

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of psychosexual counselling on the quality of sexual life of women with breast cancer

Protocol summary

Summary

This study is experimental with pre-test and post-test randomly. The aim is to determine the effect of counseling on sex sexual quality of life of women with breast cancer are under study population of 120 women with breast cancer patients Cancer Center of Sari. Put the consent form to participate in the study volunteers who are selected to participate in the study by simple random sampling. Done to them by initial screening criteria for inclusion and exclusion based on sexual evaluation Askvvr and Beck Depression Inventory and sexual function questionnaire (FSFI). They then selected 120 patients completed questionnaires for demographic information and clinical, sexual satisfaction (ISS) and sexual quality of life questionnaire (SQOL.F). In order to impress sexual function, sexual pleasure and sexual quality of life of patients counseling is designed to attach content in four 75-minute sessions. Then there will be follow-up four weeks after the intervention to assess the impact of consultations. Is a researcher in the experimental group linked via a phone call.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060528278N1**

Registration date: **2016-06-28, 1395/04/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-28, 1395/04/08

Registrant information

Name

shakiba fatehi abdolmaleki

Name of organization / entity

University of Medical Sciences Shahroud

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vico Chanellor for research Shahroud University of Medical Sciences .

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of psychosexual counselling on the quality of sexual life of women with breast cancer

Public title

Effect of psychosexual counselling on the quality of sexual life of women with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: • a history of breast cancer • traverse at least 6 months and a maximum of 3 years from completion of chemotherapy and chemotherapy (except hormonal therapy) • Having at least one type of sexual dysfunction using a classification based on the FSFI and DSM5 • sexually active before cancer • No drugs or drug

addiction couples Excluding criteria: • Having heart disease - cardiovascular, diabetes, asthma and other chronic diseases • The use of drugs affecting sexual activity • history of malignancy other the • participation in educational programs, counseling and sex • psychological disorders such as depression

Age

From **15 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Are randomized in this study using a random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Shahroud University of Medical Sciences

Street address

Hafte-Tir Square Shahroud Shahroud University of Medical Sciences

City

shahroud

Postal code

3614773955

Approval date

2015-09-29, 1394/07/07

Ethics committee reference number

ir.shmu.rec.1394.115

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C44.5

ICD-10 code description

C44.5 Skin of trunk

Primary outcomes

1

Description

Sexual quality of life

Timepoint

Before the intervention, one month after the intervention.

Method of measurement

Sexual Quality of Life Questionnaire

Secondary outcomes

1

Description

Sexual Function

Timepoint

Before the intervention, one month after the intervention.

Method of measurement

Sexual Function Questionnaire

2

Description

Sexual Satisfaction

Timepoint

Before the intervention, one month after the intervention

Method of measurement

Sexual satisfaction questionnaires

Intervention groups

1

Description

Intervention runs in the plan based on needs assessment and on the basis of sexual schover Administrative Template psychosexual counselling.and checked recent information on past medical history. Askvvr model is merely a tool for qualitative screening is that screening clinical samples. Then, using the FSFI questionnaires and entered the realm of the six samples are screened based on the type of sexual dysfunction DSM5 (ADHD interest / sexual arousal, orgasmic disorders and impaired entry / genital-pelvic pain). Then in the same groups are using this screening tool sub-groups, namely people who have similar sexual dysfunction. In order to impress sexual function, sexual pleasure and sexual quality of life of patients is designed with the content of counseling sessions: the first session (of male and female genitalia and sexual cycle) Session II (impact of breast cancer on sexuality) Third session (the impact of breast cancer on sexuality) Fourth session (interventions) In the four 75-minute sessions. Then there will be follow-up four weeks after the intervention to assess the impact of

consultations. In the meantime, a researcher with groups linked via a phone call. At the end of four weeks will test and control groups of sexual quality of life questionnaire, completed function and sexual satisfaction.

Category

Other

2

Description

The control group will follow after a counseling session

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Cancer Center of Mazandaran (Sari)

Full name of responsible person

Shakiba Fatehi Abdolmaleki

Street address

Sari Street Salman Farsi streets in paradise Basir first floor apartment unit 2

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Shahroud University of Medical Sciences

Full name of responsible person

Mohamad Hasan Emamiyan

Street address

Hafte-Tir Square Shahroud Shahroud University of Medical Sciences

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Shahroud

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 Shahroud 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

University of Medical Sciences Shahroud

Full name of responsible person

Shakiba Fatehi Abdolmaleki

Position

MSc Student in midwifery counseling

Other areas of specialty/work

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m

Web page address**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