Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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

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
2016-07-18, 1395/04/28
Ethics committee reference number
IR.SBMU.PHNM.1395.496

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.

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 15l 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 secon 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
City
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Postal code
1985717443
Phone
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Email
keshavarzzohre@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City
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Tehran
Postal code
1983963113
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+98 21 2243 9781
Email
Intl_office@sbmu.ac.ir
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

Asociate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific 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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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Marzieh Masjoudi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address

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

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ma_masjoudi@yahoo.com

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