

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### "Psychosocial Intervention on Sexual Satisfaction of Women With Breast Cancer"

#### Protocol summary

##### Study aim

Determining the Effect of Psychological Training on the Sexual Satisfaction of Women with Breast Cancer

##### Design

Clinical trials with community based and pragmatic control group, parallel groups, blind, randomized, simple blocked

##### Settings and conduct

1. Receipt of permission from the vice chancellor for research in Shiraz University of Medical Sciences and referral to Motahhari clinic of Shiraz. 2. Selection of samples and random blocking in two groups of intervention and control by the researcher but the patient does not know which group is located. 3. Complete the demographic questionnaire and sexual satisfaction and sexual schema by both groups. 4. Educational interventions and cognitive therapy by installing the program on the cellphone of the intervention group and using social networks. 5-control group does not see any training. 6. Completion of the questionnaire and analysis.

##### Participants/Inclusion and exclusion criteria

Entry: Married women with non-metallic breast cancer aged 25-55 years Non-arrival: Metastatic Breast Cancer Women, Single and Mental Illness

##### Intervention groups

After placing the samples in the intervention and control groups, the intervention group received training in the field of appropriate exercise for breast cancer, stress management and problem-solving and cognitive therapy interventions, but the control group did not receive any training, and only the questionnaire Completed.

##### Main outcome variables

"The effect of psychological training on improving female sexual satisfaction" "Use the results of the plan for future research" "Promoting Mental Health in Breast Cancer Women"

#### General information

##### Reason for update

Enter new information about sampling date

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190116042377N1**

Registration date: **2019-01-25, 1397/11/05**

Registration timing: **prospective**

Last update: **2019-11-25, 1398/09/04**

Update count: **1**

##### Registration date

2019-01-25, 1397/11/05

##### Registrant information

##### Name

Zeinab Hoseini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 4331 7905

##### Email address

hosseini@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-19, 1397/11/30

##### Expected recruitment end date

2019-04-04, 1398/01/15

##### Actual recruitment start date

2019-04-21, 1398/02/01

##### Actual recruitment end date

2019-06-21, 1398/03/31

##### Trial completion date

2019-08-22, 1398/05/31

## Scientific title

"Psychosocial Intervention on Sexual Satisfaction of Women With Breast Cancer"

## Public title

"Sexual Satisfaction in Breast Cancer"

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Married Age between 25 to 55 years old It is associated with non-Metastatic Breast Cancer. The ability to Read and Write. Ability to work with Android Mobile Phones. Medical records in Motahhari clinic in Shiraz. Would like to participate in this Project.

### Exclusion criteria:

The patient will have metastatic Breast Cancer. Crisis or unexpected illness occurs during research. Separate your spouse from the research. Participate in other educational interventions. Has chronic Psychiatric illnesses.

## Age

From **25 years** old to **55 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **102**

Actual sample size reached: **102**

## Randomization (investigator's opinion)

Randomized

## Randomization description

At first, samples are selected using a random Number Table, then randomly blocked by a researcher in Six blocks in two groups of intervention and control.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

After random selection, samples are entered into two groups of intervention and control in the case of having entered the plan and informed consent for participation in the project. By the fact that the patient knows that he is involved in the research, but in what The group is present and the educational qualities of the groups are not known to the researcher.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

National Ethics Committee for Biomedical Research

#### Street address

School of Nursing and Midwifery, Namaz Square, Shiraz

#### City

Shiraz

#### Province

Fars

#### Postal code

13119-71936

### Approval date

2018-12-25, 1397/10/04

### Ethics committee reference number

IR.SUMS.REC.1397.915

## Health conditions studied

## 1

### Description of health condition studied

Breast Cancer

### ICD-10 code

### ICD-10 code description

Malignant neoplasm of breastIncl.:connective tissue of breastExcl.:skin of breast (C43.5, C44.5)C50.0Nipple and areolaC50.1Central portion of breastC50.2Upper-inner quadrant of breastC50.3Lower-inner quadrant of breastC50.4Upper-outer quadrant of breastC5

## Primary outcomes

## 1

### Description

Sexual Satisfaction Scale in Metson and Traponel Sexual Satisfaction Questionnaire

### Timepoint

Measuring sexual satisfaction score before and after intervention

### Method of measurement

Scale sexual satisfaction, women Mattson and Trapnl (SSS-W)

## Secondary outcomes

## 1

### Description

Sexual schema score

### Timepoint

Measuring the score of sexual cognitive schemas before and after intervention

### Method of measurement

Questionnaire of Cognitive Schemas Activation in a Sexual Context

## Intervention groups

1

### Description

Intervention group: "Married women with non-metastatic breast cancer" Three sessions with appropriate sports exercises for breast cancer, stress management, and problem-solving training developed in the form of an application are installed on the mobile phone in the intervention group. This group There are also five sessions of cognitive therapy interventions using social networks that aim at these training and interventions to improve sexual behaviors and patient schemas. "The control group does not receive any training." Just complete the questionnaires before and after the end of the intervention.

### Category

Behavior

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Motahhari clinic of Shiraz

#### Full name of responsible person

Dr.Ali Jangjoo

#### Street address

Zand Avenue; Namazi Square

#### City

Shiraz

#### Province

Fars

#### Postal code

71348-14336

#### Phone

+98 71 3612 1000

#### Fax

+98 71 3235 9317

#### Email

president@sums.ac.ir

#### Web page address

http://idea.sums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Dr.Yoones Ghasemi

#### Street address

Research assistance; Shiraz University of Medical Science; Zand Blvd

#### City

Shiraz

#### Province

Fars

#### Postal code

7134814336

#### Phone

+98 71 3235 7282

#### Fax

+98 71 3212 2430

#### Email

vcrdep@sums.ac.ir

#### Web page address

https://internet.sums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shiraz University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Zeinab

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

#### Street address

15; Parseh Avenue; Farhangshahr Town

#### City

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#### Province

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#### Postal code

7371798117

#### Phone

+98 71 4331 7905

#### Email

z65hosseini@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available