Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Mindfulness Training on Rumination and Revealing Sexual Function in women with Breast Cancer.

Protocol summary

Study aim
Determining the effect of mindfulness education on reducing rumination and improving sexual function in women with breast cancer.

Design
A randomized clinical trial is being conducted on 52 patients with breast cancer. The subjects are randomly assigned to two groups of 26 test and control groups.

Settings and conduct
Individuals from among patients with breast cancer who are referred to the hematologic department of Bushehr Hospital, a hematologic clinic with a case study and are eligible to participate in the study. The purpose of the research will be provided through interviews with the clients. If you wish, you will receive written consent from the people. Sexual performance questionnaire is then completed by each woman with breast cancer. If these patients have at least one functional disorder in their area and their sexual function score is below9.3 in each area, they are considered to be disrupted and enter the study. The rumination questionnaire is then completed by women with breast cancer

Participants/Inclusion and exclusion criteria
Entry criteria: Women with breast cancer and at least lobectomy. Failure of the patient to interfere with sexual function (ovarian removal in women, mental problems, Alzheimer's and mental retardation and multiple sclerosis). Exit criteria: Physical disability due to periods of treatment Husband travels during the intervention and follow-up

Intervention groups
Interventions and training packages for the training of mind-mindedness based on stress reduction (Kabat Zayn) will be provided by the instructor during 8 sessions. The control group receives a teaching pamphlet on stress-based mind-focused exercises.

Main outcome variables
Sexual function; rumination

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090522001930N2**
Registration date: **2018-08-08, 1397/05/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-08, 1397/05/17**
Update count: **0**

Registration date
2018-08-08, 1397/05/17

Registrant information

Name
Hakimeh Vahedparast

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 77 1252 8498

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-11-22, 1397/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effect of Mindfulness Training on Rumination and Revealing Sexual Function in women with Breast Cancer.

Public title
A Survey on Mindfulness Training in women with Breast Cancer
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Women who have breast cancer and at least have lobectomy. Women of childbearing age . Minimum reading and writing education so that they can complete the questionnaire form. Have a wife. Consciousness and willingness to participate in the research. Have enough physical ability to attend meetings and collaborate on doing assignments. Do not use medicines that affect sex . Radiation therapy should last for at least three months from the last chemotherapy. From the onset of the disease to the time of research they have not received psychological treatment.
Exclusion criteria:
The intention of the husband to travel during the intervention and follow-up
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization using random numbers table
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 Bushehr University of Medical Sciences
Street address
school of nursing and midwifery,Bushehr university of medical sciences,Rishehr avenue, Sabzabad avenue, Bushehr
City
Bushehr
Province
Boushehr
Postal code
7518759577
Approval date
2018-02-19, 1396/11/30
Ethics committee reference number
IR.BPUMS.REC.1396.1396.218

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 begins, after the intervention, as well as one month after the intervention
Method of measurement
Women's Sexual Function Questionnaire 19 questions

2

Description
Rumination
Timepoint
Before the intervention begins, after the intervention, as well as one month after the intervention
Method of measurement
Nulen Hoeksma and Marlow's Rumination Questionnaire 22 Questions

Secondary outcomes

empty

Intervention groups

1

Description
The intervention of this study is based on the educational package of mind-mindedness based on reducing the stress of Mindfulness of Cubat Zayn. The content of the training has been confirmed by 2 professors in the field of clinical psychology and mindfulness with a valid degree in mind awareness. Training in 8 sessions of two hours during a two-month (weekly one-session) session

for an intervention group divided into two groups of 13 will be provided by a trainer at the Yoga Arts and Arts Hall. The homework assignments will be given in a pamphlet and the voice will be given to them, and next week they will be interviewed about the exercises, and questions will be asked about the exercises. If the individuals in the intervention group do not attend the meetings twice, they will be re-classed for them, and if they do not attend more than 2 sessions in the classroom, they will be excluded from the study. If they have a question, we will also respond.

Category

Rehabilitation

2

Description

Control group: Routine care. At the end of the study, the control group will be given an educational counseling session for mindfulness exercises.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Hematology shohadaye khalij Hospital

Full name of responsible person

Rezvan Sohrabi Nejad Masters of Nursing

Street address

shohadaye khalij Hospital, Bushehr, Bushehr Province

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+98 77 3345 5381

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rezvan.sohrabi69@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Khamisipour

Street address

school of nursing and midwifery,Bushehr university of medical sciences,Rishehr avenue, Sabzabad avenue, Bushehr

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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

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Dr. Hakimeh vahed Parast

Position

Assistant Professor of Bushehr Nursing Faculty

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

school of nursing and midwifery,Bushehr university of medical sciences,Rishehr avenue, Sabzabad avenue, Bushehr

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Boushehr 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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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