

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4293 3210

##### Email address

shakib@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Governmental( Zanjan 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

#### Contact

**Name of organization / entity**

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Phd of Reproductive Health

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### Person responsible for updating data

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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*