

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Development and validation of a smartphone application to improve the sexual health of breast cancer survivors.

Protocol summary

Study aim

Determining the development and validation of a smartphone application to improve the sexual health of breast cancer survivors

Design

Two arm parallel group randomised, Allocation of people using randomized block method, The sample size in each group is 38

Settings and conduct

The researcher selects qualified people by referring to the Motamed cancer research center . Participants are then asked to complete the Female's Sexual Function Index questionnaire. Individuals who score less than 28 will be enrolled in the study and randomly divided into two groups. Prior to the start of the study, the two groups will also complete the body image concern questionnaire and marital satisfaction questionnaires. A group will receive counseling using the developed application. The usability score of the application is also calculated at the end of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Women in the age group from 18 to 60 years old 2. Married and currently living with a spouse 3. Own a smart android cell phone 4. Presence of sexual dysfunction based on the FSFI questionnaire with a score of less than 28 5. Diagnosis of non-invasive breast cancer within the past six years 6. at least three months have passed since mastectomy or lumpectomy, and adjuvant treatment 7. Proficiency in spoken and written Persian language. 8. internet access; Exclusion criteria: 1. Existence of mental illnesses, severe problems in marital relations, polygamy 2. Simultaneous treatment for another type of cancer, reducing sexual, emotional and psychological problems

Intervention groups

In the intervention group, people will use the sexual health application and the control group will receive a sexual health booklet at the end of the study.

Main outcome variables

sexual function; Body image concern; marital satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230903059348N1**

Registration date: **2023-10-14, 1402/07/22**

Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**

Update count: **0**

Registration date

2023-10-14, 1402/07/22

Registrant information

Name

Fatemeh bagheri

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 0000

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fatemehbagheri83@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and validation of a smartphone application to improve the sexual health of breast cancer survivors.

Public title

Development and validation of sexual health application

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women in the age group of 18 to 60 years Married and currently living with a spouse Having a smart Android mobile phone Existence of sexual dysfunction based on the FSFI questionnaire and scoring less than 28 Diagnosed with non-invasive breast cancer within the last six years at most At least three months have passed since mastectomy or lumpectomy and receiving adjuvant treatment (such as radiation therapy, chemotherapy or hormone therapy) spoken and written proficiency in Persian language Internet access

Exclusion criteria:

Existence of mental illnesses Simultaneous treatment of another type of cancer The presence of severe problems in marital relationships (for example, the presence of significant violence or abuse and conflict with the spouse - measured by screening questions such as how is your general relationship with your spouse?, Do you live in the same house?, Do you share a bedroom and bed ?) Simultaneous treatment to reduce sexual, emotional and psychological problems5. Existence of polygamy

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization method will be used to allocate the participants in the study groups, so that according to the groups under investigation (2 groups), AABB blocks of 4 will be formed, and then all possible combinations of them will be formed, will be listed and a code will be assigned for each of these combinations, then according to the sample volume (76) and the volume of blocks, which will be 4, 19 blocks will be allocated.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research ethics committees of tarbiat modares university

Street address

Tehran, Jalal Al Ahmad, Nasr bridge , Tarbiat Modares University

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Postal code

1411713116

Approval date

2022-10-03, 1401/07/11

Ethics committee reference number

IR.MODARES.REC.1401.141

Health conditions studied**1****Description of health condition studied**

sexual health

ICD-10 code

XXI

ICD-10 code description

Factors influencing health status and contact with health services

Primary outcomes**1****Description**

The score of sexual function in Female Sexual Function Index(FSFI)

Timepoint

At the beginning of the study (before the start of the intervention), the end of the intervention, one month and three months after the end of the intervention

Method of measurement

Female Sexual Function Index(FSFI) questionnaire

2**Description**

Body image concern score in the Body Image Concern Index (BICI) questionnaire

Timepoint

At the beginning of the study (before the start of the intervention), the end of the intervention, one month and three months after the end of the

Method of measurement

Body Image Concern Index (BICI) questionnaire

3

Description

Marital satisfaction score from Enrich Marital Satisfaction Questionnaire

Timepoint

At the beginning of the study (before the start of the intervention), the end of the intervention, one month and three months after the end of the

Method of measurement

Enrich Marital Satisfaction Questionnaire

Secondary outcomes

1

Description

App usability evaluation

Timepoint

End of intervention

Method of measurement

Modified Persian version of the questionnaire of usefulness, satisfaction and ease of use (USE)

Intervention groups

1

Description

"Intervention group" :At first, in the intervention group, based on needs assessment, a sexual health application for people with breast cancer will be designed and implemented by the researcher.. By using the password, people are added to the application. In this research, the assessment of sexual health of people will be based on the determinants of the Woods conceptual model and the intervention based on the PLISSIT approach. Intervention strategies include four stages of questions and answers about sexual issues and sexual beliefs, education about sexual misconceptions, sexual and marital counseling, and referral to specialists including urology, infectious diseases, gynecology, and psychologists, depending on the needs of each person. The researcher will guide the participants to each of these strategies in a period of 4 months with weekly sessions (the interval between weeks will be determined based on the needs of the patient and individually) of 45 minutes and It will carry out three question and answer strategies, training and counseling, and at the end, if needed, it will refer the participants to one or more experts. The first intervention strategy includes question and answer sessions in the form of text, audio or, if the participants wish, video. Another strategy is education intervention, education is divided into two sub-sets, general education about sexual health that is done for all participants and referring the individual or couple to a specific topic that is based on the existing problem of education in that context is required and is provided to the participants in the form of a figure, text, slide or video. In another strategy, counseling intervention takes

place. Counseling will be done mainly online, and if needed, the person will be referred to specialists. The last strategy is active referral to the relevant specialist. According to the patient's needs, active referrals are made by the researcher, and according to the needs of the individual, online communication or face-to-face referrals are made. At the end of each session, the modules selected by the therapist will be provided to each person according to their needs, and then the homework results report will be sent through another module in the form of a text message.

Category

Rehabilitation

2

Description

"Control group": Control group: At the end of the study, the control group will receive the booklet "Sexual health in breast cancer patients" and if the intervention is effective, the application will also be available to them.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Motamed Research Institute (Breast Cancer Research Center) Jihad University

Full name of responsible person

Shahpar Hghighat

Street address

Address: Building No. 1: Tehran - Vanak Square - South Gandhi Beginning - No. 146 / Building No. 2: Tehran - Enghelab St. - Aburihan St. - Vahid Nazari St. - No. 45

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The university of Tarbiat Modares

Full name of responsible person

Lida Moghaddam-Banaem

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Tehran, Jalal Al Ahmad, Nasr Bridge

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Grant name
Twenty million tomans

Grant code / Reference number
70673

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

Title of funding source
The university of Tarbiat Modares

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
Tarbiat Modares University

Full name of responsible person
Fatemeh Bagheri

Position
Student

Latest degree
Master

Other areas of specialty/work
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Person responsible for scientific

inquiries

Contact

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Full name of responsible person
Lida Moghaddam-Banaem

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

The data will be available to researchers working in universities and industry.

Under which criteria data/document could be used

Any type of analysis or statistical use of data whose results help to improve the quality of life and health of

the participants under study or have a positive scientific result in this field will be allowed.

From where data/document is obtainable

Data will be sent through e-mail

fatemehbagheri83@yahoo. Fatima Bagheri Tehran, Jalal Al Ahmad, Nasr bridge , Tarbiat Modares University, PO Box: 111-14115. Faculty of Midwifery and Reproductive Health. Data will be sent via e-mail moghaddamb@modares.ac.ir. Lida Moghadam Benaim Tehran, Jalal Al Ahmad, Nasr bridge , Tarbiat Modares University, PO Box: 111-14115. Faculty of Midwifery and Reproductive Health.

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

After the request by the requester, his request will be immediately checked by the research team, after the confirmation of the research team to provide the results to the requester, verification will be done from the requester, if the verification is approved, the data will be provided within 6 weeks after the request.

Comments