Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of sexual counseling by smartphone on sexual intimacy of women with breast cancer referring to Cancer Institute of Tehran Imam Khomeini Hospital2017-2018

Protocol summary

Study aim

Determine the effect of sexual counseling by smartphone on sexual intimacy of women with breast cancer referring to Cancer Institute of Tehran Imam Khomeini Hospital2017-2018

Design

In this study, 60 women eligible for breast cancer were randomly assigned to two groups of intervention and control.The sample size is similar to other related studies, considering α = 05% and α = 2%, and the average changes (standard deviation). The score of sexual intimacy in the intervention and control groups is 6.6 (5.2) and 0.5 (10.80), respectively in the intervention and control group. Number of participants in both groups will be 35 individuals considering 10% loss in both groups that will make it to 30 induvial.

Settings and conduct

Design :It is a randomized controlled clinical trial without blinding. setting and conduct: Cancer Center of Imam Khomeini Hospital in Tehran.

Participants/Inclusion and exclusion criteria

participants:the sample cinsisted of 20to60 women with breast cancer who have had amastectomy. Entry criteria: Women aged 20 to 60 years old, being married, women with breast cancer who have had mastectomy, lack of prosthesis, having reading and writing skills, absence of chronic diseases (cardiac, diabetes, kidney, liver), having medium-to-low score based on sexual intimacy questionnaire, access to smartphone and internet, ability to use smartphone, and spouse consent. Exclusion criteria: Unwilling to continue participating in the study, not attending the maximum of two counseling sessions, history of notable physical and psychological illnesses such as psychotic disorders including schizophrenia and severe depression, the occurrence of stressful events (death of close relatives, divorces, etc) during the study, drug abuse or addiction, being divorced or widowed.

Intervention groups

Intervention group: In this group, gender related counseling along with routine consultation related to mastectomy and chemotherapy will be provided twice a week via a telegram channel, which will allow people to enter into discussions and express their opinions. The telegram channel (for a period of one month consisting of 6 counseling sessions twice weekly) will be directed by the Admin and relevant contents will be posted. To ensure that the participants use the topics that are presented in the telegram in each session, several questions will be developed by the researcher related to the subject of each session and will be asked privately after each meeting. The meetings are as follows: Session 1: Welcoming the group, introducing the participant, determining how to make relationship, the importance of marital relationships, sexual education and marital affairs. Session 2: Teaching the right techniques of sexual relation. Session 3: Introduction to the common sexual disorders of women. Session Four: Introduction to the physiology of sexual intercourse and behavior using body picture. Session 5: Training concentration skills, awareness of sensory symptoms, expression of excitement, and sexual self-expression. Session 6: Confronting negative and non-rational thoughts and reviewing the previous sessions

Main outcome variables

sexual intimacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160503027728N6**
Registration date: **2018-01-10, 1396/10/20**
Registration timing: **prospective**

Last update: **2018-01-10, 1396/10/20**

Update count: **0**

Registration date

2018-01-10, 1396/10/20

Registrant information

Name

Zohreh Mahmoodi

Name of organization / entity

Nursing&Midwifery faculty

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

zohrehmahmoodi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of sexual counseling by smartphone on sexual intimacy of women with breast cancer referring to Cancer Institute of Tehran Imam Khomeini Hospital2017-2018

Public title

Investigating the effect of sexual counseling by smartphone on sexual intimacy of women with breast cancer referring to Cancer Institute of Tehran Imam Khomeini Hospital2017-2018

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Entry criteria: Women aged 20 to 60 years old being married women with breast cancer who have had mastectomy lack of prosthesis having reading and writing skills absence of chronic diseases (cardiac, diabetes, kidney, liver) having medium-to-low score based on sexual intimacy questionnaire access to smartphone and internet ability to use smartphone and spouse consent

Exclusion criteria:

Exclusion criteria: Unwilling to continue participating in the study,, , , divorces, etc) during the study not attending the maximum of two counseling sessions history of notable physical and psychological illnesses such as psychotic disorders including schizophrenia and severe depression the occurrence of stressful events (death of close relatives drug abuse or addiction being divorced or widowed

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a randomized controlled clinical trial that will be conducted on women with breast cancer who have undergone mastectomy in 2017-18, based on randomized blocks in two groups of intervention and control

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

Alborz university of medical sciences

Street address

Karaj - Taleghani Square, North Taleghani Blvd, Administrative City, Alborz University of Medical Sciences

City

karaj

Province

Alborz

Postal code

3149779453

Approval date

2017-12-23, 1396/10/02

Ethics committee reference number

Abzums.Rec.1396.147

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
sexual intimacy questionnaire score
Timepoint
befor intervention and at the end of the consultation session
Method of measurement
sexual intimacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, gender related counseling along with routine consultation related to mastectomy and chemotherapy will be provided twice a week via a telegram channel, which will allow people to enter into discussions and express their opinions. The telegram channel (for a period of one month consisting of 6 counseling sessions twice weekly) will be directed by the Admin and relevant contents will be posted. To ensure that the participants use the topics that are presented in the telegram in each session, several questions will be developed by the researcher related to the subject of each session and will be asked privately after each meeting.
Category
Other

2

Description
Control group: In the control group, they will receive routine consultation related to mastectomy and chemotherapy through the telegram channel. In order to comply with the ethics of the weekly, after completing the consultation, they will receive an educational package related to sexual intimacyt (all the materials presented in the intervention group)
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Cancer Center of Tehran Imam Khomeini Hospital
Full name of responsible person
Dr.Zohreh Mahmoodi
Street address
End of Farmer Blvd. Imam Khomeini Hospital Complex
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1526
Email
hosp-cancer@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
Street address
Keshavarz Blvd, Corner of Quds Street, Central University
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Email
tumspr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Karaj University of Medical Sciences
Full name of responsible person
Dr.Zohreh Mahmoodi
Position

Ph.D
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data will be published as an article
When the data will become available and for how long
10 mounts after publication
To whom data/document is available
This is only available for for people working in academic institutions or people working in businesses
Under which criteria data/document could be used
path analysis
From where data/document is obtainable
Dr. Zohreh Mahmoodi
What processes are involved for a request to access data/document
send an email to Dr. Zohreh Mahmoodi
Comments