

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 Hospital 2017-2018

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 Hospital 2017-2018

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 $\alpha = 0.05$ and $\alpha = 2\%$, 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 individual.

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 consisted of 20 to 60 women with breast cancer who have had mastectomy. 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
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Iran (Islamic Republic of)
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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

before 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 intimacy (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

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1417653761

Phone

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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 scientific inquiries

Contact

Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Dr.Zohreh Mahmoodi
Position
Ph.D
Latest degree
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Person responsible for updating data

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Position
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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