

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of the effectiveness of the PLISSIT model with the Sexual health model on quality of life and sexual behavior among women with breast cancer

Protocol summary

Summary

This study is a randomized controlled clinical trial. In the study sample size is 75 women 50-20 years old, married with breast cancer who are sexually active. Subjects were randomized using a random numbers table into three groups, two experimental groups and one control group will be divided. The first group intervention model approach PILSSIT will receive counseling. The second group intervention model based sexual health Model will be to form a group. The control group, no organization would be made and the action group will receive routine. Information Demographic data questionnaire, Sexual behavior questionnaire , Quality of life questionnaire QLQ-BR 23 and QLQ-C30 ,Sexual distress questionnaire and Sexual Function questionnaire will be collected. The information collected will be analyzed by SPSS statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016083025431N2**

Registration date: **2017-10-31, 1396/08/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-31, 1396/08/09

Registrant information

Name

Elham Shakibazadeh

Name of organization / entity

Tehran University of Medical Sciences

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Phone

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Recruitment status

Recruitment complete

Funding source

Governmental(Zanzan University of Medical Sciences)

Expected recruitment start date

2016-09-04, 1395/06/14

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of the PLISSIT model with the Sexual health model on quality of life and sexual behavior among women with breast cancer

Public title

Comparison of the effectiveness of the PLISSIT model with the Sexual health model on quality of life and sexual behavior among women with breast cancer

Purpose

Other

Inclusion/Exclusion criteria

Study inclusion criteria: 1. Having a wife and sexually active individual reports 2. age between 20 and 50 years 3. Other breast cancer and non-cancer 4. Sexual Distress Scale score above 11 5. fiftieth percentile score means lower sexual behavior of women of reproductive age. 6. treatment of patients with surgery or chemotherapy or

both 7. After at least 3 months of treatment, 8. do not receive formal education about sexual issues during the last 6 months 9. no history of mental illness in the past year at least 10. No drugs or alcohol Exclusion criteria Study: 1. relapse 2. intervention during hospitalization 3. Pregnancy 4. Start the field of psychiatric medications 5. participate in therapy sessions over a meeting

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: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Sciences

Street address

Azady square. Center of Zanjan university medical science

City

Zanjan

Postal code

Approval date

2016-08-15, 1395/05/25

Ethics committee reference number

A_11-177-6

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

c50.8

ICD-10 code description

Malignant neoplasm: Overlapping lesion of breast

Primary outcomes

1

Description

sexual behavior/ quality of life

Timepoint

befor intervention/ 6 week after intervention/ 12 week after intervention

Method of measurement

DemoDemographic questionnaire, the questions related illness and treatments, native standardized questionnaire and sexual distress, sexual function questionnaire to determine the type of sexual dysfunction, native questionnaire to assess sexual behavior in women of childbearing age and quality of life questionnaire in patients with breast cancer

2

Description

sexual behavior/ quality of life

Timepoint

befor intervention/ 6 week after intervention/ 12 week after intervention

Method of measurement

Demographic questionnaire, the questions related illness and treatments, native standardized questionnaire and sexual distress, sexual function questionnaire to determine the type of sexual dysfunction, native questionnaire to assess sexual behavior in women of childbearing age and quality of life questionnaire in patients with breast cancer

Secondary outcomes

1

Description

sexual Fancion

Timepoint

befor intrvention/ 6 week intervention/ 12 week intervention

Method of measurement

Femal sexual function scale

Intervention groups

1

Description

The first group counseling wight PLISSIT model The second group counseling wight sexual health model The Third group control

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Street address

Zanjan.Sheikh Fazlollah Nori highway. above Valiasr square

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan university medical sciences

Full name of responsible person

rogheieh khareghani

Street address

Zanjan. Azady square.University of Medical Sciences and Health Services

City

Zanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan university 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

Zanjan university medical science

Full name of responsible person

Esmkhani Mina

Position

Masters student

Other areas of specialty/work

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Person responsible for scientific inquiries

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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