Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of counseling based of EXPLISSIT model on the sexual function of married women with lumpectumy 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 lumpectumy 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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horc_tums@tbzmed.ac.ir

2

Recruitment center
Name of recruitment center
Hospital Noor Negat
Full name of responsible person
Mina hasani
Street address
Hafez
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51376
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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
Phone
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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
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Tabriz
Province
East Azarbaijan
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5166614766
Phone
+98 41 3336 4658
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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Web page address

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

Contact

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Full name of responsible person
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Position
Master's degree in midwifery counseling

Latest degree
Bachelor

Other areas of specialty/work
Family Health

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zivarakbari52@gmail.com

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