

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**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**

**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 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

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1985717443

###### **Phone**

+98 21 8820 2512

###### **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**

Tehran

###### **Province**

Tehran

###### **Postal code**

1983963113

###### **Phone**

+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**  
Associate professor  
**Latest degree**  
Ph.D.  
**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  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1985717443  
**Phone**  
+98 21 8820 2512  
**Email**  
keshavarzzohre@yahoo.com

## 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  
**Street address**  
School of nursing and midwifery ,Shahid Beheshti  
University of medical sciences, Niayesh  
Intersection, Vali-e-Asr street, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1985717443  
**Phone**

+98 21 8820 2512  
**Email**  
keshavarzzohre@yahoo.com

## 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  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1985717443  
**Phone**  
+98 21 8820 2512  
**Email**  
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**