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)

Phone

+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
Street address
School of Nursing and Midwifery, Nazloo Pardis, 11 of Sero Road, Urmia
City
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5756115335
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+98 44 3275 4962
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fmtabrizi@gmail.com

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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Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Email
fmtabrizi@gmail.com
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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School of Nursing and Midwifery, Nazloo Pardis, 11 of Sero Road, Urmia
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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
Associate professor
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Person responsible for updating data

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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