

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

Marvdasht

Province

Fars

Postal code

7371798117

Phone

+98 71 4331 7905

Email

z65hosseini@gmail.com

Person responsible for scientific 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
Marvdasht
Province
Fars
Postal code
7371798117
Phone
+98 71 4331 7905
Email
z65hosseini@gmail.com

Person responsible for updating data

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
Marvdasht
Province
Fars
Postal code
7371798117
Phone
+98 71 4331 7905
Email
z65hosseini@gmail.com

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