

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of Social Network-Based Supportive Program (Whats App) on the sexual self-concept of women with breast cancer

Protocol summary

Study aim

Determining the effect of Social Network-Based Supportive Program(whatsapp) on the sexual self-concept of women with breast cancer

Design

The trial included two control and intervention groups, in parallel and not blind and random.

Settings and conduct

location: The oncologist clinic will be in Sari.
Randomization into 2 groups of intervention and control.
8 sessions of 45-minute are performed twice a week for the intervention group. The evaluation is performed in 3 times of before, immediately and one month after the intervention.

Participants/Inclusion and exclusion criteria

Admission: , At least education, married women of childbearing age,One week after the last course of treatment, stages 1 to 3 of the disease, living with a spouse, no history of adverse events, Failure to attend sexual health-related classes , no depression, anxiety and severe stress Failure to enter: absence of more than 2 sessions, exacerbation of the disease, adverse events, severe complications from radiotherapy, failure to continue cooperation.

Intervention groups

WhatsApp messenger support program sessions will be held in 8 sessions, 2 sessions of 45 minutes per week. In the intervention group awareness about breast cancer, its effects on cohabitation and sexual self-concept, anatomy and sexual cycle, misconceptions, self-esteem in sexual relations, coping with shame and body image, sensory focus technique, marital satisfaction, solving skills and acceptance of supportive relationships and answers to patients' questions in the group as well as homework assessment will be addressed. At the end and 1 month later, the questionnaires will be completed by the intervention and control group to follow up. The control group will also receive audio and video files in 8 sessions that no related to sexual self-concept.

Main outcome variables

sexual self-concept

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150608022609N8**

Registration date: **2020-07-02, 1399/04/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-02, 1399/04/12**

Update count: **0**

Registration date

2020-07-02, 1399/04/12

Registrant information

Name

Zohre Shahhosseini

Name of organization / entity

Mazandaran University of Medical Science, Nasibe School Of Nursing and Midwifery

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-20, 1399/02/31

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Social Network-Based Supportive Program (Whats App) on the sexual self-concept of women with breast cancer

Public title

The effect of supportive program on sexual self-concept of women with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Being Iranian, At least primary education, Married women of childbearing age, One week after the last course of treatment (radiotherapy), Stage 1 to 3 of the disease, Living with a spouse for the past 4 weeks , No history of adverse event (such as death of a family member and severe accident) in the last 3 months, Failure to attend sexual health-related classes in the last 6 months, No depression, anxiety and severe stress according to the DASS-21 questionnaire, Satisfaction with participating in the research.

Exclusion criteria:

Absence of more than 2 sessions in intervention meetings, Exacerbation of the disease (occurrence of new metastases), Occurrence of an adverse event (death of family members or accident leading to disability and divorce) during the study and until follow-up, Severe complications caused by radiotherapy, failure to continue cooperation in completing the questionnaire.

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)

Randomized

Randomization description

After completing the informed consent form, the eligible individuals will receive an explanation about the purpose of the study and its importance. Then the Depression, Anxiety and Stress Questionnaire (DASS-21) will be administrated to participants and the one with 15 or higher score for the depression scale and 13 and above for the anxiety scale and 18 and above for the stress scale will be excluded from the study. They will be provided with additional information on how to study and randomly assign to the control and intervention groups. Also, In terms of ethics, there will be an opportunity to answer possible questions for participants, who are not eligible to continue and if necessary, they will be advised to refer to medical centers. Then, 60 eligible patients will

be randomly divided into two groups. In this way, using computer software and based on the Permuted block randomization method, using 4 and 6 blocks between the numbers one to 60, two groups of A and group B will be determined. According to the statistical consultant, numbers from 1 to 60 were written on 60 envelopes, and the names of the groups were included in the each envelope according to the computer program. Patients will be randomly selected by the researcher according to the envelope and they will be randomly selected in one of the two intervention or control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, the first outcome is the impact of a social network-based support program (Whats App) on the sexual self-concept of women with breast cancer. As a secondary outcome of this study, the quality of sexual life of women with breast cancer will also be measured. Also, the clients' satisfaction questionnaire from counseling will be measured.

Secondary Ids

empty

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

Ethics Committee of Mazandaran University Of Medical Sciences

Street address

Deputy Of Research And Technology Of Mazandaran University Of Medical Sciences, Moallem Square, Moallem Street

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Postal code

4816715793

Approval date

2020-05-12, 1399/02/23

Ethics committee reference number

IR.MAZUMS.REC.1399.161

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 self-concept measurement

Timepoint

Before, immediately after the intervention and a month later

Method of measurement

Multidimensional Sexual Self-concept Questionnaire

Secondary outcomes

1

Description

Sexual quality of life

Timepoint

Before, immediately after the intervention and a month later

Method of measurement

Women's Sexual quality of life Questionnaire, higher scores indicate better quality of life.

2

Description

Client Satisfaction

Timepoint

Immediately after the intervention and a month later

Method of measurement

Client Satisfaction Questionnaire

Intervention groups

1

Description

Intervention group: The social network-based support program (Whats App) will be implemented in 8 sessions, 2 sessions of 45 minutes per week. Each session is dedicated to the roll call and introduction of participants in the first 10 minutes. Then listening to the pre-prepared voice file in 20 minutes. After that, there will be 15 minutes for possible questions and answers. In addition, at the end of the sessions, participants are given a series of homework assignments that they must prepare for the next session and send to the personal account of the researcher in Whats App. The summary of the sessions is as follows: The first session : providing information about breast cancer, the effects of breast cancer on patients' lives and sexual self-concept, second session: training anatomy and sex cycle in men and women, third session includes: providing information about misconceptions and replacing them with correct concepts, fourth: strengthening Self-confidence and self-esteem in sexual intercourse, fifth session includes: teaching how to deal with shame in sexual intercourse

and deciding to solve it and body image, sixth session: teaching the technique of sensory focus and explaining how to complete the session self-assessment form, session 7 includes: teaching strategies to enhance marital satisfaction and expressing feelings and opinions about sexual behavior, eighth session includes: training problem-solving skills and acceptance of supportive relationships. At the end of 8 sessions of intervention and 1 month later for follow-up, Snell's Multidimensional Sexual Self-Concept Questionnaire (MSSCQ), Rosen's The Female Sexual Function Index Questionnaire (FSFI), Body Image Scale (BIS), The sexual quality of life-female Questionnaire (SQOL-F) and Customer Satisfaction Questionnaire (CSQ-8) will be completed by the intervention group by Porss Line.

Category

Other

2

Description

Control group: The control group will also receive audio and video files in 8 sessions that no related to sexual self-concept. This group will complete the questionnaires again 4 weeks after completing the initial questionnaire and 1 month later.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Private Office of The Project's Expert Consultant (Radio-oncologist)

Full name of responsible person

Arash Ghasemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Sari 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Seyedeh Fatemeh Hamidi

Position

Student

Latest degree

Bachelor

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Person responsible for scientific**inquiries****Contact****Name of organization / entity**

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Ph.D in Reproductive Health

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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