

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of counseling based of EXPLISSIT model on the sexual function of married women with lumpectomy for Breast cancer: a randomized controlled clinical trial

Protocol summary

Study aim

Determine the impact of consultation with EXPLISSIT Model on sexual function of married women with lumpectomy of breast cancer

Design

The participants will be assigned randomly, using RAS software and blocking system of 4 and 6, in two groups of counseling and control with a 1: 1 ratio.

Settings and conduct

The researcher will refer to the Oncology Clinic of Shahid Ghazi Hospital, Nurnejat, Tabriz Central Cancer Clinic. Participants will receive written consent letter. The pre-test questionnaires consisted of Social-Demographic, Sexual Function Index, Sexual Satisfaction For Women and Sexual Quality of Life-Female will be completed by contributors. Women with score of 10-28 the FSFI will participate in the research. At the end, all the mentioned questionnaires will complete after 8 weeks of consultation in both group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women aged 18-45; Married women; stage1-3; FSFI score10- 28; Having a contact number for follow up;One year after lumpectomy. Exclusion criteria: Progression or recurrence of breast cancer over the past six months, drug addiction and smoking, treat for sexual dysfunction, history of mental disorders, history of chronic diseases, other cancers of women and use of drugs affecting sexual function.

Intervention groups

Intervention group: Intervention group (31women), will receive an individual 60-90 minutes counseling according with EXPLISSIT model and further session if needed. Control group: The control group will not receive special care in relation to sexual dysfunction.

Main outcome variables

Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036615N4**

Registration date: **2018-04-23, 1397/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-23, 1397/02/03**

Update count: **0**

Registration date

2018-04-23, 1397/02/03

Registrant information

Name

عصمت مهرابی

Name of organization / entity

دانشگاه علوم پزشکی تبریز

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 0649

Email address

mehrabie@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of counseling based of EXPLISSIT model on the sexual function of married women with lumpectomy for Breast cancer: a randomized controlled clinical trial

Public title
The effect of counseling based of EXPLISSIT model on the sexual function of married women with lumpectomy for Breast cancer

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Exclusion criteria; Women aged 18-45; Married women; Breast cancer in stage1-3; FSFI score10- 28; Having a contact number for follow up; One year's expiration of lumpectomy
Exclusion criteria:
Progression or recurrence of breast cancer over the past six months, drug addiction and smoking, women treated for sexual dysfunction, history of mental disorders, history of chronic and systemic diseases, other cancers of women and use of drugs affecting sexual function.

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be assigned randomly, using RAS software and blocking system of 4 and 6, in two groups of counselling and control with a 1: 1 ratio.

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
Ethics committee of Tabriz University of Medical Sciences

Street address
South Shariati Street, Faculty of Nursing and Midwifery of Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Approval date
2018-02-13, 1396/11/24
Ethics committee reference number
IR.TBZMED.REC.1396.998

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 function
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Sexual Function Index questionnaire

Secondary outcomes

1

Description
Sexual satisfaction
Timepoint
Before intervention and two months after the intervention
Method of measurement
Sexual Satisfaction questionnaires (SSSW)

2

Description
Sexual quality of life
Timepoint
Before intervention and two months after the intervention
Method of measurement
Sexual Quality of Life-Female questionnaires (SQOL-F)

Intervention groups

1

Description

The control group will receive counseling sessions on self-care

Category

Lifestyle

2

Description

Intervention group: including 60-90 minutes individual counseling and further session if needed

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Ghazi hospital

Full name of responsible person

Alireza Nikanfar

Street address

Shahid Ghazi hospital., Danshgah Ave., Golgasht St.,
Tabriz

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5166616471

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horc_tums@tbzmed.ac.ir

2

Recruitment center

Name of recruitment center

Hospital Noor Negat

Full name of responsible person

Mina hasani

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Hafez

City

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Postal code

51376

Phone

+98 41 3336 2201

Email

tums@tbzmed.ac.ir

3

Recruitment center

Name of recruitment center

Hospital Behboud

Full name of responsible person

Dr.Vahid Montazri

Street address

South Shariati

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Postal code

5137974351

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Email

behboudhospital@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Golgshest St. Tabriz University of Medical Sciences;
Central building

City

Tabriz

Province

East Azarbaijan

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5166614766

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Fax

Email

Medical.librarian@chmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Zivar Akbari

Position

Master Consultant in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Family Health

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Fax**Email**

zivarakbari52@gmail.com

Web page address

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Zivar Akbari

Position

Master's degree in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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

Report as scientific paper

When the data will become available and for how long

after 15 month

To whom data/document is available

Editor in chief and reviewers of the journals, Authors of systematic review and meta-analysis

Under which criteria data/document could be used

For ensuring the data originality and evidence based decision- making

From where data/document is obtainable

Corresponding author

What processes are involved for a request to access data/document

Formal request

Comments

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Esmat Mehrabi

Position

Ph.D in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data