

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

effects of sexual health education on improving sexual function in breast cancer survivors

Protocol summary

Study aim

improving sexual function in breast cancer survivors

Design

this is a quasi experimental study with control group. intervention groups include 30 participants in educational intervention group and 30 individuals in control group (without education).

Settings and conduct

Participants will be selected from the places that survivors are accessible like Cancer Research Center of Shohadaye-Tajrish hospital and their place of natural and rel life. In this way, sexual health classes will be announced in the cancer research center and through virtual media. Then we will invited who are interested for participating in our 4 session classes. FSFI-BC questionnaire will be completed for participants before intervention and again 1 week after the end of last educational session . This questionnaire will be completed for control group in those times too. The control group will be selected with the same criteria and from the attendances of cancer research center.

Participants/Inclusion and exclusion criteria

breast cancer survivors in stage 1 or 2 that are at least in a 6 month interval from their last chemotherapy or radiation therapy will be entered the study and survivors with metastatic cancer, disease recurrence and other physical or psychological disease that affect on sexual function will be excluded

Intervention groups

The intervention groups include one group with educational intervention(4 sessions) and one control group without education.

Main outcome variables

FSFI-BC have sub-scales which will be evaluated: changes after cancer, desire /arousal , lubrication,orgasm, pain and distress about sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190107042278N1**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

Marzieh Masjoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

masjoudi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effects of sexual health education on improving sexual function in breast cancer survivors

2016-07-18, 1395/04/28

Ethics committee reference number
IR.SBMU.PHNM.1395.496

Public title

improving sexual function in breast cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

married Iranian breast cancer survivors being in stage 1 or 2 at least 6 month interval from their last chemotherapy or radiation therapy

Exclusion criteria:

metastatic cancer disease recurrence other physical or psychological disease that can affect sexual function

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

FSFI-BC will be used for evaluating the effects of intervention . This instrument has been translated and validated by the research team

Health conditions studied

1

Description of health condition studied

sexual function

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

sexual function will be evaluated with FSFI-BC. It has phrases separately for sexually active and non- sexually active women .This scale has 6 domaines : changes after cancer , desire, lubrication , orgasm, pain and distress.For 5 phrases in Changes after cancer , total scores is considered between 5 and 25.

Timepoint

Firstly before education and second one week after last educational session

Method of measurement

For changes after cancer ,total score less than 15 means sexual function deterioration and need follow up.Increasing mean score in second stage is considered as improve in sexual function.

2

Description

For desire domain with 6 phrases , the scores are between minimum 5 and maximum 30.

Timepoint

Firstly before education and second one week after last educational session

Method of measurement

the total score less than 12 need follow up.Increasing mean score in second stage is considered as improve in sexual function.

3

Description

vaginal lubrication include 4 item with minimum score 4 and maximum 20.For sexually active women with adding one item for using lubricant ,the maximum score reaches to 24.

Timepoint

Firstly before education and second one week after last educational session

Method of measurement

total score less than 12 need follow up.Increasing mean score in second stage is considered as improve in sexual function.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی شهید بهشتی

Street address

Shahid Beheshti University of medical sciences, Arabi Ave.Daneshjoo Blvd.Velenjak , Tehran,Iran
Tehran,Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

4

Description

Orgasm include 3 phrases and scores between 3 and 15.

Timepoint

Firstly before education and second one week after last educational session

Method of measurement

total score less than 9 means function deterioration and need follow up. Increasing mean score in second stage is considered as improve in sexual function.

5

Description

pain is evaluated with 3 phrases and scores between 3 to 15. This domain will be evaluated through reverse scoring. So score 5 means the worst situation.

Timepoint

Firstly before education and second one week after last educational session

Method of measurement

total score less than 9 means function deterioration and need follow up. Increasing mean score in second stage is considered as improve in sexual function.

6

Description

Distress domain include 6 phrases with score from 6 to 30.

Timepoint

Firstly before education and second one week after last educational session

Method of measurement

total score less than 18 means function deterioration and need follow up. Increasing mean score in second stage is considered as improve in sexual function.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: FSI-BC questionnaire will be completed at beginning for all participants who have inclusion criteria. Then individuals will be take part in 4 educational sessions. FSFI-BC will be completed again the one week, after the last educational session.

Category

Behavior

2

Description

Control group: The second intervention group or Control group members have the same criteria of intervention group 1 and will be selected from the attendance list of cancer research center. FSFI-BC will be completed at

beginning and the end of study (the same time as intervention group).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

cancer research center of Shohadaye-Tajrish hospital and virtual campaign of combating the breast ca

Full name of responsible person

Zohre Keshavarz

Street address

School of Nursing and Midwifery of Shahid Beheshti University of medical sciences, Niayesh intersection, Vali-e-Asr street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zohre Keshavarz
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
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School of Nursing and Midwifery, Shahid Beheshti
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

we can share information about main outcome. The data will spread unknown

When the data will become available and for how long

The data will be accessible 6-12 month after publishing the results.

To whom data/document is available

researchers in academic institutes were allowed to

access data

Under which criteria data/document could be used

with stating the reference

From where data/document is obtainable

sending email to corresponding author through :
keshavarzzohre@yahoo.com

What processes are involved for a request to access data/document

getting permission from corresponding and other
research team

Comments