

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of sexual counseling using BETTER model based on virtual networks on quality of sexual life and sexual function in women surviving breast cancer.

Protocol summary

Study aim

Determining the effectiveness of sexual counseling using BETTER model based on virtual networks on quality of sexual life and sexual function in women surviving breast cancer referred to governmental and non governmental centers in Urmia in 1400

Design

Clinical trial, with intervention and control groups, one-way blind, simple randomized, sample size on 90 patients, Excel software was used

Settings and conduct

Samples will be randomly divided into intervention and control groups. Questionnaires will be completed by participants. The intervention for group A includes at least 4 counseling sessions lasting (90-60 minutes) minutes according to the BETTER model once a week (via WhatsApp) will be performed to group B (control group) after the end of the study, educational content It will be sent in the form of 4 one-hour voices in WhatsApp group.

Participants/Inclusion and exclusion criteria

Wife in the country Married and , are not on the verge of divorce Attendance of spouse at least two weeks a month Do not be pregnant or breastfeeding If the diagnosis of breast cancer has been confirmed in her Do not have an underlying or chronic illness other than breast cancer Experience one of the mastectomy methods Do not take drug and alcohol Stage I, II, IIIa cancer Last at least 6 months from illness The person's spouse, according to him, has a dysfunction Access to her for at least the next four months Smartphone and Internet access

Intervention groups

Intervention for group A includes at least 4 counseling sessions for a period of time (90-60 minutes) according to the BETTER model once a week online (contact via Whats Up) will be executed. The people of group B

(control group) after the end of the study, the educational content will be sent in the form of 4 one-hour voices in the WhatsApp group.

Main outcome variables

Sexual counseling, sexual function, quality of sexual life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210926052601N1**

Registration date: **2021-11-07, 1400/08/16**

Registration timing: **retrospective**

Last update: **2021-11-07, 1400/08/16**

Update count: **0**

Registration date

2021-11-07, 1400/08/16

Registrant information

Name

Shirin Nazarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3672 0617

Email address

nazarzadeh2019@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2021-11-01, 1400/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sexual counseling using BETTER model based on virtual networks on quality of sexual life and sexual function in women surviving breast cancer.

Public title

The effect of sexual counseling on quality of sexual life in women surviving breast cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women of childbearing age (18-49 years) Married and living together with his wife, are not on the verge of divorce Attendance of spouse at least two weeks a month Do not be pregnant or breastfeeding If the diagnosis of breast cancer has been confirmed in her, filing a case in the hospital is required to provide written confirmation of the disease by an oncologist. Do not have an underlying or chronic illness other than breast cancer, especially severe mental illness Experience one of the mastectomy methods Do not take drug and alcohol Stage I, II, IIIa cancer Last at least 6 months and at most 5 years after completing radiation therapy and chemotherapy Do not receive special treatment to treat your sexual function problems, such as psychotherapy or attend training classes The person's spouse, according to him, has a dysfunction Access to her for at least the next four months Smartphone and Internet access

Exclusion criteria:**Age**

From **18 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly assigned to the intervention and control groups using the blocking method.

Blinding (investigator's opinion)

Single blinded

Blinding description

The allocation of samples to the intervention and control groups will be random. The questionnaires will be completed by the participants, then the intervention designed for group A will be performed and will be sent to the people of group B (control group) after the study of the educational content in a WhatsApp group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Urmia University of Medical Sciences

Street address

School of Nursing and Midwifery, Nazloo Pardis, 11 of Sero Road, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5756115335

Approval date

2021-09-25, 1400/07/03

Ethics committee reference number

IR.UMSU.REC.1400.248

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

Breast cancer and sexual dysfunction and quality of sexual life

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The effect of sexual counseling on improving sexual function and quality of sexual life in breast cancer survivors

Timepoint

Evaluation of the improvement of sexual function and sexual quality in women surviving breast cancer before the intervention and then immediately and 4 weeks after the intervention

Method of measurement

General Health Questionnaire (GHQ 28), Questionnaire related to demographic characteristics and disease status, - Women's Sexual Quality of Life Questionnaire (F-SQOL, Sexual Function Scale for Adapted Women for Breast Cancer) BC-FSFI

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention for group A, including at least 4 counseling sessions for a period of time (90-60 minutes) according to the BETTER model, will be performed once a week online (call via WhatsApp).

Category

Rehabilitation

2

Description

Control group: No intervention will be sent to the control group during the study period. Only after the end of the study, the intervention performed for group a will be sent in the form of several voice to group b (control).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital , Private Offices

Full name of responsible person

Fatemeh Moghaddam Tabrizi

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School of Nursing and Midwifery, Nazloo Pardis, 11 of Sero Road, Urmia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Iraj Mohebbi

Street address

Urmia University, Emergency Ave, Resalat Blvd, Urmia

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Fatemeh Moghaddam Tabrizi

Position

Associate professor

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

Oroumia University of Medical Sciences

Full name of responsible person

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Position

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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

Person responsible for updating data**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Fatemeh Moghaddam Tabrizi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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