

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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 Mahdiah 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

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1822 4396

Email address

parsa@umsha.ac.ir

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 months 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

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

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Parisa Parsa

Position

Associate Professor

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