 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
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 Hamadan University of Medical Sciences
Street address
Shahid Fahmideh Street, Counterpoint of Mardom Park, Hamadan University of Medical Sciences, Hamadan
City
Hamadan
Postal code
65178
Approval date
2016-10-08, 1395/07/17
Ethics committee reference number
IR.UMSHA.REC.1395.320

Health conditions studied

1

Description of health condition studied
brast cancer
ICD-10 code
C50.9
ICD-10 code description
Breast, unspecified

Primary outcomes

1

Description
Sexual quality of life in breast cancer
Timepoint
Before and two months after intervention
Method of measurement
Sexual Quality of Life Questionnaire (SQOL-F)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:After completing consent form by participants, Two groups will complete demographic and SQOL-F questionnaires. After Completing the questionnaire, the intervention group will divide into groups of 25 to 30 persons that they will participate in 6 meeting. Each meeting will last 1 hour to 1 and half. At the end of women concealing meeting , a meeting will be perform for women's husbands to give them some information. Husbands will complete SQOL-M questionnaire before and after the meeting. After the meeting , two groups will give two month to practice the skills that have learned. After two months two groups will complete the SQOL-F questionnaire again.
Category
Other

2

Description
Control group: only receive routine cares.
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hamedan Mahdieh M.R.I. Center

Full name of responsible person
Nazanin Kademi

Street address
Parastar Street, Pajohesh square, Hamedan Mahdieh M.R.I. Center, Hamadan

City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Hamadan University of Medical Sciences

Full name of responsible person
Dr. Saeid Bashirian

Street address
Shahid Fahmideh Street, Counterpoint of Mardom Park, Hamadan University of Medical Sciences, Hamadan

City
Hamadan

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 of Hamadan 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
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Full name of responsible person
Dr. Parisa Parsa

Position
Associate Professor

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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